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WHEN: Tuesday, April 12, 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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A cumulative list of the parts affected this month can be found in the Reader Aids section at the end of this issue.

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Presidential Documents

Title 3—

The President

Proclamation 8647 of April 1, 2011

World Autism Awareness Day, 2011

By the President of the United States of America

A Proclamation

With autism spectrum disorders (ASDs) affecting nearly one percent of children in the United States, autism is an urgent public health issue with a profound impact on millions of Americans. World Autism Awareness Day is an opportunity to recognize the contributions of individuals with ASDs and rededicate ourselves to the cause of understanding and responding to autism.

Men and women on the autism spectrum have thrived and excelled in communities across America and around the world. Yet, despite great progress in understanding ASDs, challenges remain for these individuals and their loved ones. For too long, the needs of people living with autism and their families have gone without adequate support and understanding. While we continue to encourage the development of resources for children on the autism spectrum and provide necessary resources for their families, we must also remember that young people with ASDs become adults with ASDs who deserve our support, our respect, and the opportunity to realize their highest aspirations.

As our understanding of the autism spectrum grows, my Administration remains dedicated to supporting children and adults impacted by autism. Led by the Department of Health and Human Services, we have expanded investments in autism research, public health tracking, early detection, and services—from early intervention for children to improved long-term services and support programs for adults. My Administration maintains a firm commitment to advance autism research and treatment, as well as promote education, employment, and equality for all individuals with autism, from early childhood through employment and community life. We will continue to work with the Congress, experts, and families to improve Federal and State programs that assist individuals with ASDs and their families and to bolster the impact and reach of community support and services. I encourage all Americans to visit www.HHS.gov/autism for more information and resources on ASDs.

With each breakthrough in research and each innovative treatment, we open endless possibilities for the many American families who have been touched by autism. As we mark World Autism Awareness Day, let us recommit to improving the lives of individuals and families impacted by ASDs and creating a world free from discrimination where all can achieve their fullest potential.

NOW, THEREFORE, I, BARACK OBAMA, President of the United States of America, by virtue of the authority vested in me by the Constitution and the laws of the United States, do hereby proclaim April 2 of each year as World Autism Awareness Day. I call upon the people of the United States to learn more about autism and what they can do to support individuals on the autism spectrum and their families.

IN WITNESS WHEREOF, I have hereunto set my hand this first day of April, in the year of our Lord two thousand eleven, and of the Independence of the United States of America the two hundred and thirty-fifth.

[FR Doc. 2011–8445
Filed 4–6–11; 8:45 am]
Billing code 3195–W1–P

Rules and Regulations

Federal Register
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DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 61

[Docket No. FAA–2006–26661; Amdt. No. 61–127]

RIN 2120–AI86

Pilot, Flight Instructor, and Pilot School Certification; Technical Amendment

AGENCY: Federal Aviation Administration, DOT.

ACTION: Final rule; technical amendment.

SUMMARY: The FAA is correcting a final rule published on August 21, 2009 (74 FR 42500). In that rule, the FAA amended its regulations to revise the training, qualification, certification, and operating requirements for pilots, flight instructors, ground instructors, and pilot schools. This document reinstates two paragraphs that were inadvertently removed in one section, and amends an out-of-date cross reference in another section.

DATES: Effective April 7, 2011.

FOR FURTHER INFORMATION CONTACT: For technical questions concerning this action, contact Jeffrey Smith, Airmen Certification and Training Branch, AFS–810, General Aviation and Commercial Division, Flight Standards Service, Federal Aviation Administration, 800 Independence Avenue, SW., Washington, DC 20591; telephone (202) 493–4789; e-mail to *jeffrey.smith@faa.gov.* For legal interpretative questions about this final rule, contact: Anne Moore, AGC–240, Office of Chief Counsel, Regulations Division, Federal Aviation Administration, (202) 267–3073; e-mail to *anne.moore@faa.gov.*

SUPPLEMENTARY INFORMATION:

Background

On August 21, 2009, the FAA published a final rule entitled, "Pilot, Flight Instructor, and Pilot School Certification; Final Rule" (74 FR 42500). That final rule revised the training, qualification, certification, and operating requirements for pilots, flight instructors, ground instructors, and pilot schools. The FAA is now issuing a technical amendment to § 61.57 to reinsert paragraphs (d)(1) and (d)(2) because those paragraphs were inadvertently removed from the final rule. The FAA is also amending an incorrect reference in § 61.65(c).

Technical Amendment

Section 61.57(d) establishes the requirements for an instrument proficiency check. Prior to issuance of the 2009 final rule, § 61.57(d) contained introductory text as well as paragraph (d)(1), which set forth the aircraft in which an instrument proficiency check must be performed, and paragraph (d)(2), which set forth those persons who are authorized to conduct an instrument proficiency check. In the 2009 final rule, the FAA stated in the amendatory instructions to § 61.57(d) that it was amending paragraph (d) rather than the introductory text to paragraph (d). As a result, paragraphs (d)(1) and (d)(2) were unintentionally removed from the final rule. The FAA is issuing this technical amendment to restore paragraphs (d)(1) and (d)(2) to § 61.57.

The FAA is also correcting a minor error to a reference in paragraph (c) of § 61.65. In the 2009 final rule, the FAA added paragraphs (e) and (f) to this section. A corresponding change to a cross reference in paragraph (c) that would have accounted for these additions was unintentionally omitted. This technical edit will correct that omission.

Because the changes in this technical amendment result in no substantive change, we find good cause exists under 5 U.S.C. 553(d)(3) to make the amendment effective in less than 30 days.

List of Subjects in 14 CFR Part 61

Aircraft, Airmen, Aviation safety.

The Amendment

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

PART 61—CERTIFICATION: PILOTS, FLIGHT INSTRUCTORS, AND GROUND INSTRUCTORS

■ 1. The authority citation for part 61 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701–44703, 44707, 44709–44711, 45102–45103, 45301–45302.

■ 2. Amend § 61.57 by adding paragraphs (d)(1) and (d)(2) to read as follows:

§ 61.57 Recent flight experience: Pilot in command.

* * * * *

(d) * * *

(1) The instrument proficiency check must be—

(i) In an aircraft that is appropriate to the aircraft category;

(ii) For other than a glider, in a flight simulator or flight training device that is representative of the aircraft category; or

(iii) For a glider, in a single-engine airplane or a glider.

(2) The instrument proficiency check must be given by—

(i) An examiner;

(ii) A person authorized by the U.S. Armed Forces to conduct instrument flight tests, provided the person being tested is a member of the U.S. Armed Forces;

(iii) A company check pilot who is authorized to conduct instrument flight tests under part 121, 125, or 135 of this chapter or subpart K of part 91 of this chapter, and provided that both the check pilot and the pilot being tested are employees of that operator or fractional ownership program manager, as applicable;

(iv) An authorized instructor; or

(v) A person approved by the Administrator to conduct instrument practical tests.

* * * * *

■ 3. Amend § 61.65 by revising paragraph (c) introductory text to read as follows:

§ 61.65 Instrument rating requirements.

* * * * *

(c) *Flight proficiency.* A person who applies for an instrument rating must receive and log training from an authorized instructor in an aircraft, or in a flight simulator or flight training

device, in accordance with paragraph (g) of this section, that includes the following areas of operation:

* * * * *

Issued in Washington, DC, on April 1, 2011.

Pamela Hamilton-Powell,

Director, Office of Rulemaking.

[FR Doc. 2011–8226 Filed 4–6–11; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[TD 9521]

RIN 1545–BG54

Reduction of Foreign Tax Credit Limitation Categories Under Section 904(d)

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final regulations and removal of temporary regulations.

SUMMARY: This document contains final regulations that provide guidance relating to the reduction of the number of separate foreign tax credit limitation categories under section 904(d) of the Internal Revenue Code. Changes to the applicable law were made by the American Jobs Creation Act of 2004 (AJCA) reducing the number of section 904(d) separate categories from eight to two, effective for taxable years beginning after December 31, 2006. The final regulations provide guidance needed to comply with these changes and affect individuals and corporations claiming foreign tax credits.

DATES: *Effective Date:* These regulations are effective on April 7, 2011.

Applicability Dates: For dates of applicability *see* §§ 1.904–2(i)(3), 1.904–4(n), 1.904–5(o)(3), 1.904–7(g)(6), and 1.904(f)–12(h)(6).

FOR FURTHER INFORMATION CONTACT: Jeffrey L. Parry, (202) 622–3850 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

On December 21, 2007, a notice of proposed rulemaking by cross-reference to temporary regulations (REG–114126–07) under section 904 of the Code and temporary regulations (TD 9368) (the 2007 temporary regulations) were published in the **Federal Register** (72 FR 72645) and (72 FR 72582), respectively. Corrections to those temporary regulations were published on March 21, 2008, in the **Federal Register** (73 FR 15063). No written comments were received. A public hearing was not requested and none was held. This Treasury decision adopts the proposed regulation with the changes discussed in this preamble.

Explanation of Changes in This Final Rule

I. Gain From the Sale of a Partnership Interest

Section 954(c)(4), which was enacted by the AJCA, provides a look-through rule for sales of 25-percent-owned partnerships. Because the definition of passive income in section 904(d)(2)(B) refers to section 954(c), § 1.904–5T(h)(3)(ii) of the 2007 temporary regulations provides that in the case of a sale of a partnership interest by a 25-percent partner, under the principles of section 954(c)(4)(B) the income recognized on such sale is assigned to the separate category for general category income, to the extent that the gain would not be classified as foreign personal holding company income under the section 954(c)(4) look-through rule. The rule has been revised to clarify that the look-through rule applies to a sale by any 25-percent owner of a partnership (and not just controlled foreign corporations that are 25-percent partners). The language of this provision has also been revised to be more consistent with the language of the look-through rule as provided under section 954(c)(4).

II. Losses in and Losses With Respect to the Pre-2007 Separate Category for High Withholding Tax Interest

Section 1.904(f)–12T(h) of the 2007 temporary regulations provides transition rules for recapture in a taxable year beginning after December 31, 2006 (post-2006 taxable year) of an overall foreign loss (OFL) or separate limitation loss (SLL) in a pre-2007 separate category (as defined in § 1.904–7T(g)(ii)) that offset U.S. source income or income in another pre-2007 separate category, respectively. Section 1.904(f)–12T(h)(3) provides that to the extent a taxpayer had an OFL or SLL at the end of the taxpayer's last pre-2007 taxable year in the pre-2007 separate category for high withholding tax interest, the allocation of such OFL or SLL to the taxpayer's post-2006 separate categories follows the taxpayer's allocation of excess taxes in the high withholding tax interest loss category for section 904(c) carryover purposes. If there were no excess taxes in the loss category that carried over to post-2006 taxable years, an OFL or SLL in the pre-2007 separate category for high withholding tax interest is allocated to the post-2006 separate category for passive category income. Similarly, § 1.904(f)–12T(h)(3) provides that where a taxpayer had an SLL in a pre-2007 separate category that offset high withholding tax interest (that is, an SLL with respect to a pre-2007 separate category for high withholding tax interest), the SLL will be recaptured in subsequent taxable years pro rata as income in the post-2006 separate categories for general category income and passive category income based on how the taxpayer allocated excess taxes in the pre-2007 separate category for high withholding tax interest. If no excess taxes in the pre-2007 separate category for high withholding tax interest were carried over to post-2006 taxable years, the SLL will be recaptured in subsequent taxable years as income in the post-2006 separate category for passive category income.

A question was raised as to whether it was appropriate, in the case of a financial services entity that had a loss in, or a loss with respect to, a pre-2007 separate category for high withholding tax interest, and no excess taxes in the loss category were carried over to post-2006 taxable years, that the loss be allocated to the post-2006 separate category for passive category income (in the case of a loss in the pre-2007 separate category for high withholding tax interest) or that the loss be recaptured in subsequent taxable years as income in the post-2006 separate category for passive category income (in the case of a loss with respect to a pre-2007 separate category for high withholding tax interest).

Section 904(d)(2)(C)(i), as amended by the AJCA, provides that financial services income is treated as general category income in the case of a member of a financial services group and any other person predominantly engaged in the active conduct of a banking, insurance, financing or similar business (a financial services entity). Financial services income includes passive income that is received or accrued by any person predominantly engaged in the active conduct of a banking, insurance, financing, or similar business, but does not include specified passive category income. See section 904(d)(2)(D)(i)(II). Accordingly, in post-2006 taxable years, income that otherwise would be treated as passive income (and assigned to the separate category for passive category income) will instead be treated as general category income in the case of a financial services entity.

The IRS and the Treasury Department believe that, in the case of a financial

services entity, the appropriate treatment of a loss in, or a loss with respect to, a pre-2007 separate category for high withholding tax interest, where no excess taxes in the loss category were carried over to post-2006 taxable years, is to allocate the loss to the post-2006 separate category for general category income or to recapture the loss in subsequent years as general category income, as the case may be. Accordingly, the regulations have been revised to provide that if a financial services entity allocated under § 1.904(f)–12T(h)(3) an OFL or SLL at the end of its last pre-2007 taxable year in the pre-2007 separate category for high withholding tax interest to the post-2006 separate category for passive category income, and no excess taxes in the loss category were carried over to post-2007 taxable years, the amount of any such loss that has not yet been recaptured will be allocated to the post-2006 separate category for general category income. Similarly, if a financial services entity allocated under § 1.904(f)–12T(h)(3) at the end of its last pre-2007 taxable year an SLL with respect to a pre-2007 separate category for high withholding tax interest, and no excess taxes in the separate category for high withholding tax interest were carried over to post-2007 taxable years (that is, the SLL would be subject to recapture as passive category income), the amount of any such SLL that has not yet been recaptured will be recaptured in subsequent taxable years as general category income. The regulations have also been revised to clarify that, in the case of a financial services entity, to the extent an SLL in the post-2006 separate category for general category income is recaptured as income in the post-2006 separate category for passive category income, the amount that would otherwise be recaptured as passive income (as opposed to specified passive category income) will be recaptured as general category income.

III. Section 952(c) Recapture Accounts

Section 1.904–7(g)(3) of the final regulations clarifies that section 952(c)(2) recapture accounts maintained by a controlled foreign corporation with respect to subpart F income in a separate category that was subject to the earnings and profits limitation of section 952(c)(1)(A) are allocated to separate categories in the same manner as the associated post-1986 undistributed earnings.

IV. Safe Harbors

The 2007 temporary regulations provide several safe harbors that a taxpayer may apply in lieu of generally applicable rules. Section 1.904–2T(i)(1)(ii) provides a safe harbor for the carryover of unused foreign taxes in a pre-2007 separate category to a post-2006 separate category; § 1.904–2T(i)(2)(ii) provides a safe harbor for the carryback of unused foreign taxes in a post-2006 separate category to a pre-2007 separate category; § 1.904–7T(g)(3)(ii) provides safe harbors for allocating pools of post-1986 undistributed earnings and post-1986 foreign income taxes in the pre-2007 separate categories of controlled foreign corporations and noncontrolled section 902 corporations to the post-2006 separate categories; and § 1.904(f)–12T(h)(5) provides an alternative method for determining the recapture in post-2006 taxable years of separate limitation losses and overall foreign losses incurred in pre-2007 taxable years.

A question was raised as to how a safe harbor method election is to be made and the time frame for making the election. The final regulations provide that taxpayers may choose to use a safe harbor method on a timely filed (original or amended) tax return or during audit. If a taxpayer chooses to use the safe harbor method on an amended return or in the course of an audit, the taxpayer must make appropriate adjustments to eliminate any double benefit arising from application of the safe harbor method to years that are not open for assessment. A taxpayer's choice to use the safe harbor method is evidenced by simply employing the method in determining its foreign tax credit limitation. No separate statement need be filed.

V. Effective/Applicability Dates

The effective/applicability dates are the same as those in the proposed and temporary regulations with minor clarifying changes.

Special Analyses

It has been determined that this notice of proposed rulemaking 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. chapter 6) does not apply.

Drafting Information

The principal author of these regulations is Jeffrey L. Parry of the Office of Chief Counsel (International). However, other personnel from the Treasury Department and the IRS 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 1.904–0 is amended by adding entries for §§ 1.904–2(i), 1.904–4(a), (b), (h)(3), and (l), 1.904–5(h)(3) and (o)(3), and1.904–7(g) to read as follows:

§ 1.904–0 Outline of regulation provisions for section 904.

* * * * *

§ 1.904–2 Carryback and carryover of unused foreign tax.

* * * * *

(i) Transition rules for carryovers and carrybacks of pre-2007 and post-2006 unused foreign tax.

(1) Carryover of unused foreign tax.

(i) General rule.

(ii) Safe harbor.

(2) Carryback of unused foreign tax.

(i) General rule.

(ii) Safe harbor.

(3) Effective/applicability date.

* * * * *

§ 1.904–4 Separate application of section 904 with respect to certain categories of income.

(a) In general.

(b) Passive category income.

(1) In general.

(2) Passive income.

(i) In general.

(ii) Exceptions.

(iii) Active rents or royalties.

(A) In general.

(B) Active conduct of trade or business.

(iv) Examples.

(3) Specified passive category income.

* * * * *

(h) * * *

(3) Exception.

* * * * *

(l) Priority rule.

* * * * *

§ 1.904–5 Look-through rules as applied to controlled foreign corporations and other entities.

* * * * *

(h) * * *

(3) Income from the sale of a partnership interest.

(i) In general.

(ii) Exception for sale by 25-percent owner.

* * * * *

(o) * * *

(3) Rules for income from the sale of a partnership interest.

§ 1.904–7 Transition rules.

* * * * *

(g) Treatment of earnings and foreign taxes of a controlled foreign corporation or a noncontrolled section 902 corporation accumulated in taxable years beginning before January 1, 2007.

(1) Definitions.

(i) Pre-2007 pools.

(ii) Pre-2007 separate categories.

(iii) Post-2006 separate categories.

(2) Treatment of pre-2007 pools of a controlled foreign corporation or a noncontrolled section 902 corporation.

(3) Substantiation of post-2006 character of earnings and taxes in a pre-2007 pool.

(i) Reconstruction of earnings and taxes pools.

(ii) Safe harbor method.

(A) In general.

(B) General safe harbor method.

(C) Interest apportionment safe harbor.

(iii) Consistency rule.

(4) Treatment of pre-1987 accumulated profits.

(5) Treatment of earnings and foreign taxes in pre-2007 pools of a lower-tier controlled foreign corporation or noncontrolled section 902 corporation.

(6) Effective/applicability date.

■ **Par. 3.** Section 1.904–2(i) is revised to read as follows:

§ 1.904–2 Carryback and carryover of unused foreign tax.

* * * * *

(i) *Transition rules for carryovers and carrybacks of pre-2007 and post-2006 unused foreign tax*—(1) *Carryover of unused foreign tax*—(i) *General rule.* For purposes of this paragraph (i), the terms *post-2006 separate category* and *pre-2007 separate category* have the meanings set forth in § 1.904–7(g)(1)(ii) and (iii). The rules of this paragraph (i)(1) apply to reallocate to the taxpayer's post-2006 separate categories for general category income and passive category income any unused foreign taxes (as defined in § 1.904–2(b)(2)) that were paid or accrued or deemed paid under section 902 with respect to income in a pre-2007 separate category (other than a category described in § 1.904–4(m)). To the extent any such unused foreign taxes are carried forward to a taxable year beginning after December 31, 2006, such taxes shall be allocated to the taxpayer's post-2006 separate categories to which those taxes would have been allocated if the taxes were paid or accrued in a taxable year beginning after December 31, 2006. For example, any foreign taxes paid or accrued or deemed paid with respect to financial services income in a taxable year beginning before January 1, 2007, that are carried forward to a taxable year beginning after December 31, 2006, will be allocated to the general category because the financial services income to which those taxes relate would have been allocated to the general category if it had been earned in a taxable year beginning after December 31, 2006.

(ii) *Safe harbor.* In lieu of applying the rules of paragraph (i)(1)(i) of this section, a taxpayer may allocate all unused foreign taxes in the pre-2007 separate category for passive income to the post-2006 separate category for passive category income, and allocate all other unused foreign taxes described in paragraph (i)(1)(i) of this section to the post-2006 separate category for general category income. A taxpayer may choose to use the safe harbor method on a timely filed (original or amended) tax return or during an audit. A taxpayer that uses the safe harbor method on an amended return or in the course of an audit must make appropriate adjustments to eliminate any double benefit arising from application of the safe harbor method to years that are not open for assessment. A taxpayer's choice to use the safe harbor method is evidenced by employing the method. The taxpayer need not file any separate statement.

(2) *Carryback of unused foreign tax*—(i) *General rule.* The rules of this paragraph (i)(2) apply to any unused foreign taxes that were paid or accrued or deemed paid under section 902 with respect to income in a post-2006 separate category (other than a category described in § 1.904–4(m)). To the extent any such unused foreign taxes are carried back to a taxable year beginning before January 1, 2007, a credit for such taxes shall be allowed only to the extent of the excess limitation in the pre-2007 separate category, or categories, to which the taxes would have been allocated if the taxes were paid or accrued in a taxable year beginning before January 1, 2007. For example, any foreign taxes paid or accrued or deemed paid with respect to income in the general category in a taxable year beginning after December 31, 2006, that are carried back to a taxable year beginning before January 1, 2007, will be allocated to the same separate categories to which the income would have been allocated if such income had been earned in a taxable year beginning before January 1, 2007.

(ii) *Safe harbor.* In lieu of applying the rules of paragraph (i)(2)(i) of this section, a taxpayer may allocate all unused foreign taxes in the post-2006 separate category for passive category income to the pre-2007 separate category for passive income, and may allocate all other unused foreign taxes described in paragraph (i)(2)(i) of this section to the pre-2007 separate category for general limitation income. A taxpayer may choose to use the safe harbor method on a timely filed (original or amended) tax return or during an audit. A taxpayer that uses the safe harbor method on an amended return or in the course of an audit must make appropriate adjustments to eliminate any double benefit arising from application of the safe harbor method to years that are not open for assessment. A taxpayer's choice to use the safe harbor method is evidenced by employing the method. The taxpayer need not file any separate statement.

(3) *Effective/applicability date.* This paragraph (i) applies to taxable years beginning after December 31, 2006 and ending on or after December 21, 2007.

§ 1.904–2T [Removed].

■ **Par. 4.** Section 1.904–2T is removed.

■ **Par. 5.** In § 1.904–4, paragraphs (a), (b), (h)(3), and (l) are revised, paragraphs (f) and (g) are removed and reserved, and a new sentence is added immediately after the heading of paragraph (n) to read as follows:

§ 1.904–4 Separate application of section 904 with respect to certain categories of income.

(a) *In general.* A taxpayer is required to compute a separate foreign tax credit limitation for income received or accrued in a taxable year that is described in section 904(d)(1)(A) (passive category income), 904(d)(1)(B) (general category income), or § 1.904–4(m) (additional separate categories).

(b) *Passive category income*—(1) *In general.* The term *passive category income* means passive income and specified passive category income.

(2) *Passive income*—(i) *In general.* The term *passive income* means any—

(A) Income received or accrued by any person that is of a kind that would be foreign personal holding company income (as defined in section 954(c)) if the taxpayer were a controlled foreign corporation, including any amount of gain on the sale or exchange of stock in excess of the amount treated as a dividend under section 1248; or

(B) Amount includible in gross income under section 1293.

(ii) *Exceptions.* Passive income does not include any export financing interest (as defined in section 904(d)(2)(G) and paragraph (h) of this section), any high-taxed income (as defined in section 904(d)(2)(F) and paragraph (c) of this section), or any active rents and royalties (as defined in paragraph (b)(2)(iii) of this section). In addition, passive income does not include any income that would otherwise be passive but is characterized as income in another separate category under the look-through rules of section 904(d)(3), (d)(4), and (d)(6)(C) and the regulations under those provisions. In determining whether any income is of a kind that would be foreign personal holding company income, the rules of section 864(d)(5)(A)(i) and (6) (treating related person factoring income of a controlled foreign corporation as foreign personal holding company income that is not eligible for the export financing income exception to the separate limitation for passive income) shall apply only in the case of income of a controlled foreign corporation (as defined in section 957). Thus, income earned directly by a United States person that is related person factoring income may be eligible for the exception for export financing interest.

(iii) *Active rents or royalties*—(A) *In general.* For rents and royalties paid or accrued after September 20, 2004, passive income does not include any rents or royalties that are derived in the active conduct of a trade or business, regardless of whether such rents or royalties are received from a related or an unrelated person. Except as provided in paragraph (b)(2)(iii)(B) of this section, the principles of section 954(c)(2)(A) and the regulations under that section shall apply in determining whether rents or royalties are derived in the active conduct of a trade or business. For this purpose, the term taxpayer shall be substituted for the term controlled foreign corporation if the recipient of the rents or royalties is not a controlled foreign corporation.

(B) *Active conduct of trade or business.* Rents and royalties are considered derived in the active conduct of a trade or business by a United States person or by a controlled foreign corporation (or other entity to which the look-through rules apply) for purposes of section 904 (but not for purposes of section 954) if the requirements of section 954(c)(2)(A) are satisfied by one or more corporations that are members of an affiliated group of corporations (within the meaning of section 1504(a), determined without regard to section 1504(b)(3)) of which the recipient is a member. For purposes of this paragraph (b)(2)(iii)(B), an affiliated group includes only domestic corporations and foreign corporations that are controlled foreign corporations in which domestic members of the affiliated group own, directly or indirectly, at least 80 percent of the total voting power and value of the stock. For purposes of this paragraph (b)(2)(iii)(B), indirect ownership shall be determined under section 318 and the regulations under that section.

(iv) *Examples.* The following examples illustrate the application of paragraph (b)(2) of this section.

Example 1. P is a domestic corporation with a branch in foreign country X. P does not have any financial services income. For 2008, P has a net foreign currency gain that would not constitute foreign personal holding company income if P were a controlled foreign corporation because the gain is directly related to the business needs of P. The currency gain is, therefore, general category income to P because it is not income of a kind that would be foreign personal holding company income.

Example 2. Controlled foreign corporation S is a wholly-owned subsidiary of P, a domestic corporation. S is regularly engaged in the restaurant franchise business. P licenses trademarks, tradenames, certain know-how, related services, and certain restaurant designs for which S pays P an arm's length royalty. P is regularly engaged in the development and licensing of such property. The royalties received by P for the use of its property are allocable under the look-through rules of § 1.904–5 to the royalties S receives from the franchisees. Some of the franchisees are unrelated to S and P. Other franchisees are related to S or P and use the licensed property outside of S's country of incorporation. S does not satisfy, but P does satisfy, the active trade or business requirements of section 954(c)(2)(A) and the regulations under that section. The royalty income earned by S with regard to both its related and unrelated franchisees is foreign personal holding company income because S does not satisfy the active trade or business requirements of section 954(c)(2)(A) and, in addition, the royalty income from the related franchisees does not qualify for the same country exception of section 954(c)(3). However, all of the royalty income earned by S is general category income to S under § 1.904–4(b)(2)(iii) because P, a member of S's affiliated group (as defined therein), satisfies the active trade or business test (which is applied without regard to whether the royalties are paid by a related person). S's royalty income that is taxable to P under subpart F and the royalties paid to P are general category income to P under the look-through rules of § 1.904–5(c)(1)(i) and (c)(3), respectively.

(3) *Specified passive category income* means—

(i) Dividends from a DISC or former DISC (as defined in section 992(a)) to the extent such dividends are treated as income from sources without the United States;

(ii) Taxable income attributable to foreign trade income (within the meaning of section 923(b)); or

(iii) Distributions from a FSC (or a former FSC) out of earnings and profits attributable to foreign trade income (within the meaning of section 923(b)) or interest or carrying charges (as defined in section 927(d)(1)) derived from a transaction which results in foreign trade income (as defined in section 923(b)).

* * * * *

(f) [Reserved].

(g) [Reserved].

(h) * * *

(3) *Exception.* Unless it is received or accrued by a financial services entity, export financing interest shall be treated as passive category income if that income is also related person factoring income. For this purpose, related person factoring income is—

(i) Income received or accrued by a controlled foreign corporation that is income described in section 864(d)(6) (income of a controlled foreign corporation from a loan for the purpose of financing the purchase of inventory property of a related person); or

(ii) Income received or accrued by any person that is income described in section 864(d)(1) (income from a trade receivable acquired from a related person).

* * * * *

(l) *Priority rule.* Income that meets the definitions of a separate category described in paragraph (m) of this section and another category of income described in section 904(d)(2)(A)(i) and (ii) will be subject to the separate limitation described in paragraph (m) of this section and will not be treated as general category income described in section 904(d)(2)(A)(ii).

* * * * *

(n) * * * Paragraphs (a), (b), (h)(3), and (l) of this section shall apply to taxable years of United States persons and, for purposes of section 906, foreign persons beginning after December 31, 2006 and ending on or after December 21, 2007, and to taxable years of a foreign corporation which end with or within taxable years of its domestic corporate shareholder beginning after December 31, 2006 and ending on or after December 21, 2007. * * *

§ 1.904–4T [Removed].

■ **Par. 6.** Section 1.904–4T is removed.

■ **Par. 7.** In § 1.904–5, paragraphs (h)(3) and (o)(3) are revised to read as follows:

§ 1.904–5 Look-through rules as applied to controlled foreign corporations and other entities.

* * * * *

(h) * * *

(3) *Income from the sale of a partnership interest*—(i) *In general.* To the extent a partner recognizes gain on the sale of a partnership interest, that income shall be treated as passive category income to the partner, unless the income is considered to be high-taxed under section 904(d)(2)(B)(iii)(II) and § 1.904–4(c).

(ii) *Exception for sale by 25-percent owner.* In the case of a sale of an interest in a partnership by a partner that is a 25-percent owner of the partnership, determined by applying section 954(c)(4)(B) and substituting "controlled foreign corporation" with "partner" every place it appears, for purposes of determining the separate category to which the income recognized on the sale of the partnership interest is assigned such partner shall be treated as selling the proportionate share of the assets of the partnership attributable to such interest.

* * * * *

(o) * * *

(3) *Rules for income from the sale of a partnership interest.* Paragraph (h)(3) of this section shall apply to taxable years of United States persons and, for purposes of section 906, foreign persons beginning after December 31, 2006 and ending on or after December 21, 2007, and to taxable years of a foreign corporation which end with or within taxable years of its domestic corporate shareholder beginning after December 31, 2006 and ending on or after December 21, 2007.

§ 1.904–5T [Removed].

■ **Par. 8.** Section 1.904–5T is removed.

■ **Par. 9.** Section 1.904–7, paragraph (g) is revised to read as follows:

§ 1.904–7 Transition rules.

* * * * *

(g) *Treatment of earnings and foreign taxes of a controlled foreign corporation or a noncontrolled section 902 corporation accumulated in taxable years beginning before January 1, 2007*—(1) *Definitions*—(i) *Pre-2007 pools* means the pools in each separate category of post-1986 undistributed earnings (as defined in § 1.902–1(a)(9)) that were accumulated, and post-1986 foreign income taxes (as defined in § 1.902–1(a)(8)) paid, accrued, or deemed paid, in taxable years beginning before January 1, 2007.

(ii) *Pre-2007 separate categories* means the separate categories of income described in section 904(d) as applicable to taxable years beginning before January 1, 2007, and any other separate category of income described in § 1.904–4(m).

(iii) *Post-2006 separate categories* means the separate categories of income described in section 904(d) as applicable to taxable years beginning after December 31, 2006, and any other separate category of income described in § 1.904–4(m).

(2) *Treatment of pre-2007 pools of a controlled foreign corporation or a noncontrolled section 902 corporation.* Any post-1986 undistributed earnings in a pre-2007 pool of a controlled foreign corporation or a noncontrolled section 902 corporation shall be treated in taxable years beginning after December 31, 2006, as if they were accumulated during a period in which the rules governing the determination of post-2006 separate categories applied. Post-1986 foreign income taxes paid, accrued, or deemed paid with respect to such earnings shall be treated as if they were paid, accrued, or deemed paid during a period in which the rules governing the determination of post-2006 separate categories (including the rules of section 904(d)(3)(E)) applied as well. Any such earnings and taxes in pre-2007 pools shall constitute the opening balance of the foreign corporation's post-1986 undistributed earnings and post-1986 foreign income taxes on the first day of the foreign corporation's first taxable year beginning after December 31, 2006, in accordance with the rules of paragraph (g)(3) of this section. Similar rules shall apply to characterize any deficits in the pre-2007 pools and previously-taxed earnings and profits described in section 959(c)(1) and (2) that are attributable to earnings in the pre-2007 pools. Any section 952(c)(2) recapture account with respect to a separate category shall be allocated in the same manner as the post-1986 undistributed earnings in the associated pre-2007 pool.

(3) *Substantiation of post-2006 character of earnings and taxes in a pre-2007 pool*—(i) *Reconstruction of earnings and taxes pools.* In order to substantiate the post-2006 characterization of post-1986 undistributed earnings (as well as deficits and previously-taxed earnings, if any) and post-1986 foreign income taxes in pre-2007 pools of a controlled foreign corporation or a noncontrolled section 902 corporation, the taxpayer shall make a reasonable, good-faith effort to reconstruct the pre-2007 pools of post-1986 undistributed earnings (as well as deficits and previously-taxed earnings, if any) and post-1986 foreign income taxes following the rules governing the determination of post-2006 separate categories for each taxable year beginning before January 1, 2007, beginning with the first year in which post-1986 undistributed earnings were accumulated in the pre-2007 pool. Reconstruction shall be based on reasonably available books and records and other relevant information. To the extent any pre-2007 separate category includes earnings that would be allocated to more than one post-2006 separate category, the taxpayer must account for earnings distributed and taxes deemed paid in these years for such category as if they were distributed and deemed paid pro rata from the amounts that were added to that category during each taxable year beginning before January 1, 2007.

(ii) *Safe harbor method*—(A) *In general.* Subject to the rules of paragraph (g)(3)(iii) of this section, a taxpayer may allocate the post-1986 undistributed earnings and post-1986 foreign income taxes in pre-2007 pools of a controlled foreign corporation or a noncontrolled section 902 corporation (as well as deficits and previously-taxed earnings, if any) under one of the safe harbor methods described in paragraphs (g)(3)(ii)(B) and (g)(3)(ii)(C) of this section. A taxpayer may choose to use the safe harbor method on a timely filed (original or amended) tax return or during an audit. A taxpayer that uses the safe harbor method on an amended return or in the course of an audit must make appropriate adjustments to eliminate any double benefit arising from application of the safe harbor method to years that are not open for assessment. A taxpayer's choice to use the safe harbor method is evidenced by employing the method. The taxpayer need not file any separate statement.

(B) *General safe harbor method*—(*1*) Any post-1986 undistributed earnings (as well as deficits and previously-taxed earnings, if any) and post-1986 foreign income taxes of a noncontrolled section 902 corporation or a controlled foreign corporation in a pre-2007 separate category for passive income, certain dividends from a DISC or former DISC, taxable income attributable to certain foreign trade income, or certain distributions from a FSC or former FSC shall be allocated to the post-2006 separate category for passive category income.

(*2*) Any post-1986 undistributed earnings (as well as deficits and previously-taxed earnings, if any) and post-1986 foreign income taxes of a noncontrolled section 902 corporation or a controlled foreign corporation in a pre-2007 separate category for financial services income, shipping income or

general limitation income shall be allocated to the post-2006 separate category for general category income.

(*3*) Except as provided in paragraph (g)(3)(ii)(B)(*4*) of this section, any post-1986 undistributed earnings (as well as deficits and previously-taxed earnings, if any) and post-1986 foreign income taxes of a noncontrolled section 902 corporation or a controlled foreign corporation in a pre-2007 separate category for high withholding tax interest shall be allocated to the post-2006 separate category for passive category income.

(*4*) If a controlled foreign corporation has positive post-1986 undistributed earnings and post-1986 foreign income taxes in a pre-2007 separate category for high withholding tax interest, such earnings and taxes shall be allocated to the post-2006 separate category for general category income if the earnings would qualify as income subject to high foreign taxes under section 954(b)(4) if the entire amount of post-1986 undistributed earnings were treated as a net item of income subject to the rules of § 1.954–1(d). If the high withholding tax interest earnings would not qualify as income subject to high foreign taxes under section 954(b)(4), then the earnings and taxes shall be allocated to the post-2006 separate category for passive category income.

(C) *Interest apportionment safe harbor.* A taxpayer may allocate the post-1986 undistributed earnings (as well as deficits and previously-taxed earnings, if any) and post-1986 foreign income taxes in pre-2007 pools of a controlled foreign corporation or a noncontrolled section 902 corporation following the principles of paragraph (f)(4)(ii) of this section.

(iii) *Consistency rule.* The election to apply a safe harbor method under paragraph (g)(3)(ii) of this section in lieu of the rules described in paragraph (g)(3)(i) of this section may be made on a separate category by separate category basis. However, if a taxpayer elects to apply a safe harbor to allocate pre-2007 pools of more than one pre-2007 separate category of a controlled foreign corporation or a noncontrolled section 902 corporation, such safe harbor (the general safe harbor described in paragraph (g)(3)(ii)(B) of this section or the interest apportionment safe harbor described in paragraph (g)(3)(ii)(C) of this section) shall apply to allocate post-1986 undistributed earnings (as well as deficits and previously-taxed earnings, if any) and post-1986 foreign income taxes for the pre-2007 pools in each pre-2007 separate category of the foreign corporation for which the taxpayer elected to apply a safe harbor method in lieu of reconstructing the pre-2007 pools.

(4) *Treatment of pre-1987 accumulated profits.* Any pre-1987 accumulated profits (as defined in § 1.902–1(a)(10)) of a noncontrolled section 902 corporation or a controlled foreign corporation shall be treated in taxable years beginning after December 31, 2006, as if they had been accumulated during a period in which the rules governing the determination of post-2006 separate categories applied. Foreign income taxes paid, accrued, or deemed paid with respect to such earnings shall be treated as if they were paid, accrued, or deemed paid during a period in which the rules governing the determination of post-2006 separate categories applied as well. The taxpayer must substantiate the post-2006 characterization of the pre-1987 accumulated profits and pre-1987 foreign income taxes in accordance with the rules of paragraph (g)(3) of this section, including the safe harbor provisions. Similar rules shall apply to characterize any deficits or previously-taxed earnings and profits described in section 959(c)(1) and (2) that are attributable to pre-1987 accumulated profits.

(5) *Treatment of earnings and foreign taxes in pre-2007 pools of a lower-tier controlled foreign corporation or noncontrolled section 902 corporation.* The rules of paragraphs (g)(1) through (4) of this section apply to post-1986 undistributed earnings (as well as deficits and previously-taxed earnings, if any) and post-1986 foreign income taxes in pre-2007 pools, and pre-1987 accumulated profits and pre-1987 foreign income taxes, of a lower-tier controlled foreign corporation or noncontrolled section 902 corporation.

(6) *Effective/applicability date.* This paragraph (g) shall apply to taxable years of United States persons and, for purposes of section 906, foreign persons beginning after December 31, 2006 and ending on or after December 21, 2007, and to taxable years of a foreign corporation which end with or within taxable years of its domestic corporate shareholder beginning after December 31, 2006 and ending on or after December 21, 2007.

§ 1.904–7T [Removed].

■ **Par. 10.** Section 1.904–7T is removed.

■ **Par. 11.** Section 1.904(f)–0 is amended by adding an entry for § 1.904(f)–12(h) to read as follows:

§ 1.904(f)–0 Outline of regulation provisions.

* * * * *

§ 1.904(f)–12 Transition rules.

* * * * *

(h) Recapture in years beginning after December 31, 2006, of separate limitation losses and overall foreign losses incurred in years beginning before January 1, 2007.

(1) Losses related to pre-2007 separate categories for passive income, certain dividends from a DISC or former DISC, taxable income attributable to certain foreign trade income or certain distributions from a FSC or former FSC.

(i) Recapture of separate limitation loss or overall foreign loss incurred in a pre-2007 separate category for passive income, certain dividends from a DISC or former DISC, taxable income attributable to certain foreign trade income or certain distributions from a FSC or former FSC.

(ii) Recapture of separate limitation loss with respect to a pre-2007 separate category for passive income, certain dividends from a DISC or former DISC, taxable income attributable to certain foreign trade income or certain distributions from a FSC or former FSC.

(2) Losses related to pre-2007 separate categories for shipping, financial services income or general limitation income.

(i) Recapture of separate limitation loss or overall foreign loss incurred in a pre-2007 separate category for shipping income, financial services income or general limitation income.

(ii) Recapture of separate limitation loss with respect to a pre-2007 separate category for shipping income, financial services income or general limitation income.

(3) Losses related to a pre-2007 separate category for high withholding tax interest.

(i) Recapture of separate limitation loss or overall foreign loss incurred in a pre-2007 separate category for high withholding tax interest.

(ii) Recapture of separate limitation loss with respect to a pre-2007 separate category for high withholding tax interest.

(4) Elimination of certain separate limitation loss accounts.

(5) Alternative method.

(6) Effective/applicability date.

Par. 12. Section 1.904(f)–12(h) is revised to read as follows:

§ 1.904(f)–12 Transition rules.

* * * * *

(h) *Recapture in years beginning after December 31, 2006, of separate limitation losses and overall foreign losses incurred in years beginning before January 1, 2007*—(1) *Losses related to pre-2007 separate categories for passive income, certain dividends*

from a DISC or former DISC, taxable income attributable to certain foreign trade income or certain distributions from a FSC or former FSC—(i) *Recapture of separate limitation loss or overall foreign loss incurred in a pre-2007 separate category for passive income, certain dividends from a DISC or former DISC, taxable income attributable to certain foreign trade income or certain distributions from a FSC or former FSC.* To the extent that a taxpayer has a balance in any separate limitation loss or overall foreign loss account in a pre-2007 separate category (as defined in § 1.904–7(g)(1)(ii)) for passive income, certain dividends from a DISC or former DISC, taxable income attributable to certain foreign trade income or certain distributions from a FSC or former FSC, at the end of the taxpayer's last taxable year beginning before January 1, 2007, the amount of such balance, or balances, shall be allocated on the first day of the taxpayer's next taxable year to the taxpayer's post-2006 separate category (as defined in § 1.904–7(g)(1)(iii)) for passive category income.

(ii) *Recapture of separate limitation loss with respect to a pre-2007 separate category for passive income, certain dividends from a DISC or former DISC, taxable income attributable to certain foreign trade income or certain distributions from a FSC or former FSC.* To the extent that a taxpayer has a balance in any separate limitation loss account in any pre-2007 separate category with respect to a pre-2007 separate category for passive income, certain dividends from a DISC or former DISC, taxable income attributable to certain foreign trade income or certain distributions from a FSC or former FSC at the end of the taxpayer's last taxable year beginning before January 1, 2007, such loss shall be recaptured in subsequent taxable years as income in the post-2006 separate category for passive category income.

(2) *Losses related to pre-2007 separate categories for shipping, financial services income or general limitation income*—(i) *Recapture of separate limitation loss or overall foreign loss incurred in a pre-2007 separate category for shipping income, financial services income or general limitation income.* To the extent that a taxpayer has a balance in any separate limitation loss or overall foreign loss account in a pre-2007 separate category for shipping income, financial services income or general limitation income at the end of the taxpayer's last taxable year beginning before January 1, 2007, the amount of such balance, or balances, shall be allocated on the first day of the taxpayer's next taxable year to the taxpayer's post-2006 separate category for general category income.

(ii) *Recapture of separate limitation loss with respect to a pre-2007 separate category for shipping income, financial services income or general limitation income.* To the extent that a taxpayer has a balance in any separate limitation loss account in any pre-2007 separate category with respect to a pre-2007 separate category for shipping income, financial services income or general limitation income at the end of the taxpayer's last taxable year beginning before January 1, 2007, such loss shall be recaptured in subsequent taxable years as income in the post-2006 separate category for general category income.

(3) *Losses related to a pre-2007 separate category for high withholding tax interest*—(i) *Recapture of separate limitation loss or overall foreign loss incurred in a pre-2007 separate category for high withholding tax interest.* To the extent that a taxpayer has a balance in any separate limitation loss or overall foreign loss account in a pre-2007 separate category for high withholding tax interest at the end of the taxpayer's last taxable year beginning before January 1, 2007, the amount of such balance shall be allocated on the first day of the taxpayer's next taxable year on a pro rata basis to the taxpayer's post-2006 separate categories for general category and passive category income, based on the proportion in which any unused foreign taxes in the same pre-2007 separate category for high withholding tax interest are allocated under § 1.904–2(i)(1). If the taxpayer, other than a financial services entity as defined in § 1.904–4(e)(3), has no unused foreign taxes in the pre-2007 separate category for high withholding tax interest, then any loss account balance in that category shall be allocated to the post-2006 separate category for passive category income. If the taxpayer is a financial services entity, as defined in § 1.904–4(e)(3), and has no unused foreign taxes in the pre-2007 separate category for high withholding tax interest, then any loss account balance in that category shall be allocated to the post-2006 separate category for general category income.

(ii) *Recapture of separate limitation loss with respect to a pre-2007 separate category for high withholding tax interest.* To the extent that a taxpayer has a balance in a separate limitation loss account in any pre-2007 separate category with respect to a pre-2007 separate category for high withholding tax interest at the end of the taxpayer's last taxable year beginning before January 1, 2007, such loss shall be recaptured in subsequent taxable years on a pro rata basis as income in the post-2006 separate categories for general category and passive category income, based on the proportion in which any unused foreign taxes in the pre-2007 separate category for high withholding tax interest are allocated under § 1.904–2(i)(1). If the taxpayer, other than a financial services entity as defined in § 1.904–4(e)(3), has no unused foreign taxes in the pre-2007 separate category for high withholding tax interest, then the loss account balance shall be recaptured in subsequent taxable years solely as income in the post-2006 separate category for passive category income. If the taxpayer is a financial services entity, as defined in § 1.904–4(e)(3), and has no unused foreign taxes in the pre-2007 separate category for high withholding tax interest, then the loss account balance shall be recaptured in subsequent taxable years solely as income in the post-2006 separate category for general category income.

(4) *Elimination of certain separate limitation loss accounts.* After application of paragraphs (h)(1) through (h)(3) of this section, any separate limitation loss account allocated to the post-2006 separate category for passive category income for which income is to be recaptured as passive category income, as determined under those same provisions, shall be eliminated. Similarly, after application of paragraphs (h)(1) through (h)(3) of this section, any separate limitation loss account allocated to the post-2006 separate category for general category income for which income is to be recaptured as general category income, as determined under those same provisions, shall be eliminated.

(5) *Alternative method.* In lieu of applying the rules of paragraphs (h)(1) through (h)(3) of this section, a taxpayer may apply the principles of paragraphs (g)(1) and (g)(2) of this section to determine recapture in taxable years beginning after December 31, 2006, of separate limitation losses and overall foreign losses incurred in taxable years beginning before January 1, 2007. A taxpayer may choose to use the alternative method on a timely filed (original or amended) tax return or during an audit. A taxpayer that uses the alternative method on an amended return or in the course of an audit must make appropriate adjustments to eliminate any double benefit arising from application of the alternative method to years that are not open for assessment. A taxpayer's choice to use the alternative method is evidenced by

employing the method. The taxpayer need not file any separate statement.

(6) *Effective/applicability date.* This paragraph (h) shall apply to taxable years beginning after December 31, 2006, and ending on or after December 21, 2007. However, taxpayers may choose to apply 26 CFR 1.904(f)–12T(h) as it appeared in the Code of Federal Regulations as of April 1, 2010, in lieu of this paragraph (h) to taxable years beginning after December 31, 2006 and ending on or after December 21, 2007, but ending before April 7, 2011 provided that appropriate adjustments are made to eliminate duplicate benefits arising from application of 26 CFR 1.904(f)–12T(h) to taxable years that are not open for assessment. In addition, if a taxpayer that is a financial services entity (as defined in § 1.904–4(e)(3)) chooses to apply 26 CFR 1.904(f)–12T(h) to taxable years ending before April 7, 2011, then as of the beginning of the taxpayer's first taxable year ending on or after April 7, 2011 any remaining balance in a passive category loss account that is attributable to a loss account in a pre-2007 separate category for high withholding tax interest shall be allocated to the general category or eliminated pursuant to § 1.904(f)–12(h)(4), and any remaining balance in a separate limitation loss account with respect to passive category income that is attributable to a loss account with respect to a pre-2007 separate category for high withholding tax interest will be recaptured in such year and subsequent taxable years as general category income or eliminated pursuant to § 1.904(f)–12(h)(4).

§ 1.904(f)–12T [Removed].

■ **Par. 13.** Section 1.904(f)–12T is removed.

Approved: March 29, 2011.

Steven T. Miller,

Deputy Commissioner for Services and Enforcement.

Michael Mundaca,

Assistant Secretary of the Treasury (Tax Policy).

[FR Doc. 2011–8229 Filed 4–6–11; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

46 CFR Parts 115, 170, 176, and 178

[USCG–2007–0030]

RIN 1625–AB20

Passenger Weight and Inspected Vessel Stability Requirements

AGENCY: Coast Guard, DHS.

ACTION: Rule; information collection approval.

SUMMARY: On December 14, 2010, the Coast Guard amended its regulations governing the maximum weight and number of passengers that may safely be permitted on board a vessel and other stability regulations, including increasing the Assumed Average Weight per Person (AAWPP) to 185 lb. The amendment triggered new information collection requirements affecting documentation needed from certain inspected vessels as part of the Coast Guard commercial vessel safety program. This document announces that the Office of Management and Budget (OMB) approved changes to the collections of information with control numbers 1625–0057 and 1625–0064, which will now be enforced.

DATES: Changes to the collection of information requirements with OMB control numbers 1625–0057 and 1625–0064 will be enforced under 46 CFR parts 115, 170, 176, and 178 beginning April 7, 2011.

FOR FURTHER INFORMATION CONTACT: If you have questions about this document, contact Mr. William Peters at 202–372–1371 or *William.S.Peters@uscg.mil.* If you have questions about viewing the docket (USCG–2007–0030), call Ms. Renee V. Wright, Program Manager, Docket Operations, telephone 202–366–9826.

SUPPLEMENTARY INFORMATION: With the exception of revised collection of information provisions, the Passenger Weight and Inspected Vessel Stability Requirements rule became effective on March 14, 2011. Under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520), an agency may not conduct or sponsor a collection of information until the collection is approved by OMB. Accordingly, the preamble to the final rule stated that the Coast Guard would not enforce the new collection of information requirements in 46 CFR parts 115, 170, 176, and 178 until the collection of information requests were approved by OMB, and also stated that the Coast Guard would publish a notice in the **Federal Register** announcing the effective date of those requirements after OMB approved the collections.

The Coast Guard submitted the information collection requests to OMB for approval in accordance with the Paperwork Reduction Act of 1995. OMB approved the collections of information on March 4, 2011, for 1625–0064, and on March 14, 2011, for 1625–0057. The approval for these collections of information expires on March 31, 2014. Copies of the OMB notices of action are available in our online docket (USCG–2007–0030) at *http://www.regulations.gov.*

Dated: March 30, 2011.

F.J. Sturm,

Acting Director of Commercial Regulations and Standards, U.S. Coast Guard.

[FR Doc. 2011–8119 Filed 4–6–11; 8:45 am]

BILLING CODE 9110–04–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[MB Docket No. 11–8; RM–11618, DA 11–516]

Television Broadcasting Services; Jackson, MS

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: The Commission grants a petition for rulemaking issued in response to a petition for rulemaking filed by George S. Flinn, Jr. ("Flinn"), the licensee of WWJX, channel 51, Jackson, Mississippi, requesting the substitution of channel 23 for channel 51 at Jackson. Flinn raises concerns regarding potential interference that may occur to Long Term Evolution cellular base stations operating on adjacent channel spectrum and believes substituting channel 23 for channel 51 will better serve the public interest.

DATES: This rule is effective May 9, 2011.

FOR FURTHER INFORMATION CONTACT: Joyce L. Bernstein, joyce.bernstein@fcc.gov, Media Bureau, (202) 418–1600.

SUPPLEMENTARY INFORMATION: This is a synopsis of the Commission's *Report and Order,* MB Docket No. 11–8, adopted March 16, 2011, and released March 21, 2011. The full text of this document is available for public inspection and copying during normal business hours in the FCC's Reference Information Center at Portals II, CY–

A257, 445 12th Street, SW., Washington, DC 20554. This document will also be available via ECFS (*http://fjallfoss.fcc.gov/ecfs/*). This document may be purchased from the Commission's duplicating contractor, Best Copy and Printing, Inc., 445 12th Street, SW., Room CY–B402, Washington, DC 20554, telephone 1–800–478–3160 or via the company's Web site, *http://www.bcipweb.com.* 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), 202–418–0432 (tty).

This document does not contain information collection requirements subject to the Paperwork Reduction Act of 1995, Public Law 104–13. In addition, therefore, it does not contain any information collection burden "for small business concerns with fewer than 25 employees," pursuant to the Small Business Paperwork Relief Act of 2002, Public Law 107–198, *see* 44 U.S.C. 3506(c)(4). Provisions of the Regulatory Flexibility Act of 1980 do not apply to this proceeding.

The Commission will send a copy of this *Report and Order* in a report to be sent to Congress and the Government Accountability Office pursuant to the Congressional review Act, *see* 5 U.S.C. 801(a)(1)(A).

List of Subjects in 47 CFR Part 73

Television.

Federal Communications Commission.

Barbara A. Kreisman,

Chief, Video Division, Media Bureau.

Final Rule

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

PART 73—RADIO BROADCAST SERVICES

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

Authority: 47 U.S.C. 154, 303, 334, 336, and 339.

§ 73.622 [Amended]

■ 2. Section 73.622(i), the Post-Transition Table of DTV Allotments under Mississippi, is amended by adding channel 23 and removing channel 51 at Jackson.

[FR Doc. 2011–7792 Filed 4–6–11; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[MB Docket No. 11–4; RM–11616, DA 11–530]

Television Broadcasting Services; El Paso, TX

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: The Commission grants a petition for rulemaking issued in response to a petition for rulemaking filed by Comcorp of El Paso License Corp. ("Comcorp"), the licensee of KTSM–TV, channel 9, El Paso, Texas, requesting the substitution of channel 16 for channel 9 at El Paso. Comcorp states that this channel substitution is necessary because KTSM–TV has experienced significant technical difficulties since the station terminated its analog service and transitioned to post-transition channel 9 and believes channel 16 will allow better broadcast service to the public.

DATES: This rule is effective May 9, 2011.

FOR FURTHER INFORMATION CONTACT: Adrienne Y. Denysyk, *adrienne.denysyk@fcc.gov,* Media Bureau, (202) 418–1600.

SUPPLEMENTARY INFORMATION: This is a synopsis of the Commission's *Report and Order,* MB Docket No. 11–4, adopted March 21, 2011, and released March 22, 2011. The full text of this document is available for public inspection and copying during normal business hours in the FCC's Reference Information Center at Portals II, CY–A257, 445 12th Street, SW., Washington, DC 20554. This document will also be available via ECFS (*http://fjallfoss.fcc.gov/ecfs/*). This document may be purchased from the Commission's duplicating contractor, Best Copy and Printing, Inc., 445 12th Street, SW., Room CY–B402, Washington, DC 20554, telephone 1–800–478–3160 or via the company's Web site, *http://www.bcipweb.com.* 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), 202–418–0432 (tty).

This document does not contain information collection requirements subject to the Paperwork Reduction Act of 1995, Public Law 104–13. In addition, therefore, it does not contain any information collection burden "for small business concerns with fewer than 25 employees," pursuant to the Small Business Paperwork Relief Act of 2002, Public Law 107–198, *see* 44 U.S.C. 3506(c)(4). Provisions of the Regulatory Flexibility Act of 1980 do not apply to this proceeding.

The Commission will send a copy of this *Report and Order* in a report to be sent to Congress and the Government Accountability Office pursuant to the Congressional review Act, *see* 5 U.S.C. 801(a)(1)(A).

List of Subjects in 47 CFR Part 73

Television.

Federal Communications Commission.

Barbara A. Kreisman,

Chief, Video Division, Media Bureau.

Final Rule

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

PART 73—RADIO BROADCAST SERVICES

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

Authority: 47 U.S.C. 154, 303, 334, 336, and 339.

§ 73.622 [Amended]

■ 2. Section 73.622(i), the Post-Transition Table of DTV Allotments under Texas, is amended by adding channel 16 and removing channel 9 at El Paso.

[FR Doc. 2011–7795 Filed 4–6–11; 8:45 am]

BILLING CODE 6712–01–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 648

[Docket No. 101029427–0609–02]

RIN 0648–XA338

Fisheries of the Northeastern United States; Summer Flounder Fishery; Quota Transfer

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

ACTION: Temporary rule; quota transfer.

SUMMARY: NMFS announces that the State of North Carolina is transferring a portion of its 2011 commercial summer flounder quota to the Commonwealth of

Virginia. Vessels were authorized by Virginia to land summer flounder under safe harbor provisions, thereby requiring a quota transfer to account for an increase in Virginia's landings that would have otherwise accrued against the North Carolina quota. By this action, NMFS adjusts the quotas and announces the revised commercial quota for each state involved.

DATES: Effective April 4, 2011 through December 31, 2011.

FOR FURTHER INFORMATION CONTACT: Carly Knoell, Fishery Management Specialist, 978–281–9224.

SUPPLEMENTARY INFORMATION: Regulations governing the summer flounder fishery are found at 50 CFR part 648. The regulations require annual specification of a commercial quota that is apportioned among the coastal states from North Carolina through Maine. The process to set the annual commercial quota and the percent allocated to each state are described in § 648.100.

The final rule implementing Amendment 5 to the Summer Flounder, Scup, and Black Sea Bass Fishery Management Plan, which was published on December 17, 1993 (58 FR 65936), provided a mechanism for summer flounder quota to be transferred from one state to another. Two or more states, under mutual agreement and with the concurrence of the Administrator, Northeast Region, NMFS (Regional Administrator), can transfer or combine summer flounder commercial quota under § 648.100(d). The Regional Administrator is required to consider the criteria set forth in § 648.100(d)(3) in the evaluation of requests for quota transfers or combinations.

North Carolina has agreed to transfer 499,411 lb (226,529 kg) of its 2011 commercial quota to Virginia. This transfer was prompted by 57 summer flounder landings of North Carolina vessels that were granted safe harbor in Virginia due to hazardous shoaling in Oregon Inlet, North Carolina, severe winter storm conditions, and/or mechanical problems between March 7, 2011, and March 17, 2011. The Regional Administrator has determined that the criteria set forth in § 648.100(d)(3) have been met. The revised summer flounder quotas for calendar year 2011 are: North Carolina, 4,163,328 lb (1,888,454 kg); and Virginia, 4,309,240 lb (1,954,639 kg).

Classification

This action is taken under 50 CFR part 648 and is exempt from review under Executive Order 12866.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: April 4, 2011.

James P. Burgess,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2011–8352 Filed 4–4–11; 4:15 pm]

BILLING CODE 3510–22–P

Proposed Rules

Federal Register
Vol. 76, No. 67
Thursday, April 7, 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 TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2011–0303; Directorate Identifier 2010–NM–214–AD]

RIN 2120–AA64

Airworthiness Directives; The Boeing Company Model 747–100, 747–100B, 747–100B SUD, 747–200B, 747–200C, 747–200F, 747–300, 747–400, 747–400D, 747–400F, 747SR, and 747SP Series Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: We propose to supersede an existing airworthiness directive (AD) that applies to the products listed above. The existing AD currently requires an inspection of the No. 2 and No. 3 windows on the left and right sides of the airplane to determine their part numbers, related investigative and corrective actions if necessary, and repetitive inspections of single pane windows. Since we issued that AD, we have determined that terminating action for the repetitive inspections is necessary. This proposed AD would add a requirement to install dual pane No. 2 and No. 3 windows. This proposed AD also removes certain airplanes from the applicability. We are proposing this AD to detect and correct cracking in the fail-safe interlayer of certain No. 2 and No. 3 glass windows, which could result in loss of the window and consequent rapid loss of cabin pressure. Loss of the window could also result in crew communication difficulties or incapacitation of the crew.

DATES: We must receive comments on this proposed AD by May 23, 2011.

ADDRESSES: You may send comments by any of the following methods:

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

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

Examining the AD Docket

You may examine the AD docket on the Internet at *http://www.regulations.gov;* or in person at the Docket Management Facility between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this proposed AD, the regulatory evaluation, any comments received, and other information. The street address for the Docket Office (phone: 800–647–5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT: Steven Fox, Senior Aerospace Engineer, Airframe Branch, ANM–120S, Seattle Aircraft Certification Office (ACO), FAA, 1601 Lind Avenue, SW., Renton, Washington 98057–3356; phone: 425–917–6425; fax: 425–917–6590; e-mail: *Steven.Fox@faa.gov.*

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite you to send any written relevant data, views, or arguments about this proposed AD. Send your comments to an address listed under the **ADDRESSES** section. Include "Docket No. FAA–2011–0303; Directorate Identifier 2010–NM–214–AD" at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this proposed AD. We will consider all comments received by the closing date and may amend this proposed AD because of those comments.

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

Discussion

On July 18, 2007, we issued AD 2007–15–10, Amendment 39–15139 (72 FR 41438, July 30, 2007), for all Boeing Model 747 airplanes. A correction of that AD was published in the **Federal Register** on September 21, 2007 (72 FR 53923), which corrected a typographical error in paragraph (g) compliance times of flight cycles to flight hours. That AD requires an inspection of the No. 2 and No. 3 windows on the left and right sides of the airplane to determine their part numbers, and related investigative and corrective actions if necessary; and repetitive inspections of single pane windows. That AD resulted from loss of a No. 3 window in-flight. We issued that AD to detect and correct cracking in the fail-safe interlayer of certain No. 2 and No. 3 glass windows, which could result in loss of the window and consequent rapid loss of cabin pressure. Loss of the window could also result in crew communication difficulties or incapacitation of the crew.

Actions Since Existing AD Was Issued

The preamble of the original NPRM for AD 2007–15–10 (Docket Number FAA–2006–26441, Directorate Identifier 2006–NM–204–AD) specifies that we consider the actions an "interim action until final action is identified, at which time we may consider further rulemaking". We have determined that further rulemaking is indeed necessary; this proposed AD follows from that determination.

Relevant Service Information

AD 2007–15–10 cited Boeing Alert Service Bulletin 747–56A2012, dated August 24, 2006, as the relevant source of service information. Since we issued AD 2007–15–10, Boeing has issued Service Bulletin 747–56A2012, Revision 1, dated August 12, 2010. Boeing Service Bulletin 747–56A2012, Revision

1, dated August 12, 2010, describes essentially the same actions described in Boeing Alert Service Bulletin 747–56A2012, dated August 24, 2006, and also describes procedures for replacing single pane No. 2 and No. 3 windows with dual pane windows. Boeing Service Bulletin 747–56A2012, Revision 1, dated August 12, 2010, also removes airplanes line numbers 1418 and on from the effectivity. The inspections in Boeing Service Bulletin 747–56A2012, Revision 1, dated August 12, 2010, are not necessary on airplanes having line numbers 1418 and on, which have the new dual structural glass pane windows installed in production. Boeing Service Bulletin 747–56A2012, Revision 1, dated August 12, 2010, specifies that installation of the new dual structural glass pane windows ends the repetitive inspections specified in Boeing Alert Service Bulletin 747–56A2012, dated August 24, 2006.

FAA's Determination

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

Proposed AD Requirements

This proposed AD would retain certain requirements of AD 2007–15–10. This proposed AD would also require accomplishing the actions specified in Boeing Service Bulletin 747–56A2012, Revision 1, dated August 12, 2010, except as discussed under "Differences Between the Proposed AD and the Service Information." This proposed AD also removes airplanes having line numbers 1418 and on from the applicability.

Differences Between the Proposed AD and the Service Information

This AD proposes to prohibit installed dual structural glass pane windows from being replaced with single structural glass pane windows. This proposed AD would also add a definition of "non-clear damage", which the Accomplishment Instructions of Boeing Service Bulletin 747–56A2012, Revision 1, dated August 12, 2010, use as criteria for window replacement.

Costs of Compliance

We estimate that this proposed AD affects 144 airplanes of U.S. registry.

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

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Inspection to determine window part numbers; retained from existing AD.	4 work-hours × $85 per hour = $340	$0	$340	$48,960
Detailed inspection, if necessary; retained from existing AD.	1 work-hour × $85 per hour = $85	0	85	12,240
Dual pane window replacement; new proposed action.	16 work-hours × $85 per hour = $1,360	44,014	45,374	6,533,856

We estimate the following costs to do any necessary replacements that would be required based on the results of the proposed inspection. We have no way of determining the number of aircraft that might need these replacements:

ON-CONDITION COSTS

Action	Labor cost	Parts cost	Cost per product
Window replacement	16 work-hours × $85 per hour = $1,360	$44,014	$45,374

Authority for This Rulemaking

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

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

Regulatory Findings

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

For the reasons discussed above, I certify that the proposed regulation:

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

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

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

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

List of Subjects in 14 CFR Part 39

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

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

2. The FAA amends § 39.13 by removing airworthiness directive (AD) 2007–15–10, Amendment 39–15139 (72 FR 41438, July 30, 2007), corrected at 72 FR 53923, September 21, 2007, and adding the following new AD:

The Boeing Company: Docket No. FAA–2011–0303; Directorate Identifier 2010–NM–214–AD.

Comments Due Date

(a) The FAA must receive comments on this AD action by May 23, 2011.

Affected ADs

(b) This AD supersedes AD 2007–15–10, Amendment 39–15139.

Applicability

(c) This AD applies to The Boeing Company Model 747–100, 747–100B, 747–100B SUD, 747–200B, 747–200C, 747–200F, 747–300, 747–400, 747–400D, 747–400F, 747SR, and 747SP Series Airplanes, certificated in any category, as identified in Boeing Service Bulletin 747–56A2012, Revision 1, dated August 12, 2010.

Subject

(d) Joint Aircraft System Component (JASC)/Air Transport Association (ATA) of America Code 56, Windows.

Unsafe Condition

(e) This AD was prompted by loss of a No. 3 window in-flight. We are issuing this AD to detect and correct cracking in the fail-safe interlayer of certain No. 2 and No. 3 glass windows, which could result in loss of the window and consequent rapid loss of cabin pressure. Loss of the window could also result in crew communication difficulties or incapacitation of the crew.

Compliance

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

Restatement of Requirements of AD 2007–15–10, With New Service Information

Inspection, Related Investigative Actions, and Corrective Action

(g) Inspect the No. 2 and No. 3 windows on the left and right sides of the airplane to determine their part numbers, and do all the applicable related investigative and corrective actions, by accomplishing all of the actions specified in the Accomplishment Instructions of Boeing Alert Service Bulletin 747–56A2012, dated August 24, 2006; or Boeing Service Bulletin 747–56A2012, Revision 1, dated August 12, 2010; except as required by paragraph (j) of this AD; as applicable. Do all of these actions at the compliance times specified in Tables 1, 2, and 3 of paragraph 1.E. of Boeing Alert Service Bulletin 747–56A2012, dated August 24, 2006, as applicable, except as provided by paragraph (h) of this AD. A review of airplane maintenance records is acceptable in lieu of the inspection if the part numbers of the windows can be conclusively determined from that review. Repeat the related investigative and corrective actions thereafter at the interval specified in Table 2 or 3 of paragraph 1.E. of Boeing Alert Service Bulletin 747–56A2012, dated August 24, 2006, as applicable. As of the effective date of this AD, do the actions specified in this paragraph, in accordance with the Accomplishment Instructions of Boeing Service Bulletin 747–56A2012, Revision 1, dated August 12, 2010, except as required by (j) of this AD. Replacing a window in accordance with paragraph (i) of this AD terminates the requirements of this paragraph for that window.

Exception to Compliance Times

(h) Where Tables 1, 2, and 3 of paragraph 1.E. of Boeing Alert Service Bulletin 747–56A2012, dated August 24, 2006, specify counting the compliance time from "* * * after the date on this service bulletin," this AD requires counting the compliance time from September 4, 2007 (the effective date of AD 2007–15–10). After replacing a discrepant window with a new window, having part number (P/N) 65B27042–(), 65B27043–(), 65B27046–(), or 65B27047–(), do the initial detailed inspection of the new window at the applicable compliance time: (1) Within 5,500 flight hours after installing P/N 65B27042–() or 65B27043–(), or (2) Within 22,000 flight hours after installing P/N 65B27046–() or 65B27047–().

New Requirements of This AD

(i) Within 6 years after the effective date of this AD, replace all No. 2 windows having P/N 65B27042–() or 65B27046–(), with windows having P/N 141U4821–() or 141U4822–(), and replace all No. 3 windows having P/N 65B27043–() or 65B27047–() with windows having P/N 141U4831–() or 141U4832–(), in accordance with Part 3—Window Replacement of the Accomplishment Instructions of Boeing Service Bulletin 747–56A2012, Revision 1, dated August 12, 2010. Doing this replacement for all windows terminates the actions required by paragraphs (g) and (h) of this AD.

(j) Where Step 4.e. of Part 2 of the Work Instructions of Boeing Service Bulletin 747–56A2012, Revision 1, dated August 12, 2010, specifies "non-clear damage" as a criteria for window replacement, this AD defines non-clear damage to be any degradation of the transparency of the window, which would hinder the internal or external detailed inspections for fail-safe interlayer cracks, glass pane cracks and chips, and indications of arcing. Replacement for non-clear damage is required by this AD only if the non-clear damage hinders the inspection for fail-safe interlayer cracks, glass pane cracks and chips, or indications of arcing.

Parts Installation

(k) As of the effective date of this AD, do not install any No. 2 or No. 3 window having P/N 65B27042–(), 65B27043–(), 65B27046–(), or 65B27047–() that is not new or on which the window flight hours are not known, on any airplanes, unless the actions specified in paragraph (g) of this AD are done.

Alternative Methods of Compliance (AMOCs)

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

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

(3) An AMOC that provides an acceptable level of safety may be used for any repair required by this AD if it is approved by the Boeing Commercial Airplanes Organization Designation Authorization (ODA) that has been authorized by the Manager, Seattle ACO to make those findings. For a repair method to be approved, the repair must meet the certification basis of the airplane and the approval must specifically refer to this AD.

(4) AMOCs previously approved in accordance with AD 2007–15–10, Amendment 39–15139, are approved as AMOCs for the corresponding provisions of this AD except previous AMOCs approving window replacement that do not specify installing dual structural glass pane windows are not considered approved for corresponding inspection methods required by this AD.

Related Information

(m) For more information about this AD, contact Steven Fox, Senior Aerospace Engineer, Airframe Branch, ANM120S, Seattle Aircraft Certification Office (ACO), FAA, 1601 Lind Avenue, SW., Renton, Washington 98057–3356; phone: 425–917–6425; fax: 425–917–6590; e-mail: *Steven.Fox@faa.gov.* You may review copies of the referenced service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington. For information on the availability of this material at the FAA, call 425–227–1221.

Issued in Renton, Washington, on March 23, 2011.

Kalene C. Yanamura,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2011–8276 Filed 4–6–11; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2011–0249; Airspace Docket No. 11–ANM–6]

Proposed Amendment of Class E Airspace; Bozeman, MT

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This action proposes to modify Class E airspace at Gallatin Field Airport, Bozeman, MT, to accommodate aircraft using Instrument Landing System (ILS) Localizer (LOC) standard instrument approach procedures at the airport. The FAA is proposing this action to enhance the safety and management of aircraft operations at the airport. This action also would adjust the geographic coordinates of the airport for the Class D and E airspace areas, and would update the airport name.

DATES: Comments must be received on or before May 23, 2011.

ADDRESSES: Send comments on this proposal to the U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC 20590; telephone (202) 366–9826. You must identify FAA Docket No. FAA–2011–0249; Airspace Docket No. 11–ANM–6, at the beginning of your comments. You may also submit comments through the Internet at *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Eldon Taylor, Federal Aviation Administration, Operations Support Group, Western Service Center, 1601 Lind Avenue, SW., Renton, WA 98057; telephone (425) 203–4537.

SUPPLEMENTARY INFORMATION:

Comments Invited

Interested parties are invited to participate in this proposed rulemaking by submitting such written data, views, or arguments, as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal.

Communications should identify both docket numbers (FAA Docket No. FAA 2011–0249 and Airspace Docket No. 11–ANM–6) and be submitted in triplicate to the Docket Management System (*see* **ADDRESSES** section for address and phone number). You may also submit comments through the Internet at *http://www.regulations.gov.*

Commenters wishing the FAA to acknowledge receipt of their comments on this action must submit with those comments a self-addressed stamped postcard on which the following statement is made: "Comments to FAA Docket No. FAA–2011–0249 and Airspace Docket No. 11–ANM–6". The postcard will be date/time stamped and returned to the commenter.

All communications received on or before the specified closing date for comments will be considered before taking action on the proposed rule. The proposal contained in this action may be changed in light of comments received. All comments submitted will be available for examination in the public docket both before and after the closing date for comments. A report summarizing each substantive public contact with FAA personnel concerned with this rulemaking will be filed in the docket.

Availability of NPRMs

An electronic copy of this document may be downloaded through the Internet at *http://www.regulations.gov.* Recently published rulemaking documents can also be accessed through the FAA's Web page at *http://www.faa.gov/airports_airtraffic/air_traffic/publications/airspace_amendments/.*

You may review the public docket containing the proposal, any comments received, and any final disposition in person in the Dockets Office (*see* the **ADDRESSES** section for the address and phone number) between 9 a.m. and 5 p.m., Monday through Friday, except federal holidays. An informal docket may also be examined during normal business hours at the Northwest Mountain Regional Office of the Federal Aviation Administration, Air Traffic Organization, Western Service Center, Operations Support Group, 1601 Lind Avenue, SW., Renton, WA 98057.

Persons interested in being placed on a mailing list for future NPRMs should contact the FAA's Office of Rulemaking, (202) 267–9677, for a copy of Advisory Circular No. 11–2A, Notice of Proposed Rulemaking Distribution System, which describes the application procedure.

The Proposal

The FAA is proposing an amendment to Title 14 Code of Federal Regulations (14 CFR) Part 71 by modifying Class E airspace designated as an extension to Class D surface area at Gallatin Field Airport, Bozeman, MT. Controlled airspace is necessary to accommodate aircraft using the ILS LOC standard instrument approach procedures at the airport and would enhance the safety and management of aircraft operations. The geographic coordinates of the Gallatin Field Airport for Class D airspace, Class E surface area airspace, and Class E airspace extending upward from 700 feet above the surface, would be adjusted in accordance with the FAA's aeronautical database. This action would also update the airport name from Bozeman, Gallatin Field Airport, MT, to Gallatin Field Airport.

Class D and Class E airspace designations are published in paragraph 5000, 6002, 6004 and 6005, respectively, of FAA Order 7400.9U, dated August 18, 2010, and effective September 15, 2010, which is incorporated by reference in 14 CFR Part 71.1. The Class D and Class E airspace designation listed in this document will be published subsequently in this Order.

The FAA has determined this proposed regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. Therefore, this proposed regulation; (1) is not a "significant regulatory action" under Executive Order 12866; (2) is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified this proposed rule, when promulgated, would not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the U.S. Code. Subtitle 1, section 106, describes the authority for the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority. This rulemaking is promulgated under the authority described in subtitle VII, part A, subpart I, section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of the airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it establishes additional controlled airspace at Gallatin Field Airport, Bozeman, MT.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

Accordingly, pursuant to the authority delegated to me, the Federal Aviation Administration proposes to amend 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, B, C, D AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS

1. The authority citation for 14 CFR part 71 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

2. The incorporation by reference in 14 CFR Part 71.1 of the Federal Aviation Administration Order 7400.9U, Airspace Designations and Reporting Points, dated August 18, 2010, and effective September 15, 2010 is amended as follows:

Paragraph 5000 Class D airspace.

* * * * *

ANM MT D Bozeman, MT [Amended]

Gallatin Field Airport
(Lat. 45°46′39″ N., long. 111°09′07″ W.)

That airspace extending upward from the surface to and including 7,000 feet MSL within a 4.4-mile radius of Gallatin Field Airport. This Class D airspace area is effective during the specific dates and times established in advance by a Notice to Airmen. The effective date and time will thereafter be continuously published in the Airport/Facility Directory.

Paragraph 6002 Class E airspace designated as Surface Areas.

* * * * *

ANM MT E2 Bozeman, MT [Amended]

Gallatin Field Airport
(Lat. 45°46′39″ N., long. 111°09′07″ W.)

Within a 4.4-mile radius of Gallatin Field Airport. This Class E airspace area is effective during the specific dates and times established in advance by a Notice to Airmen. The effective date and time will thereafter be continuously published in the Airport/Facility Directory.

Paragraph 6004 Class E airspace designated as an extension to a Class D Surface Area.

* * * * *

ANM MT E4 Bozeman, MT [Modified]

Gallatin Field Airport
(Lat. 45°46′39″ N., long. 111°09′07″ W.)

That airspace extending upward from the surface within 3 miles each side of the 316° bearing of Gallatin Field Airport extending from the 4.4-mile radius of the airport to 15.5 miles northwest of the airport, and that airspace 2.4 miles each side of the 212° bearing of the Gallatin Field Airport extending from the 4.4-mile radius of the airport to 7 miles southwest of the airport.

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

* * * * *

ANM MT E5 Bozeman, MT [Amended]

Gallatin Field Airport
(Lat. 45°46′39″ N., long. 111°09′07″ W.)

That airspace extending upward from 700 feet above the surface within a 13.5-mile radius of Gallatin Field Airport, and within 4.8 miles northeast and 13 miles southwest of the 316° bearing of the airport extending from the 13.5-mile radius to 24.4 miles northwest of Gallatin Field Airport.

Issued in Seattle, Washington, on March 28, 2011.

John Warner,

Manager, Operations Support Group, Western Service Center.

[FR Doc. 2011–8311 Filed 4–6–11; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF COMMERCE

Bureau of Economic Analysis

15 CFR Part 806

[Docket No. 110321207–1206–01 0691–AA78

Direct Investment Surveys: Alignment of Regulations With Current Practices

AGENCY: Bureau of Economic Analysis, Commerce.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Bureau of Economic Analysis (BEA) proposes to amend its regulations related to direct investment surveys. Specifically, BEA proposes to eliminate reporting requirements for several direct investment surveys that are no longer necessary because the information is collected on other surveys of direct investment conducted by BEA. The surveys that would be eliminated from the regulations are: a survey of foreign direct investment in the U.S. seafood industry (BE–21), two schedules of expenditures for property, plant, and equipment of U.S. direct investment abroad (BE–133B and BE–133C), and two industry classification questionnaires (BE–507 and BE–607). In addition, BEA proposes to eliminate the reporting requirements for two surveys of new foreign direct investment in the United States (BE–13 and BE–14). BEA suspended collection of these surveys in 2009 in order to align its international survey program with available resources. BEA also proposes other minor revisions to its regulations to eliminate outdated information.

DATES: Comments on this proposed rule will receive consideration if submitted in writing on or before June 6, 2011.

ADDRESSES: You may submit comments, identified by RIN 0691–AA78, and referencing the agency name (Bureau of Economic Analysis), by any of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. For agency, select "Commerce Department—all."
- *E-mail: David.Galler@bea.gov.*
- *Fax:* Office of the Chief, Direct Investment Division, (202) 606–5318.
- *Mail:* Office of the Chief, Direct Investment Division, U.S. Department of Commerce, Bureau of Economic Analysis, BE–50, Washington, DC 20230.
- *Hand Delivery/Courier:* Office of the Chief, Direct Investment Division, U.S. Department of Commerce, Bureau of Economic Analysis, BE–50, Shipping and Receiving, Section M100, 1441 L Street, NW., Washington, DC 20005.

Written comments regarding the burden-hour estimates or other aspects of the collection-of-information requirements contained in the proposed rule should be sent both to BEA, through any of the methods above, and to the Office of Management and Budget, O.I.R.A., Paperwork Reduction Project 0608–0024, 0608–0030, 0608–0032, 0608–0035, and 0608–0050, Attention PRA Desk Officer for BEA, via e-mail at *pbugg@omb.eop.gov,* or by FAX at (202) 395–7245.

Public Inspection: All comments received are a part of the public record and will generally be posted to *http://www.regulations.gov* without change. All personal identifying information (for example, name, address, etc.) voluntarily submitted by the commentator may be publicly accessible. Do not submit confidential business information or otherwise sensitive or protected information. BEA will accept anonymous comments.

FOR FURTHER INFORMATION CONTACT: David H. Galler, Chief, Direct Investment Division (BE–50), Bureau of Economic Analysis, U.S. Department of Commerce, Washington, DC 20230; phone (202) 606–9835.

SUPPLEMENTARY INFORMATION: This proposed rule would amend 15 CFR part 806 by revising Sections 806.14, 806.15, and 806.18 to remove the reporting requirements for several direct investment surveys. The surveys are:

BE–13, Initial Report on a Foreign Person's Direct or Indirect Acquisition, Establishment, or Purchase of the Operating Assets, of a

U.S. Business Enterprise, Including Real Estate
BE–14, Report by a U.S. Person Who Assists or Intervenes in the Acquisition of a U.S. Business Enterprise by, or Who Enters into a Joint Venture With, a Foreign Person
BE–21, Survey of Foreign Direct Investment in U.S. Business Enterprises Engaged in the Processing, Packaging, or Wholesale Distribution of Fish or Seafoods
BE–133B, Follow-up Schedule of Expenditures for Property, Plant, and Equipment of U.S. Direct Investment Abroad
BE–133C, Schedule of Expenditures for Property, Plant, and Equipment of U.S. Direct Investment Abroad
BE–507, Industry Classification Questionnaire
BE–607, Industry Classification Questionnaire

The Department of Commerce, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to comment on the cancellation of the reporting requirements for these surveys, consistent with the Paperwork Reduction Act of 1995.

BEA is proposing to remove the reporting requirements for the BE–13 and the BE–14 surveys which were suspended in 2009 in order to align its international survey program with available resources. The surveys had been used to collect identification information on the U.S. business being established or acquired and on the new foreign owner, information on the cost of the investment and source of funding, and limited financial and operating data for the newly established or acquired entity. The data had been used to measure the amount of new foreign direct investment in the United States and assess its impact on the U.S. economy. BEA continues to identify newly acquired or established U.S. affiliates of foreign investors and bring them into its international survey program through the BE–12, BE–15, and BE–605 surveys, which are the benchmark, annual, and quarterly surveys of foreign direct investment in the United States, respectively, but they are not separately identified in BEA's published statistics.

BEA is proposing to eliminate the regulations for the BE–21, BE–133B, BE–133C, BE–507, and BE–607 surveys since they have not been conducted in many years and are no longer necessary because the information is collected on other surveys of direct investment conducted by BEA.

In addition, BEA proposes other minor revisions to its regulations to eliminate outdated information. These revisions eliminate references to outdated information regarding BE–10 survey forms and inactive OMB control numbers.

Executive Order 12866

This proposed rule has been determined to be not significant for purposes of E.O. 12866.

Executive Order 13132

This proposed rule does not contain policies with Federalism implications as that term is defined in E.O. 13132.

Paperwork Reduction Act

The Office of Management and Budget (OMB) approvals under the Paperwork Reduction Act for the seven surveys that BEA is proposing to eliminate have expired. The information collection approval for the BE–13 and BE–14 (under OMB control number 0608–0035) expired on August 31, 2009; the BE–21 approval (OMB control number 0608–0050) expired September 30, 1983; the BE–133B and BE–133C (OMB control number 0608–0024) expired December 31, 1994; the BE–507 approval (OMB control number 0608–0032) expired April 30, 1997; and the BE–607 approval (OMB control number 0608–0030) expired on May 31, 1991.

Regulatory Flexibility Act

The Chief Counsel for Regulation, Department of Commerce, has certified to the Chief Counsel for Advocacy, Small Business Administration, under the provisions of the Regulatory Flexibility Act (5 U.S.C. 605(b)), that this proposed rulemaking, if adopted, will not have a significant economic impact on a substantial number of small entities. Entities that have foreign affiliates, that are at least ten percent foreign-owned, or that assisted or intervened in the acquisition of a U.S. business enterprise by a foreign person would have been subject to the reporting requirements that are proposed to be eliminated in this rulemaking. However, BEA does not currently collect data that enables BEA to determine how many of these entities would be considered "small" under the Small Business Administration's size standards. Although BEA does not know the number of small entities that would have been subject to the reporting requirements being eliminated by this rulemaking, BEA has determined that this action would not have a significant economic impact as this rule proposes to merely remove references to the surveys that are no longer in use. The collection of the BE–13 and BE–14 surveys was suspended in 2009, and the BE–21, BE–133B, BE–133C, BE–507, and BE–607 surveys have not been conducted in many years. In addition, the information collection approvals for these surveys have expired and are no longer part of the inventory of active collections of information maintained by the Office of Management and Budget. Because there would be no impact to small entities as a result of this change to the regulations, the Chief Counsel certified that this proposed rulemaking, if adopted, will not have a significant economic impact on a substantial number of small entities.

List of Subjects in 15 CFR Part 806

Economic statistics, Foreign investment in the United States, International transactions, Penalties, Reporting and recordkeeping requirements.

Dated: March 16, 2011.

J. Steven Landefeld,

Director, Bureau of Economic Analysis.

For reasons set forth in the preamble, BEA proposes to amend 15 CFR part 806 as follows:

PART 806—DIRECT INVESTMENT SURVEYS

1. The authority citation for 15 CFR part 806 continues to read as follows:

Authority: 5 U.S.C. 301; 22 U.S.C. 3101–3108; E.O. 11961 (3 CFR, 1977 Comp., p. 86), as amended by E.O. 12318 (3 CFR, 1981 Comp., p. 173), and E.O. 12518 (3 CFR, 1985 Comp., p. 348).

2. Amend § 806.14 to revise paragraphs (d), (f) and (g) to read as follows:

§ 806.14 U.S. direct investment abroad.

* * * * *

(d) *Exemption levels.* Exemption levels for individual report forms will normally be stated in terms of total assets, net sales or gross operating revenues excluding sales taxes, and net income after income taxes, whether positive or negative, although different or special criteria may be specified for a given report form. If any one of the three items exceeds the exemption level and if the statistical data requested in the report are applicable to the entity being reported, then a report must be filed. Since these items may not have to be reported on a given form, a U.S. Reporter claiming exemption from filing a given form must furnish a certification as to the levels of the items on which the exemption is based or must certify that the data requested are not

applicable. The exemption-level tests shall be applied as outlined below.

(1) For quarterly report forms, as to the assets test reports are required beginning with the quarter in which total assets exceed the exemption level; as to the test for sales (revenues) and net income after income taxes, reports are required for each quarter of a year in which the annual amount of these items exceeds or can be expected to exceed, the exemption level. Quarterly reports for a year may be required retroactively when it is determined that the exemption level has been exceeded.

(2) For report forms requesting annual data after the close of the year in question, the test shall be whether any one of the three items exceeded the exemption level during that year.

If total assets, sales or net income exceed the exemption level in a given year, it is deemed that the exemption level will also be exceeded in the following year.

The number and title of each report form, its exemption level, and other reporting criteria, if any, pertaining to it, are given below.

* * * * *

(f) *Annual report forms.* (1) [Reserved.]

(2) [Reserved.]

(3) BE–11—Annual Survey of U.S. Direct Investment Abroad: A report, consisting of Form BE–11A and Form(s) BE–11B, BE–11C, BE–11D and/or BE–11E, is required of each U.S. Reporter that, at the end of the Reporter's fiscal year, had a foreign affiliate reportable on Form BE–11B, BE–11C, BE–11D or BE–11E. Forms required and the criteria for reporting on each are as follows:

(i) Form BE–11A (Report for U.S. Reporter) must be filed by each U.S. person having a foreign affiliate reportable on Form BE–11B, BE–11C, BE–11D or BE–11E. If the U.S. Reporter is a corporation, Form BE–11A is required to cover the fully consolidated U.S. domestic business enterprise.

(A) If for a U.S. Reporter any one of the following three items—total assets, sales or gross operating revenues excluding sales taxes, or net income after provision for U.S. income taxes—was greater than $300 million (positive or negative) at the end of, or for, the Reporter's fiscal year, the U.S. Reporter must file a complete Form BE–11A. It must also file a Form BE–11B, BE–11C, BE–11D or BE–11E, as applicable, for each nonexempt foreign affiliate.

(B) If for a U.S. Reporter no one of the three items listed in paragraph (f)(3)(i)(A) of this section was greater than $300 million (positive or negative) at the end of, or for, the Reporter's fiscal year, the U.S. Reporter is required to file on Form BE–11A only items 1 through 26 and Part IV. It must also file a Form BE–11B, BE–11C, BE–11D, or BE–11E as applicable, for each nonexempt foreign affiliate.

(ii) Forms BE–11B, BE–11C, BE–11D, and BE–11E (Report for Foreign Affiliate).

(A) Form BE–11B must be reported for each majority-owned foreign affiliate, whether held directly or indirectly, for which any one of the following three items—total assets, sales or gross operating revenues excluding sales taxes, or net income after provision for foreign income taxes—was greater than $60 million (positive or negative) at the end of, or for, the affiliate's fiscal year, unless the foreign affiliate is selected to be reported on Form BE–11E.

(B) Form BE–11C must be reported for each minority-owned foreign affiliate, whether held directly or indirectly, for which any one of the three items listed in paragraph (f)(3)(ii)(A) of this section was greater than $60 million (positive or negative) at the end of, or for, the affiliate's fiscal year.

(C) Form BE–11D must be reported for each majority- and minority-owned foreign affiliate, whether held directly or indirectly, established or acquired during the year for which any one of the three items listed in paragraph (f)(3)(ii)(A) of this section was greater than $25 million (positive or negative), but for which no one of these items was greater than $60 million (positive or negative), at the end of, or for, the affiliate's fiscal year. Form BE–11D is a schedule; a U.S. Reporter would submit one or more pages of the form depending on the number of affiliates that are required to be filed on this form.

(D) Form BE–11E must be reported for each foreign affiliate that is selected by BEA to be reported on this form in lieu of Form BE–11B. BEA statistically divides into panels, affiliates for which any one of the three items listed in paragraph (f)(3)(ii)(A) of this section was greater than $60 million (positive or negative), but for which no one of these items was greater than $300 million (positive or negative), at the end of, or for, the affiliate's fiscal year. At the direction of BEA, U.S. Reporters would alternate reporting these affiliates on Form BE–11B and Form BE–11E.

(iii) Based on the preceding, an affiliate is exempt from being reported if none of the three items listed in paragraph (f)(3)(ii)(A) of this section exceeds $60 million (positive or negative). However, affiliates that were established or acquired during the year and for which at least one of the items was greater than $25 million but not over $60 million must be listed, and key items reported, on schedule-type Form BE–11D.

(iv) Notwithstanding paragraph (f)(3)(iii) of this section, a Form BE–11B, BE–11C, or BE–11E must be filed for a foreign affiliate of the U.S. Reporter that owns another non-exempt foreign affiliate of that U.S. Reporter, even if the foreign affiliate parent is otherwise exempt. That is, all affiliates upward in the chain of ownership must be reported.

* * * * *

(g) *Other report forms.* (1) [Reserved.]

(2) BE–10–Benchmark Survey of U.S. Direct Investment Abroad: Section 4(b) of the Act (22 U.S.C. 3103) provides that a comprehensive benchmark survey of U.S. direct investment abroad will be conducted in 1982, 1989, and every fifth year thereafter. Exemption levels, specific requirements for, and the year of coverage of, a given BE–10 survey may be found in § 806.16.

* * * * *

3. Section 806.15(j) is revised to read as follows:

§ 806.15 Foreign direct investment in the United States.

* * * * *

(j) *Other report forms.* (1) [Reserved.]

(2) BE–12—Benchmark Survey of Foreign Direct Investment in the United States: Section 4b of the Act (22 U.S.C. 3103) provides that a comprehensive benchmark survey of foreign direct investment in the United States shall be conducted in 1980, 1987, and every fifth year thereafter. The survey is referred to as the "BE–12." Exemption levels, specific requirements for, and the year of coverage of, a given BE–12 Survey may be found in § 806.17.

* * * * *

4. Section 806.18(b) is revised to read as follows:

§ 806.18 OMB control numbers assigned to the Paperwork Reduction Act.

* * * * *

(b) *Display.*

15 CFR section where identified and described	Current OMB Control No.
806.1 through 806.17	0608–0004 0009 0034 0042 0049 0053

* * * * *

[FR Doc. 2011–7769 Filed 4–6–11; 8:45 am]

BILLING CODE 3510–06–P

DEPARTMENT OF LABOR

Employee Benefits Security Administration

29 CFR Part 2520

RIN 1210–AB50

Request for Information Regarding Electronic Disclosure by Employee Benefit Plans

AGENCY: Employee Benefits Security Administration, Department of Labor.

ACTION: Request for information.

SUMMARY: The Department of Labor is reviewing the use of electronic media by employee benefit plans to furnish information to participants and beneficiaries covered by employee benefit plans subject to the Employee Retirement Income Security Act (ERISA). In 2002, the Department adopted standards for the electronic distribution of plan disclosures required under ERISA. The purpose of the review is to explore whether, and possibly how, to expand or modify these standards taking into account current technology, best practices and the need to protect the rights and interests of participants and beneficiaries. This request for information (RFI) solicits views, suggestions, and comments from plan participants and beneficiaries, employers and other plan sponsors, plan administrators, plan service providers, health insurance issuers, and members of the financial community, as well as the general public, on this important issue.

DATES: Comments must be submitted on or before June 6, 2011.

ADDRESSES: You may submit written comments to any of the addresses specified below.

- *Federal eRulemaking Portal: http://www.regulations.gov*. Follow the instructions for submitting comments.
- *E-mail: e-ORI@dol.gov*. Include RIN 1210–AB50 in the subject line of the message.
- *Mail:* Office of Regulations and Interpretations, Employee Benefits Security Administration, Room N–5655, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210, Attention: E-Disclosure RFI.

All submissions received must include the agency name and Regulation Identifier Number (RIN) for this rulemaking. Comments received will be posted without change to *http://www.regulations.gov* and *http://www.dol.gov/ebsa*, and made available for public inspection at the Public Disclosure Room, N–1513, Employee Benefits Security Administration, 200 Constitution Avenue, NW., Washington, DC 20210, including any personal information provided. Do not include any personally identifiable information (such as name, address, or other contact information) or confidential business information that you do not want publicly disclosed. Comments posted on the Internet can be retrieved by most Internet search engines. Comments may be submitted anonymously. Persons submitting comments electronically are encouraged not to submit paper copies. All comments will be made available to the public.

FOR FURTHER INFORMATION CONTACT: Thomas M. Hindmarch, Office of Regulations and Interpretations, Employee Benefits Security Administration, (202) 693–8500. This is not a toll-free number.

SUPPLEMENTARY INFORMATION:

A. Background

On July 19, 1977, the Department of Labor (Department) adopted general standards governing the delivery of all information required to be furnished to participants, beneficiaries, and other specified individuals under title I of ERISA.[1] *See* 29 CFR 2520.104b–1. These standards require that plan administrators use delivery methods reasonably calculated to ensure actual receipt of such information by plan participants, beneficiaries and other specified individuals. *See* § 2520.104b–1(b)(1). For example, in-hand delivery to an employee at his or her worksite is acceptable, as is material sent by first-class mail. On April 9, 2002, the Department amended § 2520.104b–1 to establish a "safe harbor" for the use of electronic media to satisfy the general furnishing requirement in § 2520.104b–1(b). *See* § 2520.104b–1(c).[2] The specific requirements of the safe harbor are discussed below.

On January 18, 2011 the President issued Executive Order 13563, "Improving Regulation and Regulatory Review." Executive Order 13563 reaffirms the importance of achieving regulatory goals through the most innovative and least burdensome tools available. It also emphasizes the importance of public participation in the regulatory process (in section 2) and retrospective consideration of existing regulatory policies (in section 6).

In light of these goals, and in consideration of Administration-wide policies encouraging electronic dissemination of information to the public by federal government agencies consistent with the principles of transparency, participation, and collaboration, EBSA is issuing this RFI to facilitate consideration of its approach to electronic disclosure by employee benefit plans. The Department is aware that electronic disclosure can be as effective as paper based communications, and that it can lower costs and administrative burdens and increase timeliness and accuracy for all involved. The Department also is aware that some of America's workers may not have reasonable access to the Internet, and others may prefer traditional (paper) disclosure methods for important financial interactions regarding their pensions and other employee benefits.

The Department recognizes that there have been substantial changes in technology since over time, both in the workplace and at home, including: The expansion of broadband through cable, fiber optic and wireless networks; hardware improvements to servers and personal computers improving storage, memory, recovery, and computing power; introduction of smart phones, net books and other personal computing devices; and social networking (*e.g.*, LinkedIn, Facebook, and Twitter).

At least some evidence suggests that these changes have resulted in a substantial increase in access to and utilization of electronic media. For instance, the 2009 U.S. Census Bureau Current Population Survey (Census) found that 76.7% of the households in the United States have access to the Internet from some location.[3] The Census data further shows that of the 139.1 million private sector workers approximately 111.7 million have access to the Internet from some location. Of the remaining 27.4 million workers who do not have personal access, approximately 10.6 million reside in a household where someone else has Internet access.

Over the past few years, the Department has engaged in various rulemakings and other initiatives involving disclosures to participants and beneficiaries. Examples include the qualified default investment alternative regulation (29 CFR 2550.404c–5), the participant-level fee disclosure regulation (29 CFR 2550.404a–5, 75 FR 64910), the pension benefit statement initiative (FAB 2006–03), the annual funding notice regulation (29 CFR 2520.101–4; FAB 2009–01; proposed § 2520.101–5, 75 FR 70625), and the target date fund initiative (75 FR 73987).

[1] 42 FR 37186.

[2] 67 FR 17264.

[3] The Census information may be found at *http://www.census.gov/population/www/socdemo/computer.html.*

Increasingly, commenters on these initiatives request that the Department take recognition of changes in technology, as other federal regulatory agencies have, and revisit, update, and modernize the electronic disclosure safe harbor to promote electronic disclosure of employee benefit plan information to the greatest extent possible. They argue that such forms of disclosure would be more efficient, less burdensome, and less costly than paper for plans and, therefore, participants. Not everyone, however, agrees that electronic disclosure is appropriate for all participants and beneficiaries or for all disclosures. Some caution against broadening the electronic disclosure safe harbor, arguing that some workers do not have reasonable Internet access, or that they simply prefer paper over electronically disclosed materials even when they have access.

In light of these differing views and the significance of the issues surrounding the use of electronic disclosure, the Department has decided to explore whether and how to expand or modify the current standards under ERISA applicable to the electronic distribution of required plan disclosures. To that end, the Department, through this RFI, is soliciting the views of the public on this important issue. Set forth below are a list of questions.

In considering the questions set forth in this RFI, commenters are encouraged to take into account the following information:

Electronic Disclosure Under ERISA

As noted above, on April 9, 2002, the Department established its electronic disclosure safe harbor. *See* § 2520.104b–1(c). As a safe harbor, § 2520.104b–1(c) is not the exclusive means for using electronic media to satisfy the requirements of § 2520.104b–1(b)(1). Plan administrators may find that other procedures will allow them to meet the general delivery requirements of § 2520.104b–1. However, following the conditions of the safe harbor provides assurance that the general delivery requirements under § 2520.104b–1(b)(1) have been satisfied.

The safe harbor is available only if: (1) The plan administrator takes appropriate and necessary measures reasonably calculated to ensure that the system for furnishing documents results in actual receipt of transmitted information and protects the confidentiality of personal information relating to the individual's accounts and benefits; (2) the electronically delivered documents are prepared and furnished in a manner that is consistent with the style, format and content requirements applicable to the particular document; (3) notice is provided to each participant, beneficiary or other individual, in electronic or non-electronic form, at the time a document is furnished electronically, that apprises the individual of the significance of the document when it is not otherwise reasonably evident as transmitted and of the right to request and obtain a paper version of such document; and (4) upon request, the participant, beneficiary or other individual is furnished a paper version of the electronically furnished documents. § 2520.104b–1(c)(1)(i) through (iv).

The safe harbor applies only for two categories of individual recipients. The first category consists of participants who have the ability to effectively access documents furnished in electronic form at any location where the participant is reasonably expected to perform his or her duties as an employee and with respect to whom access to the employer's or plan sponsor's electronic information system is an integral part of those duties. *See* § 2520.104b–1(c)(2)(i). The second category consists of participants, beneficiaries and other persons who are entitled to documents under title I of ERISA, but who do not fit into the first category. For this category, the safe harbor assumes the utilization of electronic information systems beyond the control of the plan or plan sponsor. The current safe harbor, therefore, provides that the second category of individuals must affirmatively consent to receive documents electronically. *See* § 2520.104b–1(c)(2)(ii)(A). The safe harbor relief is not available with respect to these individuals in the absence of such consent.

In general, the affirmative consent condition requires plans to ensure that an individual has affirmatively consented, in electronic or non-electronic form, to receiving documents through electronic media and has not withdrawn such consent. Alternatively, in the case of documents to be furnished through the Internet or through other electronic communication networks, the individual must have affirmatively consented or confirmed consent electronically, in a manner that reasonably demonstrates the individual's ability to access information in the electronic form that will be used to provide the information that is the subject of the consent, and must have provided an address for the receipt of electronically furnished documents. In addition, prior to consenting, the individual must be provided, in electronic or non-electronic form, a clear and conspicuous statement indicating: (1) The types of documents to which the consent would apply; (2) that consent can be withdrawn at any time without charge; (3) the procedures for withdrawing consent and for updating the participant's, beneficiary's or other individual's address for receipt of electronically furnished documents or other information; (4) the right to request and obtain a paper version of an electronically furnished document, including whether the paper version will be provided free of charge; and (5) any hardware and software requirements for accessing and retaining the documents. Further, following consent, if a change in such hardware or software requirements creates a material risk that the individual will be unable to access or retain electronically furnished documents, the individual: (1) Is provided with a statement of the revised hardware or software requirements for access to and retention of electronically furnished documents; (2) is given the right to withdraw consent without charge and without the imposition of any condition or consequence that was not disclosed at the time of the initial consent; and (3) again consents in accordance with the requirements above. See § 2520.104b–1(c)(2)(ii).

Electronic Disclosure Under the Internal Revenue Code

The Department of Treasury and the Internal Revenue Service (IRS) have issued guidance relating to the use of electronic media of notices or elections with respect to a retirement plan. In 2000, final regulations were issued relating to the use of electronic media for the delivery of certain participant notices and consents that are required to be provided in connection with distributions from retirement plans.

In 2003, the Department of Treasury and IRS published final regulations under section 4980F under the Internal Revenue Code (Code) that also apply for purposes of section 204(h) of ERISA (2003 section 4980F regulations).[4] Under Q&A–13(c) of § 54.4980F–1, notice required under section 4980F of the Code or section 204(h) of ERISA (section 204(h) notice) may be provided electronically if certain requirements are satisfied. The section 204(h) notice must actually be received by the applicable individual or the plan administrator must take appropriate and necessary measures reasonably calculated to ensure that the method for providing the section 204(h) notice results in actual receipt of the notice. In addition, the

[4] 68 FR 17277.

plan administrator must provide the applicable individual with a clear and conspicuous statement that the individual has a right to receive a paper version of the section 204(h) notice without the imposition of fees and, if the individual requests a paper copy of the section 204(h) notice, the paper copy must be provided without charge. The 2003 section 4980F regulations also provide a safe harbor method at 26 CFR 54.4980F–1, Q&A–13(c)(3), for delivering a section 204(h) notice electronically, which is substantially the same as the consumer consent rules of E–SIGN (described below under the heading "*Electronic Signatures in Global and National Commerce Act*").[5]

On October 20, 2006, the Department of Treasury and IRS published final regulations under the Code setting forth standards for electronic systems that make use of an electronic medium to provide a notice to a recipient, or to make a participant election or consent, generally with respect to a retirement plan, an employee benefit arrangement, or an individual retirement plan.[6] These regulations provide two methods by which such plans or arrangements are permitted to provide an applicable notice[7] to a recipient through the use of an electronic medium. Under the first method, an applicable notice is permitted to be provided electronically after the recipient consents to the electronic delivery of the notice (consumer consent method). The consumer consent method reflects the consumer consent requirements in E–SIGN. The second method does not require consent by the recipient, but when the applicable notice is provided, the recipient must be advised that he or she may request and receive the applicable notice in writing at no charge (alternative method). In addition, any recipient of the notice must be "effectively able" to access the electronic medium used to provide the notice. *See* generally 26 CFR 1.401(a)–21(b) and (c). These regulations also modified the 2003 section 4980F regulations to require that a section 204(h) notice comply with the regulations under § 1.401(a)–21. The current section 4980F regulations retain the requirement in the 2003 section 4980F regulations that the section 204(h) notice actually be received by the applicable individual or that the plan administrator take appropriate and necessary measures reasonably calculated to ensure that the method for providing the section 204(h) notice results in actual receipt. *See* 26 CFR 54.4980F–1, Q&A–13(c)(1).

Electronic Disclosure of Proxy Materials and Prospectuses Under Securities Law

In 2007, the Securities and Exchange Commission (SEC) amended its rules under the Securities Exchange Act of 1934 to provide a method to furnish proxy materials by posting them on an Internet Web site and providing shareholders with notice of the availability of the proxy materials.[8] In 2009, the SEC adopted amendments permitting a person to satisfy its mutual fund prospectus delivery obligations under the Securities Act of 1933 by sending or giving investors a summary prospectus and providing the statutory prospectus on an Internet Web site.[9] Under both rules, copies of the documents must be sent at no charge to shareholders requesting such copies. *See* 17 CFR 240.14a–16; 17 CFR 230.498. The SEC has also previously provided interpretive guidance on the use of electronic media to deliver information under the federal securities law.[10]

2006 ERISA Advisory Council Working Group Report on Prudent Investment Process

On August 9, 2006, and September 21, 2006, a working group of the ERISA Advisory Council held a hearing on numerous issues pertaining to the management of plan assets, including the use of electronic media for disclosures required by regulations under section 404(c) of ERISA. Thirteen witnesses testified at this hearing. In response to this hearing, the working group issued the "Report of the Working Group on Prudent Investment Process." With respect to the Department's electronic disclosure safe harbor as applied to defined contribution pension plans, the Report states:

> The Working Group would like to recommend to the Department of Labor that the Department should reconsider its rules for electronic transfer of notices and the delivery of 'sufficient information.' The Working Group heard extensive testimony regarding the growth of the internet and its use by plan participants. Access to and use of the internet has grown significantly since the DOL first considered electronic delivery. The Working Group recommends that the electronic delivery standard should be relaxed from the 'integral part of the employee's duties' standard currently employed to a 'reasonable access' standard.

This Report can be accessed at *http://www.dol.gov/ebsa/publications/AC_1106A_report.html.*

2007 ERISA Advisory Council Working Group Report on Participant Benefit Statements

On July 12, 2007 and September 18, 2007, a working group of the ERISA Advisory Council held a public hearing on the pension benefit statement requirements under section 105 of ERISA, as amended by section 508 of the Pension Protection Act of 2006, Public Law 109–280, 120 Stat. 949–952. Thirteen witnesses testified at this hearing. In response to this hearing, the working group issued the "Report of the Working Group on Participant Benefit Statements." In this Report, the Working Group recommended that "the Department of Labor should update its regulations regarding electronic communication to a 'reasonable access' standard as in the Department of Treasury safe harbor regulation in recognition of the continued advancement in Web-based communication and the increase in its use by participants." In support of this recommendation, the Report explains:

> Following an animated discussion, the Working Group came to a consensus that although the American workforce is becoming more computer literate, it is not yet appropriate to make electronic delivery of participant statements the norm. In addition to access and ability to use issues, many participants who are computer literate are better served with paper when managing their plan asset. However, the Treasury rules regarding communication provide incentive for plan sponsors to migrate to electronic delivery. In any event, the new regulations should reexamine the use of electronic communication for benefit statements to recognize the changes in technology and the participant group's use of it.

This Report can be accessed at *http://www.dol.gov/ebsa/publications/AC-1107c.html.*

[5] The 2003 section 4980F regulations were issued under amendments to the Code and ERISA contained in the Economic Growth and Tax Relief Reconciliation Act of 2001 (EGTRRA), which was enacted after enactment of ESIGN. The EGTRRA amendments, at section 4980F(g) of the Code and section 204(h)(7) of ERISA, authorize regulations allowing section 204(h) notice to be provided using new technologies.

[6] 71 FR 61877.

[7] Section 1.401(a)–21(e) defines an applicable notice as any notice, report, statement, or other document required to be provided to a recipient under a retirement plan, employee benefit arrangement, or individual retirement plan. Section 1.401(a)–21(a)(3) provides that § 1.401(a)–21 does not apply to any notice, election, consent, disclosure, or other obligation over which the Department of Labor or the Pension Benefit Guaranty Corporation (PBGC) has interpretive authority under Title I or IV of ERISA or to any provision of the Internal Revenue Code over which the Labor Department or PBGC has interpretive authority.

[8] 72 FR 4148 and 72 FR 42221.

[9] 74 FR 4546.

[10] 60 FR 53458, 61 FR 24644, 65 FR 25843, and 73 FR 45862.

2009 ERISA Advisory Council Report on Promoting Retirement Literacy and Security by Streamlining Disclosures

On July 23, 2009 and September 15, 2009, the ERISA Advisory Council, in furtherance of its focus on the issue of promoting retirement literacy and security by streamlining disclosures to participants and beneficiaries, held a public hearing to study the efficacy of ERISA's reporting and disclosure schemes, as well as problems and costs related to such disclosures. Approximately 18 witnesses testified at this hearing. Upon conclusion of the hearing, the full ERISA Advisory Council reached consensus and issued a report entitled "Promoting Retirement Literacy and Security by Streamlining Disclosures." In this Report, the Council recommended that:

> [T]he Department of Labor permits plan administrators to rely on the IRS Regulations in order to comply with ERISA's disclosure requirements. The Council believes that the IRS Regulations will adequately protect the rights of those participants who are actively employed because it will generally be very simple for administrators to determine whether active employees have reasonable access to the electronic medium used to furnish the disclosure. The Council believes that administrators will not furnish those individuals who are not working actively—such as retirees or beneficiaries—with electronic disclosure unless the administrator has a working electronic mail address for such individuals. In that way, participants who are not actively employed and plan beneficiaries will be protected.

In support of this recommendation, the Report explains:

> Electronic communications have enormously improved the retirement system for both plans covered by ERISA and their participants. They have improved participant education, retirement planning, and plan participation. Electronic communications have allowed plans to furnish more information to participants and beneficiaries for less cost. They have simplified plan administration and improved plan recordkeeping. All of these benefits of electronic communication have improved retirement security, which was and remains an underlying goal of ERISA. The Council believes that this goal of retirement security would be better served if the DOL would expand the array of electronic media that plan administrators may use to satisfy ERISA's disclosure requirements.

The Report can be reviewed at *http://www.dol.gov/ebsa/publications/2009ACreport2.html.*

Electronic Signatures in Global and National Commerce Act

The Electronic Signatures in Global and National Commerce Act (E–SIGN), 17 U.S.C. 7001–7021, generally provides that electronic records and signatures have the same legal effect as their paper counterparts.[11] When a statute, regulation, or other rule of law requires that information relating to a transaction be provided or made available to a consumer[12] in writing, section 101(c) of E–SIGN requires that the consumer must first affirmatively consent to receive the information electronically in a manner that reasonably demonstrates the consumer's ability to access the information in electronic form. 17 U.S.C. 7001(c). However, section 104(d)(1) of E–SIGN, 17 U.S.C. 7004(d)(1), authorizes a Federal regulatory agency to exempt, without condition, a specified category or type of record from the consumer consent requirements in section 101(c). The agency may issue an exemption only if it is necessary to eliminate a substantial burden on electronic commerce and will not increase the material risk of harm to consumers.

B. Request for Information

The purpose of this RFI is to solicit views, suggestions and comments from plan participants and beneficiaries, employers and other plan sponsors, plan administrators, plan service providers, health insurance issuers, and members of the financial community, as well as the general public on whether, and possibly how, to expand or modify the Department's current electronic disclosure safe harbor. To facilitate consideration of the issues, the Department has set forth below a number of questions. Respondents need not answer every question, but should identify, by its number, each question addressed. Interested persons are also encouraged to address any other matters they believe germane to the general topic of the RFI.

Access and Usage Questions

1. What percentage of people in this country has access to the Internet at work or home? Of this percentage, what percentage has access at work versus at home? Does access vary by demographic groups (*e.g.,* age, socioeconomic, race, national origin, *etc.*)?

2. What percentage of participants and beneficiaries covered by an ERISA plan has access to the Internet at work or home? Of this percentage, what percentage has access at work, at home, or both? Does access vary by demographic groups (*e.g.,* age, socioeconomic, race, national origin, etc.)? What percentage of participants and beneficiaries uses the Internet to access private information such as personal bank accounts?

3. What percentage of pension benefit plans covered by ERISA currently furnish some or all disclosures required by ERISA electronically to some or all participants and beneficiaries covered under these plans? Please be specific regarding types of plans (*e.g.,* single-employer plans versus multiemployer plans, defined benefit pension plans versus defined contribution pension plans, *etc.*), types of participants and beneficiaries (*e.g.,* active, retired, deferred vested participants) and types of disclosures (*e.g.,* all required title I disclosures versus select disclosures).

4. What percentage of employee welfare benefit plans covered by ERISA currently furnish some or all disclosures required by ERISA electronically to some or all participants and beneficiaries covered under these plans? Please be specific regarding types of welfare plans (*e.g.,* health, disability, *etc.*), types of participants and beneficiaries (*e.g.,* active employees, retirees, COBRA Qualified Beneficiaries, *etc.*) and types of disclosures (*e.g.,* all required title I disclosures versus select disclosures).

5. What are the most common methods of furnishing information electronically (*e.g.,* e-mail with attachments, continuous access Web site, *etc.*)?

6. What are the most significant impediments to increasing the use of electronic media (*e.g.,* regulatory impediments, lack of interest by participants, lack of interest by plan sponsors, access issues, technological illiteracy, privacy concerns, etc.)? What steps can be taken by employers, and others, to overcome these impediments?

7. Is there evidence to suggest that any increase in participant and beneficiary access to, and usage of, the Internet and similar electronic media in general equates to an increased desire or willingness on the part of those participants and beneficiaries to receive employee benefit plan information electronically? If so, what is it?

8. Are there any new or evolving technologies that might impact electronic disclosure in the foreseeable future?

[11] The rules of section 101 of E–SIGN do not apply to certain consumer notices. These include consumer notices that are necessary for the protection of a consumer's health, safety, or shelter (e.g., cancellation of health benefits or life insurance and foreclosure on a credit agreement secured by an individual's primary residence). *See* section 103(b)(2)(B) and (C) of E–SIGN.

[12] Section 106(1) of E–SIGN generally defines a consumer as an individual who obtains products or services used primarily for personal, family, or household purposes.

General Questions

9. Should the Department's current electronic disclosure safe harbor be revised? If so, why? If not, why not?

10. If the safe harbor should be revised, how should it be revised? Please be specific.

11. Should a revised safe harbor have different rules or conditions for different types of employee benefit plans (*e.g.,* pension versus welfare plans)? If so, why and what differences?

12. Should a revised safe harbor have different rules or conditions for different types of disclosures (*e.g.,* annual funding notice, quarterly benefit statement, COBRA election notice, *etc.*)? If so, why and what differences?

13. Should a revised safe harbor have different rules or conditions for different recipients entitled to disclosures (active employees, retirees, COBRA Qualified Beneficiaries, *etc.*)? If yes, why, and how should the rules or conditions differ?

14. To what extent should the Department encourage or require pension and welfare benefit plans to furnish some or all disclosures required under title I of ERISA through a continuous access Web site(s)? In responding to this question, please address whether and how frequently participants and beneficiaries should be notified of their ability to access benefit information at the Web site(s) and the most appropriate means to provide such notice. For example, should participants and beneficiaries receive a monthly notification of their ability to access benefit information or should they receive a notification only when an ERISA-required disclosure is added to the Web site? How should such notifications be furnished (*e.g.,* paper, e-mail, *etc.*)? Please also address what steps would be needed to ensure that participants and beneficiaries understand how to request and receive paper copies of the disclosures provided on the Web site(s).

15. Who, as between plan sponsors and participants, should decide whether disclosures are furnished electronically? For example, should participants have to opt into or out of electronic disclosures? *See* Question 26.

16. Should a revised safe harbor contain conditions to ensure that individuals with disabilities are able to access disclosures made through electronic media, such as via continuous access Web sites? If so, please describe the conditions that would be needed. Also, please identify whether such conditions would impose any undue burdens on employee benefit plans, including the costs associated with meeting any such conditions. What burden and difficulty would be placed on employees with disabilities if the Web sites and/or other electronic communication were not accessible?

Technical Questions

17. If a plan furnishes disclosures through electronic media, under what circumstances should participants and beneficiaries have a right to opt out and receive only paper disclosures?

18. The Department's current regulation has provisions pertaining to hardware and software requirements for accessing and retaining electronically furnished information. In light of changes in technology, are these provisions adequate to ensure that participants and beneficiaries, especially former employees with rights to benefits under the plan, have compatible hardware and software for receiving the documents distributed to their non-work e-mail accounts?

19. Some have indicated that the affirmative consent requirement in the Department's current electronic disclosure safe harbor is an impediment to plans that otherwise would elect to use electronic media. How specifically is this requirement an impediment? Should this requirement be eliminated? Is the affirmative consent requirement a substantial burden on electronic commerce? If yes, how? Would eliminating the requirement increase a material risk of harm to participants and beneficiaries? If yes, how? *See* section 104(d)(1) of E–SIGN.

20. In general, the E–SIGN Act permits electronic disclosure of health plan materials but does not apply to cancellation or termination of health insurance or benefits electronically. Are there special considerations the Department should take into account for group health plan disclosures (including termination of coverage and privacy issues)?

21. Many group health plan disclosures are time-sensitive (*e.g.,* COBRA election notice, HIPAA certificate of creditable coverage, special enrollment notice for dependents previously denied coverage under the ACA, denials in the case of urgent care claims and appeals). Are there special considerations the Department should take into account to ensure actual receipt of time-sensitive group health plan disclosures?

22. Do spam filters and similar measures used by non-workplace (personal) e-mail accounts, pose particular problems that should be taken into consideration?

23. What is the current practice for confirming that a participant received a time-sensitive notice that requires a participant response?

24. What are current practices for ensuring that the e-mail address on file for the participant is the most current e-mail address? For example, what are the current practices for obtaining and updating e-mail addresses of participants who lose their work e-mail address upon cessation of employment or transfer to a job position that does not provide access to an employer provided computer?

Comments Regarding Economic Analysis, Paperwork Reduction Act, and Regulatory Flexibility Act

Executive Order 12866 (EO 12866) requires an assessment of the anticipated costs and benefits to the government and the public of a significant rulemaking action, and of the alternatives considered, using the guidance provided by the Office of Management and Budget. Under EO 12866, a determination must be made whether implementation of this rule will be economically significant. A rule that has an annual effect on the economy of $100 million or more is considered economically significant.

In addition, the Regulatory Flexibility Act may require the preparation of an analysis of the impact on small entities of proposed rules and regulatory alternatives. A regulatory flexibility analysis must generally include, among other things, an estimate of the number of small entities subject to the regulations (for this purpose, plans, employers, and issuers and, in some contexts small governmental entities), the expense of the reporting, recordkeeping, and other compliance requirements (including the expense of using professional expertise), and a description of any significant regulatory alternatives considered that would accomplish the stated objectives of the statute and minimize the impact on small entities. For this purpose, the Agency considers a small entity to be an employee benefit plan with fewer than 100 participants.

The Paperwork Reduction Act requires an estimate of how many "respondents" will be required to comply with any "collection of information" requirements contained in regulations and how much time and cost will be incurred as a result. A collection of information includes recordkeeping, reporting to governmental agencies, and third-party disclosures.

The Department is requesting comments that may contribute to the analyses that will be performed under these requirements, both generally and

with respect to the following specific areas:

25. What costs and benefits are associated with expanding electronic distribution of required plan disclosures? Do costs and benefits vary across different types of participants, sponsors, plans, or disclosures? Are the printing costs being transferred from plans to plan participants and beneficiaries when information is furnished electronically?

26. If electronic disclosure were the default method for distributing required plan disclosures, and assuming "opting out" were an option, what percentage of participants would likely "opt-out" of electronic disclosure in order to receive paper disclosures? Should participants be informed of increased plan costs, if any, attendant to furnishing paper disclosures at the time they are afforded the option to opt out or into an electronic disclosure regime?

27. Do participants prefer receiving certain plan documents on paper rather than electronically (*e.g.,* summary plan descriptions versus quarterly benefit statements), and what reasons are given for such preference? Would this preference change if participants were aware of the additional cost associated with paper disclosure?

28. What impact would expanding electronic disclosure have on small plans? Are there unique costs or benefits for small plans? What special considerations, if any, are required for small plans?

29. Is it more efficient to send an e-mail with the disclosure attached (e.g., as a PDF file) versus a link to a Web site? Which means of furnishing is more secure? Which means of furnishing would increase the likelihood that a worker will receive, read, retain and act upon the disclosure?

30. Employee benefit plans often are subject to more than one applicable disclosure law (*e.g.,* ERISA, Internal Revenue Code) and regulatory agency. To what extent would such employee benefit plans benefit from a single electronic disclosure standard?

Signed at Washington, DC, this 1st day of April, 2011.

Phyllis C. Borzi,

Assistant Secretary, Employee Benefits Security Administration, Department of Labor.

[FR Doc. 2011–8288 Filed 4–6–11; 8:45 am]

BILLING CODE 4510–29–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket No. USCG–2011–0197]

RIN 1625–AA00

Safety Zone; Commencement Bay, Tacoma, WA

AGENCY: Coast Guard, DHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Coast Guard is proposing to amend 33 CFR 165.1305 to expand the established safety zone during the annual Tacoma Freedom Air Show on the fourth of July. The proposed safety zone expansion would establish a larger clear area for low flying aircraft during this event. This rule is necessary to help ensure the safety of the maritime public and event participants during this annual event and will do so by prohibiting any person or vessel from entering or remaining within the safety zone during this event.

DATES: Comments and related material must be received by the Coast Guard on or before May 9, 2011. Requests for public meetings must be received by the Coast Guard on or before May 9, 2011.

ADDRESSES: You may submit comments identified by docket number USCG–2011–0197 using any one of the following methods:

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

(2) *Fax:* 202–493–2251.

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

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

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

FOR FURTHER INFORMATION CONTACT: If you have questions on this proposed rule, call or e-mail Ensign Anthony P. LaBoy, USCG Sector Puget Sound Waterways Management Division, Coast Guard; telephone 206–217–6323, e-mail *SectorPugetSoundWWM@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–2011–0197), 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 (via *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://www.regulations.gov,* it will be considered received by the Coast Guard when you successfully transmit the comment. If you fax, hand deliver, or mail your comment, it will be considered as having been received by the Coast Guard when it is received at the Docket Management Facility. We recommend that you include your name and a mailing address, an e-mail address, or a telephone number in the body of your document so that we can contact you if we have questions regarding your submission.

To submit your comment online, go to *http://www.regulations.gov*, click on the "submit a comment" box, which will then become highlighted in blue. In the "Document Type" drop down menu select "Proposed Rule" and insert "USCG–2011–0197" in the "Keyword" box. Click "Search" 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 comments by mail and would like to know that they reached the Facility, please enclose a stamped, self-addressed postcard or envelope. We will consider all comments and material received during the comment period and may change the rule based on your comments.

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–2011–0197" 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 one of the four methods specified under **ADDRESSES**. Please explain why you believe a public meeting would be beneficial. If we determine that one would aid this rulemaking, we will hold one at a time and place announced by a later notice in the **Federal Register**.

For information on facilities or services for individuals with disabilities or to request special assistance at the public meeting, contact Ensign Anthony P. LaBoy at the telephone number or e-mail address indicated under the **FOR FURTHER INFORMATION CONTACT** section of this notice.

Basis and Purpose

The Coast Guard is proposing to modify the boundaries of the safety zone established in 33 CFR 165.1305. In general, this safety zone is necessary because of the numerous potential hazards associated with the Tacoma Freedom Fair Air Show events. The proposed modification is necessary because the air show has expanded since the initial final rule was codified and the event sponsor has requested a larger safety zone to protect participants and spectators. In addition, expanding the zone would allow safety vessels to patrol inside the safety zone and would minimize vessel traffic along the shoreline which could impede the movement of the safety vessels.

Discussion of Proposed Rule

The safety zone created by this proposed rule encompasses all waters bounded by the following points Latitude 47°17′38″ N, Longitude 122°28′43″ W; thence south easterly to Latitude 47°17′4″ N, Longitude 122°27′32″ W; thence south westerly to Latitude 47°16′35″ N, Longitude 122°28′1″ W; thence north westerly along the shoreline to Latitude 47°17′10″ N, Longitude 122°29′14″ W; thence returning to the origin. This safety zone resembles a rectangle protruding from the shoreline along Ruston Way. Floating markers will be placed by the sponsor of the event to delineate the boundaries of the safety zone. All persons and vessels are prohibited from entering or remaining in the safety zone unless authorized by the Captain of the Port, Puget Sound or Designated Representative. The Captain of the Port Puget Sound may be assisted by other local, state, and Federal agencies in the enforcement of this safety zone.

Regulatory Analyses

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

Regulatory Planning and Review

This proposed 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 bases this finding on the fact that the safety zone is small in size, short in duration, and maritime traffic will be able to safely transit the area outside of this safety zone. Maritime traffic may also request permission to transit through the zone from the Captain of the Port, Puget Sound or Designated Representative.

Small Entities

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

The Coast Guard certifies under 5 U.S.C. 605(b) that this proposed rule would not have a significant economic impact on a substantial number of small entities. This proposed rule would affect the following entities, some of which might be small entities: The owners or operators of vessels intending to enter or transit in a portion of Commencement Bay, Tacoma, Washington on July 4th from 2 p.m. until 12:30 a.m. July 5th, annually. This safety zone will not have a significant economic impact on a substantial number of small entities, because the safety zone is short in duration, minimal in size, and maritime traffic will be allowed to transit through the safety zone with permission.

If you think that your business, organization, or governmental jurisdiction qualifies as a small entity and that this rule would have a significant economic impact on it, please submit a comment (*see* **ADDRESSES**) explaining why you think it qualifies and how and to what degree this rule would economically affect it.

Assistance for Small Entities

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

The Coast Guard will not retaliate against small entities that question or complain about this proposed rule or any policy or action of the Coast Guard.

Collection of Information

This proposed rule would call 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 proposed 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 proposed rule would not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

Taking of Private Property

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

Civil Justice Reform

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

Protection of Children

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

Indian Tribal Governments

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

Energy Effects

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

Technical Standards

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

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

Environment

We have analyzed this proposed rule under Department of Homeland Security Management Directive 023–01 and Commandant Instruction M16475.lD, which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321–4370f), and have made a preliminary determination that this action is one of a category of actions which do not individually or cumulatively have a significant effect on the human environment. A preliminary environmental analysis checklist supporting this determination will be made available in the docket where indicated under **ADDRESSES**. This proposed rule involves the establishment of a safety zone. We seek any comments or information that may lead to the discovery of a significant environmental impact from this proposed rule.

List of Subjects in 33 CFR Part 165

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

For the reasons discussed in the preamble, the Coast Guard proposes to amend 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. 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, 160.5; Pub. L. 107–295, 116 Stat. 2064; Department of Homeland Security Delegation No. 0170.1.

2. The Coast Guard proposes to amend § 165.1305 by revising paragraph (a) to read as follows:

§ 165.1305 Commencement Bay, Tacoma, WA.

(a) *Location.* The following area is a safety zone for the Tacoma Freedom Fair Air Show: All portions of Commencement Bay bounded by the following coordinates: Latitude 47°17′38″ N, Longitude 122°28′43″ W; thence south easterly to Latitude 47°17′4″ N, Longitude 122°27′32″ W; thence south westerly to Latitude 47°16′35″ N, Longitude 122°28′1″ W; thence north westerly along the shoreline to Latitude 47°17′10″ N, Longitude 122°29′14″ W; thence returning to the origin. This safety zone resembles a rectangle protruding from the shoreline along Ruston Way. Floating markers will be placed by the sponsor of the event to delineate the boundaries of the safety zone.

* * * * *

Dated: March 24, 2011.

S. J. Ferguson,

Captain, U.S. Coast Guard, Captain of the Port, Puget Sound.

[FR Doc. 2011–8370 Filed 4–6–11; 8:45 am]

BILLING CODE 9110–04–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R10–OAR–2011–0003; FRL–9291–4]

Approval and Promulgation of Implementation Plans; Oregon; Interstate Transport of Pollution; Significant Contribution to Nonattainment and Interference With Maintenance Requirements

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing to approve a portion of the State Implementation Plan (SIP) revision submitted by the State of Oregon for the purpose of addressing the interstate transport provisions of Clean Air Act (CAA) section 110(a)(2)(D)(i)(I) for the 1997 8-hour ozone National Ambient Air

Quality Standards (NAAQS or standards) and the 1997 fine particulate matter ($PM_{2.5}$) NAAQS. Section 110(a)(2)(D)(i) of the CAA requires that each State have adequate provisions to prohibit air emissions from adversely affecting air quality in other States through interstate transport. EPA is proposing to approve Oregon's SIP revision for the 1997 8-hour ozone and 1997 $PM_{2.5}$ NAAQS as meeting the requirements of CAA section 110(a)(2)(D)(i)(I) to prohibit emissions that will contribute significantly to nonattainment of the these standards in any other State and to prohibit emissions that will interfere with maintenance of these standards by any other State.

DATES: Written comments must be received on or before May 9, 2011.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R10–OAR–2011–0003, by one of the following methods:

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

B. *E–Mail: R10-Public_Comments@epa.gov.*

C. *Mail:* Donna Deneen, U.S. Environmental Protection Agency, Region 10, 1200 Sixth Avenue, Suite 900, *Mail Stop:* AWT–107, Seattle, WA 98101.

D. *Hand Delivery:* U.S. Environmental Protection Agency, Region 10, *Attn:* Donna Deneen (AWT–107), 1200 Sixth Avenue, Suite 900, Seattle, Washington 98101, 9th Floor. Such deliveries are only accepted during normal hours of operation, and special arrangements should be made for deliveries of boxed information.

Instructions: Direct your comments to Docket ID No. EPA–R10–OAR–2011–0003. 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 you 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 electronic docket are listed in the www.regulations.gov index. Although listed in the index, some information, *i.e.,* CBI or other information whose disclosure is restricted by statute, is not publicly available. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically in *http://www.regulations.gov* or in hard copy during normal business hours at the Office of Air, Waste and Toxics, U.S. Environmental Protection Agency, Region 10, 1200 Sixth Avenue, Suite 900, Seattle, Washington 98101.

FOR FURTHER INFORMATION CONTACT: Donna Deneen, (206) 553–6706 or *deneen.donna@epa.gov.*

SUPPLEMENTARY INFORMATION: Throughout this notice, the words "we", "us", or "our" means the Environmental Protection Agency (EPA).

Table of Contents

I. What proposed action is EPA taking?

EPA is proposing to approve a portion of Oregon's Interstate Transport State Implementation Plan (SIP) revision for the 1997 8-hour ozone and 1997 $PM_{2.5}$ NAAQS submitted by the Oregon Department of Environmental Quality (ODEQ) on June 23, 2010.[1] Specifically, we are proposing to approve the portion of the interstate transport SIP revision that addresses the following elements of CAA section 110(a)(2)(D)(i): (1) Significant contribution to nonattainment of these NAAQS in any other state; and (2) interference with maintenance of these NAAQS by any other state. EPA will address element (3), interference with any other state's required measures to prevent significant deterioration (PSD) of its air quality; and element (4), interference with any other state's required measures to protect visibility, in a separate action.[2] This proposed action does not address the requirements of the 2006 $PM_{2.5}$ NAAQS or the 2008 8-hour ozone NAAQS; those standards will be addressed in future actions.

II. What is a SIP?

Section 110(a) of the CAA requires each state to develop a plan that provides for the implementation, maintenance, and enforcement of the NAAQS. EPA establishes NAAQS under section 109 of the CAA. Currently, the NAAQS address six criteria pollutants: Carbon monoxide, nitrogen dioxide, ozone, lead, particulate matter, and sulfur dioxide.

The plan developed by a state is referred to as the SIP. The content of the SIP is specified in section 110 of the CAA, other provisions of the CAA, and applicable regulations. SIPs can be extensive, containing state regulations or other enforceable measures and various types of supporting information, such as emissions inventories, monitoring networks, and modeling demonstrations.

A primary purpose of the SIP is to provide the air pollution regulations, control strategies, and other means or techniques developed by the state to

[1] *See* transmittal letters dated June 23, 2010, from Joni Hammond, Deputy Director, ODEQ, and December 23, 2010, from Dick Pedersen, Director, ODEQ, to Dennis McLerran, Regional Administrator, EPA Region 10.

[2] On March 8, 2011, EPA proposed to approve the Oregon interstate transport SIP provisions addressing interference with any other state's required measures to protect visibility. *See* 76 FR 12651 (March 8, 2011).

ensure that the ambient air within that state meets the NAAQS. However, another important aspect of the SIP is to ensure that emissions from within the state do not have certain prohibited impacts upon the ambient air in other states through interstate transport of pollutants. This SIP requirement is specified in section 110(a)(2)(D). Pursuant to that provision, each state's SIP must contain provisions adequate to prevent emissions that significantly contribute to violations of the NAAQS in any other state, interfere with maintenance in any other state, interfere with any other state's required measures to prevent significant deterioration of its air quality, and interfere with any other state's required measures to protect visibility.

States are required to update or revise SIPs under certain circumstances. One such circumstance is EPA's promulgation of a new or revised NAAQS. Each state must submit these revisions to EPA for approval and incorporation into the federally-enforceable SIP.

III. What is the background for this proposed action?

On July 18, 1997, EPA promulgated new standards for 8-hour ozone [3] and fine particulate matter [4] ($PM_{2.5}$). This proposed action is in response to the promulgation of these standards (the 1997 8-hour ozone NAAQS and 1997 $PM_{2.5}$ NAAQS).

Section 110(a)(1) of the CAA requires states to submit SIPs to address a new or revised NAAQS within three years after promulgation of such standards, or within such shorter period as EPA may prescribe. Section 110(a)(2) lists the elements that such new SIPs must address, as applicable, including section 110(a)(2)(D)(i) which pertains to interstate transport of certain emissions. On August 15, 2006, EPA issued a guidance memorandum that provides recommendations to states for making submissions to meet the requirements of section 110(a)(2)(D)(i) for the 1997 8-hour ozone and 1997 $PM_{2.5}$ standards (2006 Guidance).[5]

The interstate transport SIP provisions in section 110(a)(2)(D)(i) (also called "good neighbor" provisions) require each state to submit a SIP that prohibits emissions that adversely affect another state in the ways contemplated in the statute. Section 110(a)(2)(D)(i) identifies four distinct elements related to the evaluation of impacts of interstate transport of air pollutants. In this rulemaking EPA is addressing the first two elements of this subsection.

The first element of section 110(a)(2)(D)(i)(I) requires that a state's SIP for a new or revised NAAQS must contain adequate measures to prohibit emissions from sources within the state that "contribute significantly" to nonattainment of the NAAQS in another state. The second element of CAA section 110(a)(2)(D)(i)(I) requires that a state's SIP must prohibit any source or other type of emissions activity in the state from emitting pollutants that will "interfere with maintenance" of the applicable NAAQS in any other state.

The CAA does not specifically mandate how to determine significant contribution to nonattainment or interference with maintenance. Therefore, EPA has interpreted these terms in past regulatory actions, such as the 1998 NO_X SIP Call, in which EPA took action to remediate emissions of nitrogen oxides (NO_X) that significantly contributed to nonattainment of, or interfered with maintenance of, the then applicable ozone NAAQS through interstate transport of NO_X and the resulting ozone.[6] The NO_X SIP Call was the mechanism through which EPA evaluated whether or not the NO_X emissions from sources in certain states had such prohibited interstate impacts, and if they had such impacts, required the states to adopt substantive SIP revisions to eliminate the NO_X emissions, whether through participation in a regional cap and trade program or by other means.

After promulgation of the 1997 8-hour ozone NAAQS and the 1997 $PM_{2.5}$ NAAQS, EPA again recognized that regional transport was a serious concern throughout the eastern United States and therefore developed the 2005 Clean Air Interstate Rule (CAIR) to address emissions of sulfur dioxide (SO_2) and NO_X that exacerbate ambient ozone and $PM_{2.5}$ levels in many downwind areas through interstate transport.[7] Within CAIR, EPA interpreted the term "interfere with maintenance" as part of the evaluation of whether or not the emissions of sources in certain states had such impacts on areas that EPA determined would either be in violation of the NAAQS, or would be in jeopardy of violating the NAAQS, in a modeled future year unless action were taken by upwind states to reduce SO_2 and NO_X emissions. Through CAIR, EPA again required states that had such interstate impacts to adopt substantive SIP revisions to eliminate the SO_2 and NO_X emissions, whether through participation in a regional cap and trade program or by other means.

EPA's 2006 Guidance addressed CAA section 110(a)(2)(D)(i) requirements for the 1997 8-hour ozone NAAQS and 1997 $PM_{2.5}$ NAAQS. For those states subject to CAIR, EPA indicated that compliance with CAIR would meet the two requirements of section 110(a)(2)(D)(i)(I) for these NAAQS. For states outside of the CAIR region, the 2006 Guidance recommended various methods by which states might evaluate whether or not their emissions significantly contribute to nonattainment of the 1997 8-hour ozone or the 1997 $PM_{2.5}$ NAAQS in another state. Among other methods, EPA recommended consideration of available EPA modeling conducted in conjunction with the CAIR, or in the absence of such EPA modeling, consideration of other information such as the amount of emissions, the geographic location of violating areas, meteorological data, or various other forms of information that would be relevant to assessing the likelihood of significant contribution to violations of the NAAQS in another state.

The assessment of significant contribution to nonattainment is not restricted to impacts upon areas that are formally designated nonattainment. Consistent with EPA's approach in CAIR and recently in the Transport Rule

[3] *See* 62 FR 38856. The level of the 1997 8-hour ozone NAAQS is 0.08 parts per million (ppm). 40 CFR part 50.10. The 8-hour ozone standard is met when the 3-year average of the annual 4th highest daily maximum 8-hour ozone concentrations is 0.08 ppm or less (*i.e.,* less than 0.085 ppm based on the rounding convention in 40 CFR part 50 Appendix I). This 3-year average is referred to as the "design value."

[4] *See* 62 FR 38652. The level of the 1997 $PM_{2.5}$ NAAQS are 15.0 $\mu g/m^3$ (annual arithmetic mean concentration) and 65 $\mu g/m^3$ (24-hour average concentration). 40 CFR part 50.7. The annual standard is met when the 3-year average of the annual mean concentrations is 15.0 $\mu g/m^3$ or less (*i.e.,* less than 15.05 $\mu g/m^3$ based on the rounding convention in 40 CFR part 50 Appendix N Section 4.3). The 24-hour standard is met when the 3-year average annual 98th percentile of 24-hour concentrations is 65 $\mu g/m^3$ or less (*i.e.,* less than 65.5 $\mu g/m^3$ based on the rounding convention in 40 CFR part 40 Appendix N Section 4.3). *Id.* These 3-year averages are referred to as the annual $PM_{2.5}$ and 24-hour $PM_{2.5}$ "design values," respectively.

[5] Memorandum from William T. Harnett entitled "Guidance for State Implementation Plan (SIP) Submissions to Meet Current Outstanding Obligations Under Section 110(a)(2)(D)(i) for the 8-hour ozone and $PM_{2.5}$ National Ambient Air Quality Standards," August 15, 2006.

[6] *See* 63 FR 57356 (October 27, 1998). EPA's general approach to section 110(a)(2)(D) in the NO_X SIP Call was upheld in *Michigan* v. *EPA, 213 F.3d 663* (DC Cir. 2000), cert denied, 532 U.S. 904 (2001). However, EPA's approach to interference with maintenance in the NO_X SIP Call was not explicitly reviewed by the court. *See, North Carolina* v. *EPA, 531 F.3d 896, 907–09* (DC Cir. 2008).

[7] *See* "Rule to Reduce Interstate Transport of Fine Particulate Matter and Ozone (Clean Air Interstate Rule); Revisions to Acid Rain Program; Revisions to the NO_X SIP Call; Final Rule," at 70 FR 25162 at 25263–69 (May 12, 2005).

Proposal, as discussed further below, this impact must be evaluated with respect to monitors showing a violation of the NAAQS.[8] Furthermore, although relevant information other than modeling may be considered in assessing the likelihood of significant contribution to nonattainment of the 8-hour ozone or $PM_{2.5}$ NAAQS in another state, EPA notes that no single piece of information is by itself dispositive of the issue. Instead, the total weight of all the evidence taken together is used to evaluate significant contributions to violations of the 1997 8-hour ozone or 1997 $PM_{2.5}$ NAAQS in another state.

As to the second element of section 110(a)(2)(D)(i), for states not within the CAIR region, EPA recommended that states evaluate whether or not emissions from their sources would "interfere with maintenance" in other states following the conceptual approach adopted by EPA in CAIR. After recommending various types of information that could be relevant for the technical analysis to support the SIP submission, such as the amount of emissions and meteorological conditions in the state, EPA further indicated that it would be appropriate for the state to assess impacts of its emissions on other states using considerations comparable to those used by EPA "in evaluating significant contribution to nonattainment in the CAIR."[9] EPA did not make specific recommendations for how states should assess interference with maintenance separately, and discussed the first two elements of section 110(a)(2)(D)(i) together without explicitly differentiating between them.

In 2008, the U.S. Court of Appeals for the D.C. Circuit found that CAIR and the related CAIR federal implementation plans were unlawful.[10] Among other issues, the court held that EPA had not correctly addressed the second element of section 110(a)(2)(D)(i)(I) in CAIR and noted that "EPA gave no independent significance to the 'interfere with maintenance' prong of section 110(a)(2)(D)(i)(I) to separately identify upwind sources interfering with downwind maintenance."[11] EPA's approach, the court reasoned, would leave areas that are "barely meeting attainment" with "no recourse" to address upwind emissions sources.[12] The court therefore concluded that a plain language reading of the statute requires EPA to give independent meaning to the interfere with maintenance requirement of section 110(a)(2)(D)(i) and that the approach used by EPA in CAIR failed to do so. In addition to affecting CAIR directly, the court's decision in the *North Carolina* case indirectly affects EPA's recommendations to states in the 2006 Guidance with respect to the interfere with maintenance element of section 110(a)(2)(D)(i) because the agency's guidance suggested that states use an approach comparable to that used by EPA in CAIR.

To address the judicial remand of CAIR, EPA has recently proposed a new rule to address interstate transport of air pollution pursuant to section 110(a)(2)(D)(i), the "Federal Implementation Plans to Reduce Interstate Transport of Fine Particulate Matter and Ozone" (Transport Rule Proposal).[13] As part of the Transport Rule Proposal, EPA specifically reexamined the section 110(a)(2)(D)(i)(I) requirements that emissions from sources in a state must not "contribute significantly to nonattainment" or "interfere with maintenance" of the 1997 8-hour ozone NAAQS and 1997 $PM_{2.5}$ NAAQS in other states. In the proposal, EPA developed an approach to identify areas that it predicts to be violating the 1997 8-hour ozone and $PM_{2.5}$ NAAQS in the future, and areas that it predicts to be close to the level of these NAAQS in the future and therefore at risk to become nonattainment unless emissions from sources in other states are appropriately controlled. This approach starts by identifying those specific geographic areas for which further evaluation is appropriate, and differentiates between areas where the concern is significant contribution to nonattainment as opposed to interference with maintenance.

As described in more detail below, EPA evaluated data from existing monitors over three overlapping 3-year periods (*i.e.,* 2003–2005, 2004–2006, and 2005–2007), as well as air quality modeling data, in order to determine which areas are predicted to be violating the 1997 8-hour ozone and $PM_{2.5}$ NAAQS in 2012, and which areas are predicted potentially to have difficulty maintaining attainment as of that date. In essence, if an area's projected data for 2012 indicates that it would be violating the NAAQS based on the average of these three overlapping periods, then this monitor location is appropriate for comparison for purposes of the significant contribution to nonattainment element of section 110(a)(2)(D)(i). If, however, an area's projected data indicate that it would be violating the NAAQS based on the highest single period, but not over the average of the three periods, then this monitor location is appropriate for comparison for purposes of the interfere with maintenance element of the statute.[14]

By this method, EPA has identified those areas with monitors that are appropriate "nonattainment receptors" or "maintenance receptors" for evaluating whether the emissions from sources in another state could significantly contribute to nonattainment in, or interfere with maintenance in, that particular area. EPA believes that this approach for identifying areas that are predicted to be nonattainment or to have difficulty maintaining the NAAQS, is appropriate to evaluate a state's submission in relation to the elements of CAA section 110(a)(2)(D)(i)(I) pertaining to significant contribution to nonattainment and interference with maintenance.[15] EPA's 2006 Guidance did not provide this specific recommendation to states, but in light of the court's decision on CAIR, EPA will itself follow this approach in evaluating the Oregon submission.

As explained in the 2006 Guidance, EPA does not believe that section 110(a)(2)(D)(i) SIP submissions from all states necessarily need to follow precisely the same analytical approach of CAIR. In the 2006 Guidance, EPA stated that: "EPA believes that the contents of the SIP submission required by section 110(a)(2)(D) may vary, depending upon the facts and circumstances related to the specific NAAQS. In particular, the data and analytical tools available at the time the State develops and submits a SIP for a new or revised NAAQS necessarily

[8] *See* 63 FR 57371 (October 27, 1998), NO_X SIP Call; 70 FR 25172 (May 12, 2005), CAIR; and 75 FR 45210 (August 2, 2010), Transport Rule Proposal.

[9] 2006 Guidance at 5.

[10] *See North Carolina* v. *EPA,* 531 F.3d 896 (DC Circuit 2008).

[11] 531 F.3d at 909.

[12] *Ibid.*

[13] *See* 75 FR 45210 (August 2, 2010).

[14] A memorandum in the docket for this action provides the information EPA used to identify monitors that are receptors for evaluation of significant contribution or interference with maintenance for certain states in the western United States. *See* Memorandum from Brian Timin, EPA Office of Air Quality Planning and Standards, "Documentation of Future Year Ozone and Annual $PM_{2.5}$ Design Values for Monitors in Western States," August 23, 2010 (Timin Memo).

[15] To begin this analysis, EPA first identifies all monitors projected to be in nonattainment or, based on historic variability in air quality, projected to have maintenance problems in 2012. Monitors projected to be in nonattainment are those with future year design values that violate the standard, based on the projection of 5-year weighted average concentrations. Monitors projected to have maintenance problems are those at risk of not staying in attainment because the air quality data is close enough to the level of the 1997 8-hour ozone and $PM_{2.5}$ NAAQS that minor variations in weather or emissions could result in violations of the NAAQS in 2012.

affects the contents of the required submission."[16] EPA also indicated in the 2006 Guidance that it did not anticipate that sources in states outside the geographic area covered by CAIR were significantly contributing to nonattainment, or interfering with maintenance, in other states.[17] As noted in the Transport Rule Proposal, EPA continues to believe that the more widespread and serious transport problems in the eastern United States are analytically distinct.[18] For the 1997 8-hour ozone and $PM_{2.5}$ NAAQS, EPA believes that nonattainment and maintenance problems in the western United States are relatively local in nature with only limited impacts from interstate transport. In the Transport Rule Proposal, EPA did not calculate the portion of predicted ozone or PM concentrations in any downwind state that would result from emissions from individual western states, such as Oregon.

Accordingly, EPA believes that section 110(a)(2)(D)(i) SIP submissions for states outside the geographic area of the Transport Rule Proposal may be evaluated using a "weight of the evidence" approach that takes into account the available relevant information, such as that recommended by EPA in the 2006 Guidance for states outside the area affected by CAIR. Such information may include, but is not limited to, the amount of emissions in the state relevant to the NAAQS in question, the meteorological conditions in the area, the distance from the state to the nearest monitors in other states that are appropriate receptors, or such other information as may be probative to consider whether sources in the state may significantly contribute to nonattainment or interfere with maintenance of the 1997 8-hour ozone and 1997 $PM_{2.5}$ NAAQS in other states. These submissions can rely on modeling when acceptable modeling technical analyses are available, but EPA does not believe that modeling is necessarily required if other available information is sufficient to evaluate the presence or degree of interstate transport in a given situation.

II. What is the state process to submit these materials to EPA?

CAA sections 110(a)(1) and (2) and section 110(l) require that revisions to a SIP be adopted by the State after reasonable notice and public hearing. EPA has promulgated specific procedural requirements for SIP revisions in 40 CFR part 51, subpart F. These requirements include publication of notices, by prominent advertisement in the relevant geographic area, of a public hearing on the proposed revisions, a public comment period of at least 30 days, and an opportunity for a public hearing.

On June 23, 2010, and December 23, 2010, the Oregon Department of Environmental Quality (ODEQ) submitted a SIP revision to update Oregon's infrastructure SIP for ozone and $PM_{2.5}$. Included in this submittal was a SIP revision entitled "Oregon SIP Infrastructure for Addressing the Interstate Transport of Ozone and Fine Particulate Matter" to address the interstate transport SIP requirements of CAA section 110(a)(2)(D)(i) for the 1997 8-hour ozone and 1997 $PM_{2.5}$ NAAQS (2010 interstate transport SIP).[19] ODEQ's June 23, 2010, submittal includes public process documentation for the 2010 interstate transport SIP submittal. In addition, the SIP revision includes documentation of a duly noticed public hearing held on December 22, 2009.

We find that the process followed by ODEQ in adopting the 2010 interstate transport SIP complies with the procedural requirements for SIP revisions under CAA section 110 and EPA's implementing regulations.

V. What is EPA's evaluation of the state's submission?

A. EPA's Evaluation of Significant Contribution to Nonattainment

This proposed approval evaluates the significant contribution to nonattainment element of section 110(a)(2)(D)(i)(I) for the 1997 8-hour ozone and 1997 $PM_{2.5}$ NAAQS in several ways. It takes into account Oregon's 2010 interstate transport SIP, in which the State explains that based on meteorological and other characteristics in Oregon and in the surrounding areas, $PM_{2.5}$ and ozone precursor emissions from Oregon sources do not significantly contribute to violations of the $PM_{2.5}$ or ozone NAAQS in other states.[20] In addition, EPA has supplemented the State's analysis with its own evaluation of the evidence, including a review of the nearest monitors in other states that are appropriate nonattainment receptors, in order to assess whether emissions sources in Oregon contribute significantly to nonattainment of the 1997 8-hour ozone and $PM_{2.5}$ NAAQS in other states.

Finally, EPA has also reviewed recent ozone and $PM_{2.5}$ monitoring data for the states bordering Oregon to consider whether Oregon emissions could significantly contribute to violations of the 1997 8-hour ozone or $PM_{2.5}$ NAAQS in those states.

1. Significant Contribution to Nonattainment Evaluation for the 1997 8-Hour Ozone NAAQS

To address whether emissions from Oregon sources significantly contribute to nonattainment of the 8-hour ozone NAAQS in another state, the State argued in the 2010 interstate transport SIP that meteorological and other characteristics of the Pacific Northwest support a finding that emissions from Oregon sources do not significantly contribute to violations of the $PM_{2.5}$ or ozone NAAQS in other states. Oregon pointed out that, in the Pacific Northwest, exceedances of the 8-hour ozone standard occur in the summer months, and during that season the prevailing winds[21] are predominantly from the north to northwest and, consequently, preclude any significant influence from Oregon on Washington ozone nonattainment areas.[22] While acknowledging the possibility that prevailing summer winds could result in some interstate transport of ozone forming emissions to western Idaho, Nevada and northern California, the State asserted in the 2010 interstate transport SIP that significant distances and topography (such as major mountain ranges that separate Oregon from California, Idaho and Nevada) would likely minimize the significance of these impacts on other states. Oregon gave as an example the largest major urban center in Oregon (the greater Portland area), which it estimated is 400 to 700 miles away from urban areas in western Idaho, Nevada, and northern California, and is separated by at least one major mountain range (the Cascades).

Oregon also pointed to its section 110 infrastructure SIP to show that ODEQ

[16] 2006 Guidance at 4.

[17] *Ibid.* at 5.

[18] *See* Transport Rule Proposal, 75 FR 45210 at 45227 (August 2, 2010).

[19] Oregon's submission addresses the interstate transport requirements of the 1997 $PM_{2.5}$ NAAQS, the 1997 8-hour ozone NAAQS, the 2006 $PM_{2.5}$ NAAQS, and the 2008 8-hour ozone NAAQS. In this action, EPA is only taking action with respect to CAA section 110(a)(2)(D)(i)(I) for the 1997 $PM_{2.5}$ and 1997 8-hour ozone NAAQS.

[20] Oregon's submission makes this conclusion with respect to not only the 1997 PM 2.5 NAAQS and 1997 8-hour ozone NAAQS, but also the 2006 PM 2.5 NAAQS and the 2008 8-hour ozone NAAQS.

[21] This north/northwest prevailing wind direction was derived from surface level winds and airport data and is not necessarily indicative of the prevailing wind direction of typical weather systems in the west.

[22] Note that there are currently no ozone nonattainment areas in Oregon or Washington.

has the ability to participate as needed in future studies on regional air pollution issues, or collaborate with other states if air quality concerns are identified that require a case-specific evaluation of interstate transport, and also ensures the legal mechanism for ODEQ to take action as needed to reduce emissions to help attain compliance with Federal NAAQS.

Finally, the State explained that it consulted with air agencies in Washington, Idaho, Nevada, and California and other agencies to evaluate case-specific air quality problems that may involve regional transport of air pollution. These staff-level communications indicated no impacts on ozone concentrations in other states caused by transport from the State of Oregon. The State added that if any future violations of ozone standards occur, Oregon would work with other air agencies and EPA as necessary to evaluate the role of interstate air pollution transport. This consultation provided additional support for the state's view that emissions from Oregon sources do not significantly contribute to violations of the 1997 8-hour ozone NAAQS in other states.

Based on the information provided in its 2010 interstate transport SIP, ODEQ concluded that emissions from air pollution sources in Oregon do not significantly contribute to nonattainment of the 1997 8-hour ozone NAAQS in other states.

EPA does not necessarily agree that Oregon's methodology is adequate for purposes of a section 110(a)(2)(D)(i) analysis. Therefore, EPA is supplementing the State's submission with additional, and more recent, information in order to assess this issue more fully. As noted above, EPA is evaluating the State's 2010 interstate transport SIP taking into account methodologies and analyses for the identification of receptor monitors that was developed in the Transport Rule Proposal, as well as EPA's projections of future air quality at monitors in western states in the Timin Memo, and preliminary air quality data from monitors in the states bordering Oregon. Although each of the factors considered in the following analysis are not in and of themselves determinative, consideration of these factors together provides a reliable qualitative conclusion that emissions from Oregon do not contribute significantly to nonattainment of the 1997 8-hour ozone NAAQS at monitors in other states.

The Transport Rule Proposal includes an approach to determining whether emissions from a state contribute significantly to nonattainment of the 1997 8-hour ozone NAAQS in other states. Specifically, EPA used existing monitoring data to project future concentrations of ozone at monitors to identify areas that are expected to be violating the 1997 8-hour ozone NAAQS in 2012, based on the 5-year weighted average design value. We call these monitors "nonattainment receptors." To identify the states with emissions that may contribute significantly to ozone nonattainment in other states, the Transport Rule Proposal models the states' contributions to ambient ozone levels at these nonattainment receptors.[23] Because the Transport Rule Proposal does not model the contribution of emissions from Oregon (nor other western states not fully inside the Transport Rule Proposal's modeling domain) to 8-hour ozone nonattainment receptors in other states, our assessment in this proposed action relies on a weight of evidence approach that considers relevant information from the Transport Rule Proposal pertaining to states within its modeling domain, and additional material such as geographical and meteorological factors, EPA's projections of future air quality at monitors in western states in the Timin Memo, and AQS monitoring data.

Our analysis begins by assessing Oregon's contribution to the closest nonattainment receptors for the 1997 8-hour ozone standard. The Transport Rule Proposal identifies within its modeling domain (consisting of 37 states east of the Rocky Mountains, and the District of Columbia) 11 nonattainment receptors for the 1997 8-hour ozone standard. Of these, the nonattainment receptors closest to Oregon are seven receptors in the Dallas-Fort Worth and Houston-Galveston-Brazoria 8-hour ozone nonattainment areas in eastern Texas. The remaining four nonattainment receptors for the 1997 8-hour ozone NAAQS are in Louisiana, New York, and Pennsylvania.[24]

The nonattainment receptors in Dallas-Fort Worth and Houston areas are over 1200 miles from the closest point on Oregon's border, and the receptors in Louisiana, New York, and Pennsylvania are significantly further away. Although distance alone is not determinative in the analysis of potential ozone transport, with increasing distance there are greater opportunities for ozone and NO_X dispersion and/or removal from the atmosphere due to the effect of winds or chemical sink processes. Moreover, the intervening Rocky Mountains act as a natural barrier to air pollution transport. These factors together support a conclusion that Oregon sources do not contribute significantly to nonattainment of the 1997 8-hour ozone NAAQS in the nearest areas with nonattainment receptors identified in the Transport Rule Proposal.

To assist in the evaluation of the potential for ozone transport among western states, EPA also developed an additional analysis in the Timin Memo identifying monitors projected to record violations of the 1997 8-hour ozone NAAQS in the western U.S. The Timin Memo identified predicted future nonattainment receptors for the 1997 8-hour ozone NAAQS in southern and central California. This analysis did not, however, identify any projected nonattainment receptors for the 1997 8-hour ozone NAAQS in any other western state.[25] The nonattainment receptor nearest to Oregon for the 1997 8-hour ozone NAAQS was identified as Nevada County, California. Nevada County is approximately 170 miles south/southeast of the closest point on Oregon's border and on the other side of intervening mountain ranges that act as a natural barrier to air pollution transport. Although not determinative by themselves, distance and topography are not favorable to 8-hour ozone transport from Oregon to central California. In addition, prevailing winds in the west generally move from south-westerly, westerly, or north-westerly directions, as indicated by the typical movement of weather systems. Hence central and southern California are not in the predominant direction of winds from Oregon. Given the distance between Oregon's border and central and southern California nonattainment receptors, the intervening mountainous topography, and the general direction of transport winds in the Western U.S., it is reasonable to conclude that Oregon sources do not contribute significantly to nonattainment of the 1997 8-hour ozone NAAQS in Nevada County or to any more distant nonattainment receptors in California. EPA's analysis for western states therefore supports our proposal to conclude that Oregon sources do not contribute significantly to nonattainment of the 1997 8-hour ozone NAAQS in any other state.

In addition to the information in the 2010 interstate transport SIP and EPA's projections of future air quality in the Transport Rule Proposal and in the

[23] Transport Rule Proposal, 75 FR 45210 at 45253–45273.

[24] *See* Transport Rule Proposal, Table IV.C–11, 75 FR 45210 at 45252.

[25] *See* Timin Memo at Appendix B ("Base year 2003–2007 and Future Year 2012 8-Hour Average Ozone Design Values—Western States").

Timin Memo, EPA also evaluated preliminary air quality monitoring data for the areas in states bordering Oregon that are designated nonattainment for the 1997 8-hour ozone NAAQS. While significant contribution must be measured not just against designated nonattainment areas but also against areas with monitors showing violations of the NAAQS, nonattainment areas are a convenient point of analysis. Two states bordering Oregon—California and Nevada—have areas currently designated nonattainment for the 1997 8-hour ozone standard. In California, the closest nonattainment area is Butte County, and in Nevada, the closest nonattainment area is the Las Vegas area in Clark County. EPA designated both of these areas as nonattainment for the 1997 8-hour ozone standard in 2004. *See* 69 FR 23858 (April 30, 2004); 40 CFR 81.305 and 81.329. Both of these areas, however, have current design values indicating attainment of the 1997 8-hour ozone NAAQS. Our review of preliminary monitoring data for the 2007–2009 period available in EPA's Air Quality System (AQS) database indicates that the 8-hour ozone design values for Butte County and Las Vegas during this period were 82 and 74 ppb, respectively.[26] We therefore believe it is reasonable to conclude that Oregon sources are not contributing significantly to nonattainment of the 1997 8-hour ozone NAAQS in Butte County, California or Clark County, Nevada. The closest nonattainment area to the Oregon border that had a design value above the 1997 8-hour ozone NAAQS for the 2007–2009 period was Nevada County, California. As noted above, given the distance between the Oregon border and Nevada County, the intervening mountainous topography, and the general direction of transport winds in the Western U.S., it is reasonable to conclude that Oregon sources do not contribute significantly to nonattainment in Nevada County or to any more distant central or southern California 1997 8-hour ozone nonattainment areas. There are no designated nonattainment areas in Idaho and Washington for the 1997 8-hour ozone NAAQS. This is further support that Oregon sources do not contribute significantly to nonattainment of the 1997 8-hour ozone NAAQS in any other state.

We also evaluated ozone monitoring data from the 2007–2009 period from each of the ozone monitoring sites in Washington, Idaho, Nevada and California, to determine whether the ozone levels in any of these states violate the 1997 8-hour ozone NAAQS.[27] We have identified no design values above the 1997 8-hour ozone NAAQS at any of the monitors in Washington, Idaho, or Nevada, nor any indication that emissions from Oregon sources contribute significantly to nonattainment of the 1997 8-hour ozone NAAQS in these adjacent states. Although AQS data for California show 8-hour ozone design values above the 1997 NAAQS during the 2007–2009 period, the closest monitor to Oregon that has a 2007–2009 8-hour ozone design value above the 1997 NAAQS is located in Nevada County. As noted above, given the distance between the Oregon border and Nevada County, the intervening mountainous topography, and the general direction of transport winds in the Western U.S., it is reasonable to conclude that Oregon sources do not contribute significantly to nonattainment in Nevada County or to any more distant central or southern California monitors. This is further support that Oregon sources do not contribute significantly to nonattainment of the 1997 8-hour ozone NAAQS in any other state.

Finally, none of the ozone monitors in Oregon have themselves indicated a violation of the 1997 8-hour ozone NAAQS. The absence of violations in Oregon itself does not rule out the possibility of transport, but taken in conjunction with other relevant information, including the distance from Oregon to areas with design values above the 1997 8-hour ozone NAAQS and Pacific Northwest meteorology and topography, this fact helps to support the conclusion that there is no transport from Oregon resulting in significant contribution to nonattainment in another state. Distance *per se* is also not an obstacle to long range transport of ozone and its precursors, as discussed above. However, with increasing distance there are greater opportunities for ozone and NO_X dispersion and removal from the atmosphere due to the effects of winds and chemical sink processes. In this context, the distance between Oregon sources and areas not meeting the 8-hour ozone standard reduces, but does not exclude, the possibility of significant contribution to nonattainment. Nevertheless, the absence of violations in Oregon combined with the total weight of all of the factors discussed above supports a conclusion that emissions from its sources do not significantly contribute to nonattainment in other states, in accordance with section 110(a)(2)(D)(i).

2. Significant Contribution to Nonattainment Evaluation for the 1997 $PM_{2.5}$ NAAQS

To address whether emissions from sources in Oregon significantly contribute to nonattainment of the 1997 $PM_{2.5}$ NAAQS in another state, the State argued in its 2010 interstate transport SIP that meteorological and other characteristics of any areas designated nonattainment for the 1997 $PM_{2.5}$ NAAQS in the surrounding states of Washington, Idaho, Nevada, and California support a finding that emissions from Oregon sources do not significantly contribute to violations of the $PM_{2.5}$ NAAQS or ozone NAAQS in other states. Oregon explained that the closest nonattainment areas in neighboring states are the Tacoma area (Pierce County) in Washington; the Chico area (portions of Butte County) in California, and the Cache Valley area in Southeast Idaho (portions of Cache County, Utah and Franklin County, Idaho).[28] Oregon argues that the area of highest Oregon emission densities (Portland Metro area) is separated from these $PM_{2.5}$ nonattainment areas by significant distances and major mountain ranges up to approximately 7000 feet. Oregon identifies one exception—the Portland-Vancouver metro area, which shares a common air shed between Oregon and Washington. Oregon, however, notes that both Portland and Vancouver are in attainment with the $PM_{2.5}$ NAAQS.

Oregon described typical seasonal wind patterns during the winter when $PM_{2.5}$ levels are the highest. It noted that wind speeds are typically variable with the majority of wind speeds occurring at less than 8 miles per hour, and a significant portion of low winds at less than 5 miles per hour. Oregon explained that these low wind speeds and air stagnation conditions do not lend themselves to long distance air pollution transport, and noted that the Portland area can experience high wind speeds in the winter travelling through the Columbia River Gorge east of Portland that are not conducive to the buildup of air pollution. Oregon concluded that general meteorology

[26] *See* EPA AQS, "Preliminary Design Value Report," 2007–2009, for Washington, Idaho, Nevada, and California.

[27] *Id.*

[28] Although the 2010 Interstate transport SIP identified these areas as $PM_{2.5}$ nonattainment areas, they are all 2006 24-hour $PM_{2.5}$ nonattainment areas. There are no 1997 $PM_{2.5}$ nonattainment areas in Washington or Idaho, and the closest 1997 $PM_{2.5}$ nonattainment area to Oregon is in California (San Joaquin County). Oregon asserts that its evaluation of more stringent 2006 24-hour $PM_{2.5}$ NAAQS nonattainment areas is indicative of potential contribution to nonattainment of the less stringent 1997 $PM_{2.5}$ NAAQS.

supports the conclusion that high winter time $PM_{2.5}$ levels in Pacific Northwest communities are typically dominated by local emission sources.

Oregon also pointed to its section 110 infrastructure SIP to show that ODEQ has the ability to participate as needed in future studies on regional air pollution issues, or collaborate with other states if air quality concerns are identified that require a case-specific evaluation of interstate transport, and also ensures the legal mechanism for ODEQ to take action as needed to reduce emissions to help attain compliance with Federal NAAQS. Oregon stated that that high $PM_{2.5}$ levels that threaten the NAAQS are investigated as needed to identify contributing sources, including any potential role of interstate transport.

Finally, the state explained that it had consulted with air agencies in Washington, Idaho, Nevada, and California and other agencies to evaluate case-specific air quality problems that may involve regional transport of air pollution. These staff-level communications indicated no impacts on $PM_{2.5}$ concentrations in other states caused by transport from the state of Oregon, providing additional support for the state's view that emissions from Oregon sources do not significantly contribute to violations of the 1997 $PM_{2.5}$ NAAQS in other states.

Based on this and other information provided in its 2010 interstate transport SIP, ODEQ concluded that emissions from air pollution sources in Oregon do not significantly contribute to nonattainment of the 1997 $PM_{2.5}$ NAAQS in other states.

EPA does not necessarily agree that Oregon's methodology is adequate for purposes of a section 110(a)(2)(D)(i) analysis. Therefore, EPA is supplementing the State's submission with additional, and more recent, information in order to assess this issue more fully. As noted above, EPA is evaluating the 2010 interstate transport SIP taking into account methodologies and analyses for the identification of the receptor monitors that was developed in the Transport Rule Proposal, as well as EPA's projections of future air quality at monitors in western states in the Timin Memo, and air quality data from monitors in the states bordering Oregon. Although each of the factors considered in the following analysis are not in and of themselves determinative, consideration of these factors together provides a reliable qualitative conclusion that emissions from Oregon do not contribute significantly to nonattainment of the $PM_{2.5}$ NAAQS at monitors in other states.

Specifically, we identified the nonattainment receptors for the 1997 annual $PM_{2.5}$ NAAQS closest to Oregon to evaluate whether emissions from Oregon sources contribute significantly to nonattainment of the 1997 $PM_{2.5}$ NAAQS in any other state.[29] For the 1997 annual $PM_{2.5}$ NAAQS, the projected nonattainment receptors closest to Oregon that EPA identified from the modeling analyses conducted for the Transport Rule Proposal are all east of the Mississippi River.[30] Given the significant distance between Oregon and these nonattainment receptors and the intervening mountainous terrain, we believe it is reasonable to conclude that Oregon sources do not significantly contribute to nonattainment of the 1997 annual $PM_{2.5}$ NAAQS in any of these areas.

To address the potential for $PM_{2.5}$ transport among western states, EPA also relied on the additional analysis in the Timin Memo identifying monitors projected to record violations of the 1997 annual $PM_{2.5}$ NAAQS. The Timin Memo identified predicted future nonattainment receptors for the 1997 annual $PM_{2.5}$ NAAQS in southern and central California but did not identify predicted future nonattainment receptors for the 1997 annual $PM_{2.5}$ NAAQS in any other western state.[31] For Oregon, the closest nonattainment receptor in California for the 1997 annual $PM_{2.5}$ NAAQS was Fresno County. Fresno County is over 300 miles south of the closest point on Oregon's border and is on the other side of intervening mountain ranges that act as a natural barrier to air pollution transport. Although not determinative by themselves, distance and topography are not favorable to $PM_{2.5}$ transport from Oregon to central California. In addition, prevailing winds in the west generally move from south-westerly, westerly, or north-westerly directions, as indicated by the typical movement of weather systems. Hence central and southern California are not in the predominant direction of winds from Oregon. Given the distance between the Oregon border and central and southern California nonattainment receptors, the intervening mountainous topography, and the general westerly direction of transport winds in the Western U.S., EPA concludes that Oregon sources do not contribute significantly to nonattainment of the 1997 annual $PM_{2.5}$ NAAQS in Fresno County or to any more distant nonattainment receptors in California. EPA's analysis for western states therefore supports our proposal to conclude that Oregon sources do not contribute significantly to nonattainment of the 1997 annual $PM_{2.5}$ NAAQS in any other state.

The analysis for the Transport Rule Proposal did not identify any nonattainment receptors for the 1997 24-hour $PM_{2.5}$ NAAQS in the portions of the U.S. covered by the Transport Rule Proposal modeling domain (*i.e.,* the 12 km grid covering the continental U.S. east of the Rockies).[32] Recent monitoring data in EPA's Air Quality System (2007–2009 design values) indicate that the highest 24-hour $PM_{2.5}$ design value in the 47 states of the continental U.S. (excluding California) is 50 $\mu g/m^3$,[33] which is well below the level of the 1997 24-hour $PM_{2.5}$ NAAQS of 65 $\mu g/m^3$. In California, 2007–2009 AQS data indicate that only one area, Kern County, has a design value above the level of the 1997 24-hour $PM_{2.5}$ NAAQS. As discussed above, EPA believes that given the relatively long distance between the Oregon border and Kern County, the intervening mountainous topography, and the generally westerly direction of transport winds in the Western U.S., emissions from Oregon sources do not interfere with maintenance of the 1997 24-hour $PM_{2.5}$ NAAQS in Kern County. These data and factors further support our proposed finding that Oregon sources do not significantly contribute to nonattainment of the 1997 24-hour $PM_{2.5}$ NAAQS in any other state.

In addition to the information in the 2010 interstate transport SIP and our review of the nearest nonattainment receptors identified from the modeling analyses conducted for the Transport Rule Proposal, EPA evaluated air quality data for the areas in states bordering Oregon that are designated nonattainment for the 1997 $PM_{2.5}$

[29] For $PM_{2.5}$, the Transport Rule Proposal identified nonattainment receptors for the 1997 annual $PM_{2.5}$ NAAQS and the 2006 24-hour $PM_{2.5}$ NAAQS. *See* 75 FR 45210 at 45212. Because our proposal on Oregon's 2010 Interstate transport SIP addresses requirements of CAA section 110(a)(2)(D)(i) only for purposes of the 1997 ozone and $PM_{2.5}$ NAAQS, for $PM_{2.5}$ purposes we consider only the nonattainment receptors for the 1997 annual $PM_{2.5}$ NAAQS identified in the Transport Rule Proposal.

[30] Specifically, the nonattainment receptors for the 1997 annual $PM_{2.5}$ standard are located in Alabama, Georgia, Illinois, Indiana, Kentucky, Michigan, Ohio, Pennsylvania, and West Virginia. *See* Transport Rule Proposal, 75 FR 45210 at 45247–45248 (August 2, 2010).

[31] *See* Timin Memo at Appendix B ("Base year 2003–2007 and Future Year 2012 8-Hour Average Ozone Design Values—Western States").

[32] 75 FR 45210 at 45249–45251 (August 2, 2010).

[33] These values were recorded at monitors in Liberty-Clairton, Pennsylvania and Provo, Utah. *See http://epa.gov/airtrends/pdfs/PM2.5%202007–2009%20design%20value%20update.pdf.* Data from EPA's Air Quality System can be viewed at *http://www.epa.gov/ttn/airs/airsaqs/.*

NAAQS. Although significant contribution must be measured not just against nonattainment areas but also against areas with monitors showing violations of the NAAQS, nonattainment areas are a convenient point of analysis.

The closest 1997 $PM_{2.5}$ nonattainment area in any state bordering Oregon is the San Joaquin Valley in California.[34] This nonattainment area is located in central California and is over 250 miles from the closest point on Oregon's border and on the other side of intervening mountain ranges that act as a natural barrier to air pollution transport. In addition, prevailing winds in the western U.S. generally move from south-westerly, westerly, or north-westerly directions, as indicated by the typical movement of weather systems. Hence, Joaquin Valley, California, is not in the predominant direction of winds from Oregon. Given the relatively long distance between Oregon and the San Joaquin Valley, the intervening mountainous topography, and the general direction of transport winds in the Western U.S., EPA believes that Oregon sources do not significantly contribute to nonattainment of the 1997 $PM_{2.5}$ NAAQS in the San Joaquin Valley nonattainment area or to any more distant California 1997 $PM_{2.5}$ nonattainment areas. There are no areas in Idaho and Washington currently designated nonattainment for the 1997 $PM_{2.5}$ NAAQS. This is further support that Oregon sources do not contribute significantly to nonattainment of the 1997 $PM_{2.5}$ NAAQS in any other state.

Although not located in a state bordering Oregon, the closest designated nonattainment area to Oregon for the 1997 $PM_{2.5}$ NAAQS is Libby, in Lincoln County, Montana.[35] In 2005, EPA designated this area nonattainment for the 1997 annual $PM_{2.5}$ NAAQS. 70 FR 944 (January 5, 2005) and 40 CFR 81.327. A number of factors provide evidence that Oregon emissions do not significantly contribute to past violations of the 1997 annual $PM_{2.5}$ standards in Libby, Montana.

First, in the process of designating Libby nonattainment for both the 1997 $PM_{2.5}$ NAAQS and the 2006 24-hour $PM_{2.5}$ NAAQS, EPA noted the predominantly local origins of $PM_{2.5}$ nonattainment in Libby.[36] [37] Residential wood-burning stoves during the wintertime, when frequent and persistent temperature inversions occurred, were specifically identified as a key source of PM emissions. The fact that nonattainment in a given area is primarily the result of local emissions sources does not, however, exclude the possibility of significant contribution to nonattainment from interstate transport. EPA believes that other evidence supports the conclusion that emissions from Oregon sources are not significantly contributing to violations in Libby, Montana.

Second, monitoring data from 1999 through 2009 from areas outside of Libby in Montana support a determination that Oregon does not significantly contribute to nonattainment in Libby. At all other sites in Montana, annual $PM_{2.5}$ design value levels have remained below the 15 $\mu g/m^3$ nonattainment threshold. Annual $PM_{2.5}$ design values for this period for most of these monitors remained at levels equal to, or less than, two-thirds of the 1997 annual $PM_{2.5}$ NAAQS. Even the three highest design values at these monitors were 20 percent below the level of the annual standard.[38] The lower $PM_{2.5}$ levels elsewhere in Montana are evidence that local sources, and not interstate transport, are key contributors to past nonattainment in Libby.

Third, for 2007–2009, AQS data show that the annual $PM_{2.5}$ design values for the Libby nonattainment area themselves fell below the levels of the NAAQS. This reduction has been attributed to an effective wood stove replacement program that decreased $PM_{2.5}$ emissions by approximately 59 percent.[39] In other words, even if emissions from Oregon sources were reaching Libby, they would not significantly contribute to violations of the 1997 annual $PM_{2.5}$ NAAQS because monitoring data demonstrate that Libby is not violating the 1997 annual $PM_{2.5}$ NAAQS.

Finally, EPA's conclusion that emissions from Oregon do not significantly contribute to nonattainment in Libby, Montana, is further supported by the analysis of monitors in the western United States.[40] This analysis concludes that in 2012 the average annual $PM_{2.5}$ design values in Lincoln County, Montana will be below the threshold for consideration as a nonattainment receptor. These factors together support a conclusion that Oregon sources do not contribute significantly to nonattainment of the 1997 annual $PM_{2.5}$ NAAQS in the Libby 1997 $PM_{2.5}$ nonattainment area.

As mentioned above, EPA considers not only significant contribution to designated nonattainment areas, but also significant contribution to areas with monitors showing violations of the NAAQS. A review of the most recent three years (2007–2009) of monitoring data in AQS for the bordering states of Washington, Idaho, Nevada, and California shows that the only monitors with design values above the 1997 annual $PM_{2.5}$ NAAQS are located in central and southern California. The county closest to the Oregon border that has a design value above the 1997 annual $PM_{2.5}$ NAAQS is Kern County, California. Kern County is more than 400 miles from the closest point on Oregon's border and is on the other side of intervening mountain ranges that act as a natural barrier to air pollution transport. Although not determinative by themselves, distance and topography are not favorable to $PM_{2.5}$ transport from Oregon to central California. In addition, prevailing winds in the west generally move from south-westerly, westerly, or north-westerly directions, as indicated by the typical movement of weather systems. Hence Kern County, California is not in the predominant direction of winds from Oregon. Given the relatively long distance between the Oregon border and Kern County, the intervening mountainous topography, and the generally westerly direction of transport winds in the Western U.S., it is reasonable to conclude that Oregon sources do not significantly contribute to nonattainment of the 1997 $PM_{2.5}$ NAAQS in Kern County or to any more distant monitors in California.

As noted above no monitors in Washington, Idaho and Nevada or Northern California had design values above the 1997 annual $PM_{2.5}$ NAAQS for the 2007–2009 period. The fact that monitors in these areas are not registering violations of the 1997 $PM_{2.5}$ NAAQS does not in itself conclusively establish that emissions from Oregon could not contribute in the aggregate to

[34] In 2005, EPA designated this area nonattainment for violations of the 1997 and annual $PM_{2.5}$ NAAQS. 70 FR 944 (January 5, 2005), and 40 CFR 81.305.

[35] Libby is in a narrow valley surrounded by mountains 4,000 feet higher than the town. The Rocky Mountain Range to the west of Libby (and east of the Idaho border) reaches summit elevations of 12,000 feet with most summit elevations between 6000 and 7000 feet that act as a barrier to air movement between Idaho and Montana.

[36] "Technical Support for State and Tribal Air Quality Fine Particle ($PM_{2.5}$) Designations," (for Montana) Chapter 6, pp. 347–352, December 2004.

[37] "Technical Support for State and Tribal Air Quality Fine Particle ($PM_{2.5}$) Designations," (for Montana) Chapter 4.8.1, pp. 1–15, December 2008.

[38] In 2001, 2002 and 2006, design values for two monitors in Missoula County were 11.1, 11.4 and 11.8 $\mu g/m^3$. Computed from AQS monitoring data. 75 FR 16028 (March 31, 2010).

[39] State of Montana, Department of Environmental Quality, "State Implementation Plan-Libby Annual $PM_{2.5}$ Control Plan," submitted to EPA April 1, 2008.

[40] *See* Timin Memo at Appendix A ("Base year 2003–20007 and Future Year 2012 Annual Average $PM_{2.5}$ Design Values—Western States").

violations in these areas. But this fact combined with our above evaluation of the nearest nonattainment receptors, nearest nonattainment areas, and nearest monitors with design values above the 1997 annual $PM_{2.5}$ NAAQS, supports a conclusion that Oregon sources do not significantly contribute to nonattainment of the 1997 $PM_{2.5}$ NAAQS in other states.

Finally, none of the $PM_{2.5}$ monitors in Oregon have themselves indicated a violation of the 1997 annual $PM_{2.5}$ NAAQS. The absence of violations in Oregon itself does not rule out the possibility of transport, but taken in conjunction with other relevant information, including the distance from Oregon to areas with design values above the 1997 annual $PM_{2.5}$ NAAQS and Pacific Northwest meteorology and topography, this fact helps to support the conclusion that there is no transport from Oregon resulting in significant contribution to nonattainment in another state. Taking into account the total weight of all of the factors discussed above, EPA concludes that Oregon does not significantly contribute to the 1997 annual $PM_{2.5}$ NAAQS nonattainment in any other state.

3. Conclusion Regarding Significant Contribution to Nonattainment

Based on the weight of evidence discussed above, including the location of the nearest projected nonattainment receptors, distance to the nearest designated $PM_{2.5}$ nonattainment area, meteorology, topography, and recent air quality monitoring data, we propose to determine that Oregon's 2010 interstate transport SIP is adequate to ensure that emissions from Oregon do not significantly contribute to nonattainment in any other state for the 1997 8-hour ozone or 1997 $PM_{2.5}$ NAAQS, consistent with the requirements of CAA section 110(a)(2)(D)(i)(I). Thus, we propose to determine that Oregon's SIP includes the measures necessary to prevent such prohibited interstate transport impacts for these NAAQS.

B. EPA's Evaluation of Interference With Maintenance

This proposed approval evaluates the interfere with maintenance element of section of section 110(a)(2)(D)(i)(I) for the 1997 8-hour ozone and 1997 $PM_{2.5}$ NAAQS in several ways. It takes into account Oregon's 2010 interstate transport SIP, in which the State explains that based on meteorological and other characteristics in Oregon and in the surrounding areas, $PM_{2.5}$ and ozone precursor emissions do not interfere with maintenance of the 1997 8-hour ozone or 1997 $PM_{2.5}$ NAAQS in other states.[41] In addition, EPA has supplemented the State's analysis with its own evaluation of the evidence, including a review of the nearest monitors in other states that are appropriate maintenance receptors, consistent with EPA's approach in the Transport Rule Proposal, in order to assess whether emissions sources in Oregon interfere with maintenance of the 1997 8-hour ozone and $PM_{2.5}$ NAAQS in other states.

1. Oregon's 2010 Interstate Transport SIP

To show that Oregon emissions, as controlled under its SIP, do not interfere with maintenance of the 1997 8-hour ozone NAAQS and 1997 $PM_{2.5}$ NAAQS in another state, Oregon's 2010 interstate transport SIP analyzed several types of factors to support its assertion. First, the State pointed to topography and meteorology for its evaluation, maintaining that high $PM_{2.5}$ concentrations in adjacent states typically occur under winter conditions when air speeds are low and/or localized air inversions occur. Describing wind direction as being typically variable with the majority of wind speeds less than 8 miles per hour, and a significant portion of low winds less than 5 miles per hour, the state noted that these low wind speeds and air stagnation conditions do not lend them to long distance air pollution transport. The State indicated that there are occasional high 8-hour ozone levels that occur in the summer months, but maintained that prevailing winds[42] in Oregon are predominantly from the north to northwest.[43] The state indicated that prevailing summer winds could theoretically result in some interstate transport of ozone forming emission from Oregon to western Idaho, Nevada and northern California. It also noted, however, that significant distances and topography (such as major mountain ranges that separate Oregon from California, Idaho, and Nevada) would likely minimize the significance of these impacts on other states. It pointed to, for example, the approximately 400 to 700 miles distance between the largest major urban center in Oregon (the greater Portland area) and urban areas in western Idaho, Nevada, and northern California and at least one major mountain range between those areas.

Second, Oregon used AQS monitoring data for 2006–2008 from other states in its analysis. Oregon pointed out that both $PM_{2.5}$ and ozone design values in all counties adjacent to Oregon are below the $PM_{2.5}$ and 8-hour ozone NAAQS. Oregon also consulted with each of the state air agencies for Washington, Idaho, Nevada, and California to get a sense of what the local air agencies believe are the likely causes of any air quality concerns for maintaining compliance with the $PM_{2.5}$ and ozone NAAQS. Based on these consultations and the other information above, Oregon concluded that emissions from air pollution sources in Oregon do not interfere with the maintenance of the 8-hour ozone or $PM_{2.5}$ NAAQS in other states.

Oregon also relied on information about air stagnation conditions in other states to support its assertions that Oregon sources do not interfere with maintenance of the 1997 8-hour ozone NAAQS and 1997 $PM_{2.5}$ NAAQS in other states. Oregon noted that stagnant air conditions are associated with weak transport and that high $PM_{2.5}$ concentrations in adjacent states typically occur under winter conditions when air speeds are low and/or localized air inversions occur. Oregon also pointed to examples of where it has collaborated with other states to demonstrate its ability and willingness to address problems involving interstate transport. Examples included the Portland-Vancouver 1-hour ozone attainment and maintenance plans, and Oregon's regional haze plan. Oregon described how in the mid-1990s and again in 2007, ODEQ collaborated with the Southwest Clean Air Agency (*i.e.,* the State of Washington air agency with jurisdiction over Vancouver) to develop bi-state ozone attainment and maintenance plans with emission reduction strategies needed to attain and maintain compliance with federal ozone standards. In 2008–09, ODEQ worked with the states of Washington, Idaho and California, as well as Federal Land Managers in developing Oregon's Regional Haze plan. Oregon described how under that plan ODEQ adopted several emission reduction strategies, including emission control requirements to reduce the interstate transport of haze forming emissions.

Finally, Oregon pointed to its section 110 infrastructure SIP to show that ODEQ has the ability to participate as needed in future studies on regional air pollution issues, or collaborate with

[41] Oregon's submission makes this conclusion with respect to not only the 1997 $PM_{2.5}$ NAAQS and 1997 8-hour ozone NAAQS, but also the 2006 $PM_{2.5}$ NAAQS and the 2008 8-hour ozone NAAQS.

[42] This north/northwest prevailing wind direction was derived from surface level winds and airport data and is not necessarily indicative of the prevailing wind direction of typical weather systems in the west.

[43] There are currently no 1997 8-hour ozone nonattainment areas in Oregon or Washington.

other states if air quality concerns are identified that require a case-specific evaluation of interstate transport. Oregon added that its infrastructure SIP also ensures the legal mechanism for ODEQ to take action as needed to reduce emissions to help maintain compliance with federal NAAQS.

EPA does not necessarily agree that Oregon's methodology is adequate for purposes of a section 110(a)(2)(D)(i) analysis. Therefore, EPA is supplementing the State's submission with additional, and more recent, information in order to assess this issue more fully. As noted above, EPA is evaluating the 2010 interstate transport SIP taking into account methodologies and analyses for the identification of the receptor monitors that was developed in the Transport Rule Proposal, as well as EPA's projections of future air quality at monitors in western states in the Timin Memo and preliminary air quality data from monitors in the states bordering Oregon. Although each of the factors considered in the following analysis are not in and of themselves determinative, consideration of these factors together provides a reliable qualitative conclusion that emissions from Oregon do not interfere with maintenance of the 1997 8-hour ozone and $PM_{2.5}$ NAAQS at monitors in other states.

2. Interfere With Maintenance Evaluation for the 8-Hour Ozone NAAQS

As discussed above, in the Transport Rule Proposal, EPA projected future concentrations of ozone at monitors to identify areas that are expected to be violating the NAAQS or to have difficulty maintaining compliance with the NAAQS in 2012. For purposes of the interference with maintenance evaluation, EPA projected future concentrations of ozone at monitors to identify areas that are expected to have a maximum design value (based on a single 3-year period) that exceeds the 1997 8-hour ozone NAAQS, and EPA anticipates that by 2012 these maintenance receptors will have difficulty in maintaining attainment of the NAAQS if there are adverse variations in meteorology or emissions.

To identify the states with emissions that may cause interference with maintenance of the NAAQS at maintenance receptors, the Transport Rule Proposal modeled the states' contributions to ambient ozone levels at these maintenance receptors.[44] Because the Transport Rule Proposal did not identify the contribution of emissions from Oregon (and other western states not fully inside the Transport Rule Proposal's modeling domain) to 8-hour ozone maintenance receptors in other states, our assessment relies on a weight of evidence approach that considers relevant information from the Transport Rule Proposal pertaining to states within its modeling domain, and additional information such as geographical and meteorological factors, EPA's projections of future air quality at monitors in western states in the Timin Memo, and AQS monitoring data. Although each of the factors considered in the following analysis is not in and of itself determinative, consideration of these factors together supports a reliable qualitative conclusion that emissions from Oregon do not interfere with maintenance of the 1997 8-hour ozone NAAQS at monitors in other states.

Our analysis begins by assessing Oregon's contribution to the closest maintenance receptors for the 1997 8-hour ozone standard. The Transport Rule Proposal identifies 16 maintenance receptors for the 1997 8-hour ozone standard within its modeling domain (consisting of 37 states east of the Rocky Mountains, and the District of Columbia). Of these, the receptors closest to Oregon are eight receptors in the Dallas-Fort Worth and Houston-Galveston-Brazoria 8-hour ozone nonattainment areas in eastern Texas. The remaining eight maintenance receptors are located in Connecticut, Georgia, New York and Pennsylvania.[45]

As discussed above in section V.A.1, the Dallas-Fort Worth and Houston areas are over 1200 miles from the closest point on Oregon's border. The maintenance receptor monitors located in Connecticut, Georgia, New York and Pennsylvania are significantly further away. Although distance alone is not determinative in the analysis of potential ozone transport, with increasing distance there are greater opportunities for ozone and NO_X dispersion and/or removal from the atmosphere. Moreover, the intervening Rocky Mountains act as a natural barrier to air pollution transport. These factors together support a conclusion that emissions from Oregon sources do not interfere with maintenance of the 1997 8-hour ozone NAAQS in the nearest areas with monitors projected to violate the 1997 8-hour ozone NAAQS as part of the Transport Rule Proposal.

EPA's analysis in the Timin Memo identified four maintenance receptors for the 1997 8-hour ozone NAAQS in southern and central California.[46] The closest 8-hour ozone maintenance receptor to Oregon was in Placer County, California. Placer County is approximately 185 miles south of the closest point on Oregon's border and is not in the predominant direction of transport winds. As noted earlier, prevailing winds generally move from south-westerly, westerly, or northwesterly directions, as indicated by the typical movement of weather systems. Given the relatively long distance between Oregon and central California, the intervening mountainous topography, and the general direction of west-to-east transport winds across Oregon, it is reasonable to conclude that Oregon sources do not interfere with maintenance of the 1997 8-hour ozone NAAQS in Placer County, California. It is also reasonable to conclude that emissions from sources in Oregon would not have such impacts at other identified maintenance receptor sites that are in central or southern California that are in the same direction and further away from the Oregon border. All of these factors taken together supports a conclusion that emissions from Oregon sources do not interfere with maintenance of the 1997 8-hour ozone NAAQS in any other state.

Finally, none of the ozone monitors in Oregon have themselves indicated a violation of the 1997 8-hour ozone NAAQS. The absence of violations in Oregon itself does not rule out the possibility of transport, but taken in conjunction with other relevant information, including the distance from Oregon to areas with design values above the 1997 8-hour ozone NAAQS and Pacific Northwest meteorology and topography, this fact helps to support a conclusion that there is no transport from Oregon resulting in interference with maintenance in another state. Taking into account the total weight of all of the factors discussed above, EPA concludes that Oregon does not interfere with maintenance of the 1997 8-hour ozone NAAQS in any other state.

3. Interference With Maintenance Evaluation for the 1997 $PM_{2.5}$ NAAQS

The Transport Rule Proposal identifies within its modeling domain 16 predicted future maintenance receptors for the 1997 annual $PM_{2.5}$ NAAQS. Of these, the closest to Oregon are receptors located in Harris County, Texas. Harris County, Texas, is over 1,400 miles from the closest point on Oregon's border and on the other side of

[44] *See* Transport Rule Proposal, 75 FR 45210 at 45253–45273.

[45] *See* Transport Rule Proposal, Table IV.C–12, 75 FR 45210 at 45252–45253.

[46] *See* Timin Memo at Appendix B ("Base year 2003–2007 and Future Year 2012 8-Hour Average Ozone Design Values—Western States").

the Rocky Mountains. Given the long distance and intervening mountainous topography between Oregon and this area, it is reasonable to conclude that there is a very low probability that Oregon sources interfere with maintenance in that area or at the other identified maintenance sites east of Harris County, Texas.[47] EPA, therefore, concludes that Oregon sources do not interfere with maintenance of the 1997 annual $PM_{2.5}$ NAAQS in other states within the geographic region covered by the Transport Rule Proposal.

EPA's analysis in the Timin Memo identified Los Angeles County, California, as the closest projected maintenance receptor to Oregon's border. Los Angeles County is located almost 500 miles south of the closest point on Oregon's border and is on the other side of intervening mountain ranges that act as a natural barrier to air pollution transport. Although not determinative by themselves, distance and topography are not favorable to $PM_{2.5}$ transport from Oregon to central California. In addition, prevailing winds in the west generally move from south-westerly, westerly, or north-westerly directions, as indicated by the typical movement of weather systems. Given the relatively long distance between Oregon and Los Angeles County, the intervening mountainous topography, and the general westerly direction of transport winds in the Western U.S., it is reasonable to conclude that Oregon sources do not interfere with maintenance of the 1997 annual $PM_{2.5}$ NAAQS in Los Angeles County or to any more distant maintenance receptors in central or southern California. EPA's analysis for the western states therefore supports our proposal to conclude that Oregon sources do not interfere with maintenance of the 1997 annual $PM_{2.5}$ NAAQS in any other states. Based on all of these factors taken together, EPA further believes it is reasonable to conclude that Oregon emissions under the SIP do not interfere with maintenance of the 1997 $PM_{2.5}$ NAAQS in any other state.

The analysis for the Transport Rule Proposal did not identify any maintenance receptors for the 1997 24-hour $PM_{2.5}$ NAAQS in the portions of the U.S. covered by the Transport Rule Proposal modeling domain.[48] Recent monitoring data in EPA's AQS Database (2007–2009 design values that are under final EPA review) indicate that the highest 24-hour $PM_{2.5}$ design value in the 47 states of the continental U.S. (excluding California) is 50 $\mu g/m^3$, which is well below the level of the 1997 24-hour $PM_{2.5}$ NAAQS of 65 $\mu g/m^3$.[49] For California, AQS data indicate that only Kern County has a 24-hour design value above the level of the 1997 24-hour $PM_{2.5}$ NAAQS. As discussed above, EPA believes that, based on the relatively long distance between the Oregon border and Kern County, the intervening mountainous topography, and the generally westerly direction of transport winds in the Western U.S., emissions from Oregon sources do not interfere with maintenance of the 1997 24-hour $PM_{2.5}$ NAAQS in Kern County.

4. Conclusion Regarding Interference With Maintenance

Based on the weight of evidence, including the location of the nearest projected maintenance sites, taking into account distance, meteorology, topography, and recent air quality monitoring data, as discussed above, we propose to determine that Oregon's 2010 interstate transport SIP is adequate and that emissions from Oregon do not interfere with maintenance in any other state for the 1997 8-hour ozone or 1997 $PM_{2.5}$ NAAQS, consistent with the requirements of element (2) of CAA section 110(a)(2)(D)(i)(I). Thus, we propose to determine that Oregon's SIP contains adequate provisions necessary to prevent such prohibited interstate transport impacts for these NAAQS and does not require any additional measures for this purpose at this time.

VI. Proposed Action

In light of the data and the weight of evidence analysis presented above, EPA is proposing to approve revisions to the Oregon SIP, submitted on June 23, 2010, and December 23, 2010, and concludes that for the 1997 8-hour ozone and 1997 $PM_{2.5}$ NAAQS, air pollutant emissions from sources within Oregon do not either (1) significantly contribute to nonattainment of the NAAQS in any other state; or (2) interfere with maintenance of the NAAQS by any other state.

As noted previously, EPA will address element (3) interference with any other state's required measures to prevent significant deterioration of its air quality and element (4), interference with any other state's required measures to protect visibility, in a separate action. EPA will also take action on the portion of Oregon's SIP that addresses the 2006 $PM_{2.5}$ and 2008 8-hour ozone NAAQS in a separate action.

VII. 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 proposes to approve state law as meeting Federal requirements and does not impose additional requirements beyond those imposed by state law. For that reason, this action:

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

In addition, this proposed rule does not have tribal implications as specified by Executive Order 13175 (65 FR 67249, November 9, 2000), because the SIP is not approved to apply in Indian country

[47] Specifically, the remaining 15 maintenance sites for the 1997 annual $PM_{2.5}$ NAAQS are located in Kentucky, New York, Ohio, Pennsylvania, and West Virginia.

[48] 75 FR 45210 at 45249–45251 (August 2, 2010). *See also* fn. 39 and fn. 47.

[49] Data from EPA's Air Quality System can be viewed at *http://www.epa.gov/ttn/airs/airsaqs/.*

located in the state, and EPA notes that it will not impose substantial direct costs on tribal governments or preempt tribal law.

List of Subjects in 40 CFR Part 52

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

Dated: March 30, 2011.

Dennis J. McLerran,

Regional Administrator, Region 10.

[FR Doc. 2011–8330 Filed 4–6–11; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

[Docket No. FWS–R2–ES–2010–0041;MO 92210–0–0008]

RIN 1018–AV97

Endangered and Threatened Wildlife and Plants; Endangered Status for Dunes Sagebrush Lizard

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Proposed rule; reopening of comment period and announcement of public hearings.

SUMMARY: We, the U.S. Fish and Wildlife Service, announce the reopening of the public comment period on the December 14, 2010, proposed rule to list the dunes sagebrush lizard *(Sceloporus arenicolus)* under the Endangered Species Act of 1973, as amended (Act). We are reopening the comment period to allow all interested parties another opportunity to comment on the proposed rule. Comments previously submitted need not be resubmitted and will be fully considered in preparation of the final rule. We will also hold two public informational sessions and hearings (*see* **DATES** and **ADDRESSES** sections).

DATES: We will consider comments received on or before May 9, 2011. Comments must be received by 11:59 p.m. Eastern Time on the closing date. Any comments that we receive after the closing date may not be fully considered in the final decision on this action.

We will hold a public informational session from 3:30 p.m. to 5 p.m., followed by a public hearing from 6:30 p.m. to 8 p.m., on each of the following dates:

1. April 27, 2011: Midland, Texas.
2. April 28, 2011: Roswell, New Mexico.

ADDRESSES: You may submit comments by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments to Docket No. FWS–R2–ES–2010–0041.
- *U.S. mail or hand-delivery:* Public Comments Processing, Attn: FWS–R2–ES–2010–0041; Division of Policy and Directives Management; U.S. Fish and Wildlife Service; 4401 N. Fairfax Drive, Suite 222; Arlington, VA 22203.

We will post all comments on *http://www.regulations.gov.* This generally means that we will post any personal information you provide us (*see* the Public Comments section below for more information).

Information Sessions and Hearings

The public informational sessions and hearings will be held at the following locations:

1. Midland, Texas: Midland Center & Centennial Plaza, 105 N. Main Street, Midland, Texas 79701.
2. Roswell, New Mexico: ENMU—Roswell, Performing Arts Center, 64 University Blvd., Roswell, New Mexico 88202.

People needing reasonable accommodations in order to attend and participate in the public hearings should contact Wally "J" Murphy, New Mexico Ecological Services Field Office, at 505–761–4718 as soon as possible (*see* **FOR FURTHER INFORMATION CONTACT**). In order to allow sufficient time to process requests, please call no later than one week before the hearing date.

FOR FURTHER INFORMATION CONTACT: Wally "J" Murphy, Field Supervisor, New Mexico Ecological Services Field Office, 2105 Osuna NE., Albuquerque, NM 87113; by telephone 505–761–4781 or by facsimile 505–346–2542. Persons who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 800–877–8339.

SUPPLEMENTARY INFORMATION:

Public Comments

We will accept written comments and information during this reopened comment period for the proposed rule to list the dunes sagebrush lizard (*Sceloporus arenicolus*) that was published in the **Federal Register** on December 14, 2010 (75 FR 77801). We intend that any final action resulting from this proposed rule will be based on the best scientific and commercial data available and be as accurate and as effective as possible. Therefore, we request comments or information from the public, other concerned government agencies, the scientific community, industry, or other interested parties concerning this proposed rule. Verbal testimony or written comments may also be presented during the public hearing. We will consider information and recommendations from all interested parties. We are particularly interested in comments concerning:

(1) Information on the dunes sagebrush lizard relevant to the factors that are the basis for making a listing determination for a species under section 4(a) of the Endangered Species Act of 1973, as amended (Act) (16 U.S.C. 1531 *et seq.*). These factors are:

(a) The present or threatened destruction, modification, or curtailment of its habitat or range;

(b) Overutilization for commercial, recreational, scientific, or educational purposes;

(c) Disease or predation;

(d) The inadequacy of existing regulatory mechanisms; or

(e) Other natural or manmade factors affecting its continued existence.

(2) Additional information concerning the range, distribution, and population size of this species, including the locations of any additional populations of this species.

(3) Any information on the biological or ecological requirements of the species.

If you submitted comments or information on the proposed rule (75 FR 77801, December 14, 2010) during the initial comment period from December 14, 2010, to February 14, 2011, please do not resubmit them. We will incorporate them into the public record as part of this comment period, and we will fully consider them in the preparation of our final determination. Our final determination will take into consideration all written comments and any additional information we receive during both comment periods.

You may submit your comments and materials concerning the proposed rule by one of the methods listed in the **ADDRESSES** section.

We will post your entire comment—including your personal identifying information—on *http://www.regulations.gov.* If you provide personal identifying information, such as your street address, phone number, or e-mail address, you may request at the top of your document that we withhold this information from public review. However, we cannot guarantee that we will be able to do so.

Comments and materials we receive, as well as supporting documentation we used in preparing the proposed rule,

will be available for public inspection on *http://www.regulations.gov* at Docket No. FWS–R2–ES–2010–0041, or by appointment, during normal business hours, at the U.S. Fish and Wildlife Service, New Mexico Ecological Services Field Office (*see* **FOR FURTHER INFORMATION CONTACT**). You may obtain copies of the proposed rule on the Internet at *http://www.regulations.gov* at Docket Number FWS–R2–ES–2010–0041, or by mail from the New Mexico Ecological Services Field Office (*see* **FOR FURTHER INFORMATION CONTACT** section).

Background

It is our intent to discuss only those topics directly relevant to the proposed rule to list the dunes sagebrush lizard as endangered in this document.

On December 14, 2010, we published a proposed rule (75 FR 77801) to list the dunes sagebrush lizard, a lizard known from southeastern New Mexico and adjacent west Texas, as endangered under the Act. For a description of previous Federal actions concerning the dunes sagebrush lizard (formerly known as the sand dunes lizard), please refer to the proposed rule. In response to comments received during the initial public comment period, we have decided to allow the public more time to submit comments and to hold informational sessions as described previously.

If we finalize the rule as proposed, it would extend the Act's protections to this species. We have determined that critical habitat for the dunes sagebrush lizard is prudent but not determinable at this time. The final decision on whether to list the dunes sagebrush lizard as endangered will be based on the best scientific data available, including information obtained during the comment period.

Authors

The primary authors of this notice are the staff members of the New Mexico Ecological Services Field Office, Region 2, U.S. Fish and Wildlife Service.

Authority

The authority for this action is the Endangered Species Act of 1973 (16 U.S.C. 1531 *et seq.*).

Dated: March 11, 2011.

Will Shafroth,

Assistant Secretary for Fish and Wildlife and Parks.

[FR Doc. 2011–7339 Filed 4–6–11; 8:45 am]

BILLING CODE 4310–55–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 648

[Docket No. 110311194–1193–02]

RIN 0648–BA88

Fisheries of the Northeastern United States; Northeast Multispecies Fishery; Notice of a Control Date for the Purpose of Limiting Excessive Accumulation of Control in the Northeast (NE) Multispecies Fishery; NE Multispecies Fishery Management Plan (FMP)

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

ACTION: Advance notice of proposed rulemaking (ANPR); request for comments.

SUMMARY: At the request of the New England Fishery Management Council (Council), this notification announces that the Council and NMFS is considering and seeking public comment on, potential changes to the Northeast Multispecies Fishery Management Plan that would be implemented through proposed rulemaking, under the authority of the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act), to limit the accumulation of excessive control or ownership of fishing privileges in the NE multispecies groundfish fishery. The date of publication of this notification, April 7, 2011, shall be known as the "control date," and may be used as a reference date for future management measures related to such rulemaking. In particular this notification is intended to promote awareness of this possible rulemaking; provide notice to the public that any current or future accumulation of fishing privilege interests in the NE multispecies fishery may be affected, restricted, or even nullified; and to discourage speculative behavior in the market for fishing privileges while the Council considers whether and how such limitations on accumulation of fishing privileges should be developed. This notification also gives the public notice that interested participants should locate and preserve records that substantiate and verify their ownership or control of groundfish permits and other fishing privileges in the NE multispecies fishery in Federal waters.

DATES: April 7, 2011, shall be known as the "control date" and may be used as a reference date for future management measures related to the maintenance of a fishery with characteristics consistent with the Council's objectives and applicable Federal laws. Written comments must be received on or before 5 p.m., local time, May 9, 2011.

ADDRESSES: You may submit comments, identified by RIN 0648–BA88, by any one of the following methods:

- Written comments (paper, disk, or CD–ROM) should be sent to Paul J. Howard, Executive Director, New England Fishery Management Council, 50 Water Street, Mill 2, Newburyport, MA 01950. Mark the outside of the envelope, "Comments on Multispecies Accumulation Limits Control Date."
- Comments also may be sent via facsimile (fax) to (978) 465–3116.
- Submit all electronic public comments via the Federal e-Rulemaking Portal: *http://www.regulations.gov.*

Instructions: Comments will be posted for public viewing as they are received. All comments received are a part of the public record and will generally be posted to *http://www.regulations.gov* without change. All Personal Identifying Information (for example, name, address, etc.) voluntarily submitted by the commenter may be publicly accessible. Do not submit Confidential Business Information or otherwise sensitive or protected information.

NMFS will accept anonymous comments (enter N/A in the required fields, if you wish to remain anonymous). You may submit attachments to electronic comments in Microsoft Word, Excel, WordPerfect, or Adobe PDF file formats only.

FOR FURTHER INFORMATION CONTACT: Travis Ford, Fishery Management Specialist, 978–281–9233; fax 978–281–9135; *e-mail: travis.ford@noaa.gov.*

SUPPLEMENTARY INFORMATION: The NE Multispecies FMP manages 20 individual stocks comprised of the following species: Cod, haddock, white hake, pollock, Acadian redfish, yellowtail flounder, winter flounder, witch flounder, American plaice, windowpane flounder, Atlantic halibut, ocean pout, and Atlantic wolffish. The Council has managed most of these species as a unit under the FMP since 1985. Many of these stocks remain overfished, and strict regulations have been adopted to control catch and promote stock rebuilding. Current management measures include limited and open-access permit categories, limits on fishing time through days-at-sea (DAS) allocations, gear requirements, closed areas, retention limits, and sector allocation. These

measures have been adopted through a series of amendments and adjustments to the original FMP. The most recent amendment, Amendment 16, implemented on May 1, 2010 (75 FR 18262), expanded the use of sectors to manage the fishery. Sectors are voluntary, self-selected groups of fishermen that are allocated a portion of the available catch. Amendment 16 also implemented Annual Catch Limits (ACLs). Exceeding these limits triggers responsive management actions referred to as Accountability Measures (AMs).

In the most recent specification process (Framework Adjustment 44 (75 FR 18356)), ACLs for many NE multispecies stocks were set at very low levels. For certain stocks, catch limits are expected to remain low for the near future. Some members of the fishing industry and the Council have expressed concern that the low catch limits, in conjunction with expanded sector management, will lead to excessive consolidation of fishing privileges and lack of diversity in the groundfish fleet. For example, for several stocks, the potential sector contribution (PSC) associated with a small number of vessel owners enrolled in a sector represents a large percentage of the total allocation to the fishery. In addition, NMFS, in its letter to the Council partially approving Amendment 16, requested the Council to consider developing measures that would mitigate potential negative impacts stemming from the consolidation of permits, both within sectors and among individual permit holders, as they relate to some of the social and economic objectives established in the NE multispecies FMP.

In light of these concerns, the Council, at its January, 2011 meeting, requested that "NMFS publish in the **Federal Register** as soon as possible a control date to establish accumulation limits in the groundfish fishery." The Council also indicated at the time that Council staff should coordinate with NMFS in drafting the "control date" so that it reflected Council concerns about accumulation limits. Based on this coordination, this notification announces that the Council is considering management measures that would address, but would not be limited to, concerns related to preventing excessive control or ownership of fishing privileges, maintaining the diversity of the fleet, addressing impacts of market forces on a highly regulated industry, and maintaining fishery infrastructure and fishing ports throughout New England. Fishing privileges include, but are not limited to, vessels, fishing permits, DAS, fishing quotas, PSCs, annual catch entitlements, sector allocations and any other type of catch share.

The date of publication of this notification, April 7, 2011, shall be known as the "control date," and may be used as a reference date for future management measures in determining how to treat fishing privileges acquired before this date and those acquired after this date, depending on the Council's determinations on limiting control and ownership of such privileges. The establishment of a control date, however, does not obligate the Council to use this control date or take any action, nor does it prevent the Council from picking another control date or imposing limits on permits acquired prior to the control date.

Accordingly, this notification is intended to promote awareness that the Council may be developing management measures to address these concerns, to provide notice to the public that any current or future accumulation of fishing privilege interests in the NE multispecies fishery may be affected, restricted, or even nullified, and discourage speculative behavior in the market for fishing privileges while the Council considers whether and how such limitations on accumulation of fishing privileges should be developed. Any measures the Council is considering may require changes to the NE multispecies FMP. Such measures may be adopted in a future amendment to the FMP, which would include opportunity for further public participation and comment.

This notification also gives the public notice that interested participants should locate and preserve records that substantiate and verify their ownership or control of groundfish permits and other fishing privileges in the NE multispecies fishery in Federal waters.

This notification and control date do not impose any legal obligations, requirements, or expectation. This ANPR has been determined to be not significant for purposes of Executive Order 12866.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: April 4, 2011.

John Oliver,

Deputy Assistant Administrator for Operations, National Marine Fisheries Service.

[FR Doc. 2011–8353 Filed 4–6–11; 8:45 am]

BILLING CODE 3510–22–P

Notices

Federal Register
Vol. 76, No. 67
Thursday, April 7, 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

Office of the Secretary

Privacy Act of 1974; Amendment of Privacy Act System of Records

AGENCY: Office of the Secretary, U.S. Department of Agriculture.

ACTION: Notice of revised system of records; request for comment.

SUMMARY: In accordance with the Privacy Act of 1974, as amended, the U.S. Department of Agriculture (USDA) is amending an existing Forest Service Privacy Act system of records, USDA/FS–3, Uniform Allowance System.

DATES: Comments must be received in writing, on or before May 9, 2011. The System of Records USDA/FS–3 Uniform Allowance is amended, without further notice, on June 6, 2011, unless modified to respond to comments received from the public and published in a subsequent notice.

ADDRESSES: Questions can be addressed to the Forest Service Privacy Act Officer, USDA Forest Service, 1400 Independence Avenue, SW., Mail Stop 1143, Washington, DC 20250–1143. Comments may also be sent via e-mail to *wo_foia@fs.fed.us,* or via facsimile to (202) 260–3245.

FOR FURTHER INFORMATION CONTACT: Karren Y. Alexander, Director, USDA Forest Service, Financial Management Systems, 1400 Independence Avenue, SW., Mailstop 1149, Washington, DC 20250–1149, *kalexander@fs.fed.us,* (703) 605–5199.

SUPPLEMENTARY INFORMATION: Established in 1905, the Forest Service is an agency of the U.S. Department of Agriculture. The mission of the Forest Service is to sustain the health, diversity, and productivity of the Nation's forests and grasslands that encompass 193 million acres of land, to meet the needs of present and future generations. The purpose of this system is to allow the Forest Service to maintain records that identify individuals who apply for and are approved to purchase and wear the Forest Service uniform.

Pursuant to the Privacy Act (5 U.S.C. 552a), the Forest Service has amended the system of records to include new system location, new system manager, new storage type, new routine uses; and new policies and practices for storing, retrieving, accessing, retaining, and disposing of records in the system. This system of records provides information for internal processing purposes to track uniform allowances and expenditures for authorized individuals.

A report of the amended system of records, required by 5 U.S.C. 552a(r) as implemented by Office of Management and Budget (OMB) Circular A–130, was sent to the Chairman, Committee on Homeland Security and Governmental Affairs, United States Senate; the Chairman, Committee on Oversight and Government Reform, U.S. House of Representatives; and the Administrator, Office of Information and Regulatory Affairs, OMB.

Thomas J. Vilsack,
Secretary.

SYSTEM NAME:

Uniform Allowance System (UNAW), USDA/FS–3.

SECURITY CLASSIFICATION:

None.

SYSTEM LOCATION:

The records in this system are collected in a web-based system located on servers maintained by a Federal contractor in St. Louis, Missouri, and in Omaha, Nebraska. The addresses for the Contractor may be obtained by writing to the Director of Financial Management Systems, USDA Forest Service, 1400 Independence Avenue, SW., Mailstop 1149, Washington, DC 20250–1149. Paper records for use with the uniform system are maintained at Forest Services offices nationwide. The addresses for the Regions, Stations, International Institute for Tropical Forestry, and Forests are listed in 36 CFR Part 200, Subpart A; and the addresses for Districts are in the telephone directory of the applicable locality under the heading, United States Government, Department of Agriculture, Forest Service.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Individuals who are authorized a monetary allowance to purchase and wear a Forest Service uniform while performing official duties.

CATEGORIES OF RECORDS IN THE SYSTEM:

The system of records consists of completed Forest Service form FS–6100–36 (Uniform Authorization) and information on uniform allowances and expenditures for authorized individuals. Information includes the individual's name, social security number, employee location, allowance category, job code, and current status (active or terminated). The purpose of collecting social security numbers is to administer the uniform allowance program and ensure proper approval, and payment of the individual's uniform allowance.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

5 U.S.C. 5901–5903.

PURPOSE(S):

Information in this system is used for internal processing purposes to track uniform allowances and expenditures for authorized individuals.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

(1) When a record on its face, or in conjunction with other records, indicates a violation or potential violation of law, whether civil, criminal, or regulatory in nature, and whether arising by general statute or particular program statute, or by regulation, rule, or order issued pursuant thereto, disclosure may be made to the appropriate agency, whether Federal, foreign, State, local, or Tribal, or other public authority responsible for enforcing, investigating, or prosecuting such violation or charged with enforcing or implementing the statute, or rule, regulation, or order issued pursuant thereto, if the information disclosed is relevant to any enforcement, regulatory, investigative, or prosecutive responsibility of the receiving entity.

(2) To the Department of Justice when: (a) The agency or any component thereof; or (b) any employee of the agency in his or her official capacity where the Department of Justice has agreed to represent the employee; or (c) the United States Government, is a party to litigation or has an interest in such

litigation, and by careful review, the agency determines that the records are both relevant and necessary to the litigation and the use of such records by the Department of Justice is therefore deemed by the agency to be for a purpose that is compatible with the purpose for which the agency collected the records.

(3) To a court or adjudicative body in a proceeding when: (a) The agency or any component thereof; or (b) any employee of the agency in his or her official capacity; or (c) any employee of the agency in his or her individual capacity where the agency has agreed to represent the employee; or (d) the United States Government, is a party to litigation or has an interest in such litigation, and by careful review, the agency determines that the records are both relevant and necessary to the litigation and the use of such records is therefore deemed by the agency to be for a purpose that is compatible with the purpose for which the agency collected the records.

(4) To a Member of Congress or to a Congressional staff member in response to an inquiry of the Congressional office made at the written request of the constituent about whom the record is maintained.

(5) Records from this system of records may be disclosed to the National Archives and Records Administration or to the General Services Administration for records management inspections conducted under 44 U.S.C. 2904 and 2906.

(6) To agency contractors, grantees, experts, consultants, or volunteers who have been engaged by the agency to assist in the performance of a service related to this system of records and who need to have access to the records in order to perform the activity. Recipients shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).

(7) To appropriate agencies, entities, and persons when: (a) The Forest Service suspects or has confirmed that the security or confidentiality of information in the system of records has been compromised; (b) the Department has determined that as a result of the suspected or confirmed compromise there is a risk of harm to economic or property interests, identity theft or fraud, or harm to the security or integrity of this system or other systems or programs (whether maintained by the Department or another agency or entity) that rely upon the compromised information; and (c) the disclosure made to such agencies, entities, and persons is reasonably necessary to assist in connection with the Department's efforts to respond to the suspected or confirmed compromise and prevent, minimize, or remedy such harm.

DISCLOSURE TO CONSUMER REPORTING AGENCIES:

None.

Policies and practices for storing, retrieving, accessing, retaining, and disposing of records in the system: Records are maintained in electronic format pursuant to Forest Service file code 6500. Only those specifically authorized individuals can access the information.

STORAGE:

All electronic information is maintained in a web-based database and stored on secured servers at St. Louis, Missouri, and on backup copies at Omaha, Nebraska. Hard copy records are maintained, retrievable by employee's name, in locked file cabinets in secured office buildings.

RETRIEVABILITY:

Records are indexed and retrieved electronically using multiple queries including name, social security number, allowance, home unit, or other criteria.

SAFEGUARDS:

All records containing personal information are maintained electronically in secured computer rooms. Access to the database and all electronic folders with personal information are password protected and stored on secure servers. Computer access to information provided by applicants is limited to the individual employee, contractor, and the system manager. The review of records once retrieved is limited to the employee, supervisor, contractor, and system manager.

RETENTION AND DISPOSAL:

Records are maintained in electronic format under Forest Service file code 6500 established for General Finance and Accounting information. Access to the information is restricted to the individual employee, the contractor, and the system manager.

SYSTEM MANAGER(S) AND ADDRESS:

Director, USDA, Forest Service, Financial Management Systems, 1400 Independence Avenue, SW., Mailstop 1149, Washington, DC 20250–1149.

NOTIFICATION PROCEDURE:

Individuals may request information regarding this system of records, or information as to whether the system contains records pertaining to them from the System Manager (address above). A request for information should contain name, address, and particulars involved (for example, the date of action giving rise to the inquiry or complaint).

RECORD ACCESS PROCEDURES:

Individuals who wish to gain access to or amend records pertaining to them should submit a written request to the System Manager (address above). The envelope should be marked "Privacy Act Request."

CONTESTING RECORD PROCEDURES:

Same as record access procedures.

RECORD SOURCE CATEGORIES:

Information in this system is collected voluntarily from individuals, who are authorized Forest Service uniform allowances, and from the individual's supervisor.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

U.S. Department of Agriculture

Privacy Act System of Records

Uniform Allowance System (UNAW) USDA/FS–3

Narrative Statement

The purpose of this system is to provide the U.S. Department of Agriculture's (USDA) Forest Service (FS) to maintain records that identify individuals who apply for and are approved to purchase and wear the Forest Service uniform. The Uniform Allowance System (UNAW) is managed by the Financial Management Systems Staff (FIN). FIN is a staff under the Office of the Chief Financial Officer.

The authority for maintaining this system of records is 5 U.S.C. 5901–5903.

The information gathered is voluntarily submitted by individuals who are authorized to purchase and wear a Forest Service uniform while performing official duties. The system of records consists of completed Forest Service form FS–6100–36 (Uniform Authorization), and information on uniform allowances and expenditures for authorized individuals. Information collected includes the individual's name, social security number, employee location, allowance category, job code, and current status (active or terminated).

The system provides for the following routine use disclosures that are necessary and proper for the agency's administration of its duties in connection with operating the program: disclosures in connection with litigation; for law enforcement purposes; for responses to Congressional inquiries; to the National Archives and Records Administration and the General Services Administration for records inspections; limited disclosure to entities engaged by the agency in the performance of a service; and for disclosure in connection with information security breaches in order to protect the interests of the individuals covered by the system. While these routine uses allow disclosures outside USDA, and so have some

impact on privacy of individuals, they are either necessary for carrying out the agency mission and minimizing waste, fraud, and abuse, are required by law, or benefit the subjects of the records. On balance, the needs of the agency and the benefits to the individuals of these disclosures justify the minimal impact on privacy.

All hard copy records are maintained in secured locked file cabinets in agency offices which are locked during non-duty hours. All electronic information is maintained in a web-based database and stored and backed-up on secured servers. Computer access to information on individuals in the system is limited to the individual, contractor, and the system manager. The review of records retrieved is limited to the individual, supervisor, approved contractors, and system manager.

A copy of the form, used to collect the information from individuals, is attached to this report. The system of records is not exempt from any provisions of the Privacy Act.

[FR Doc. 2011–7722 Filed 4–6–11; 8:45 am]

BILLING CODE 3410–11–P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS–2010–0117]

Solicitation of Letters of Interest To Participate in National Environmental Policy Act Pilot Project

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice.

SUMMARY: The Animal and Plant Health Inspection Service is soliciting letters of interest from entities subject to the regulations governing the introduction of genetically engineered (GE) organisms in 7 CFR part 340 to participate in a National Environmental Policy Act (NEPA) Pilot Project. The NEPA Pilot Project will test new approaches to developing environmental analyses and documents required under NEPA to determine the extent to which these approaches improve the quality, timeliness, and cost effectiveness of such analyses and documents. The pilot project will focus only on NEPA analyses and documents associated with petitions for nonregulated status for GE organisms.

DATES: Letters of interest may be submitted through April 8, 2013 to the person listed under **FOR FURTHER INFORMATION CONTACT**.

FOR FURTHER INFORMATION CONTACT: Mr. David Reinhold, Assistant Director, Environmental Risk Analysis Programs, BRS, APHIS, 4700 River Road Unit 146, Riverdale, MD 20737–1238; (301) 734–0660; *e-mail: david.reinhold@aphis.usda.gov.*

SUPPLEMENTARY INFORMATION:

Background

The regulations in 7 CFR part 340, "Introduction of Organisms and Products Altered or Produced Through Genetic Engineering Which Are Plant Pests or Which There Is Reason to Believe Are Plant Pests," regulate, among other things, the introduction (importation, interstate movement, or release into the environment) of organisms and products altered or produced through genetic engineering that are plant pests or that there is reason to believe are plant pests. Such genetically engineered organisms and products are considered "regulated articles." The regulations in § 340.6(a) provide that any person may submit a petition to the Animal and Plant Health Inspection Service (APHIS) seeking a determination that an article should not be regulated under 7 CFR part 340, also referred to as a request to grant nonregulated status or to deregulate an article.

Before APHIS determines whether an article can be deregulated, APHIS prepares a plant pest risk assessment (PPRA) to assess the plant pest risk of the article. In accordance with The National Environmental Policy Act of 1969 (NEPA), as amended (42 U.S.C. 4321 *et seq.*), APHIS also prepares an environmental assessment (EA) or an environmental impact statement (EIS) to examine potential environmental impacts that may result from an Agency determination of nonregulated status.

The regulations in § 340.6(c)(1) through (c)(5) require the petitioner to submit specific information to meet regulatory requirements and inform APHIS' evaluation of the petition. While petitioners may submit much of the necessary information, APHIS retains primary responsibility for researching and analyzing all the data necessary to prepare the environmental documents. APHIS also evaluates all comments received on the environmental documents. APHIS has, on occasion, used consultants and contractors to perform some of these functions under APHIS guidance and oversight. In APHIS' experience, the cost of a draft EA generally ranges from $60,000–$80,000, and the cost of a complete EIS can exceed $1,000,000.

To explore ways to enhance APHIS' NEPA compliance, APHIS is implementing a NEPA Pilot Project that will involve working with petitioners and outside experts to develop high-quality environmental analyses and documents in a timelier manner. This pilot project is part of a larger effort to improve the petition evaluation process and is one of the strategies identified in USDA's High Priority Performance Goal for biotechnology regulation in the President's Performance Agenda.[1]

The pilot project will explore two voluntary mechanisms: (1) A petitioner-submitted environmental report based upon which APHIS would develop an EA or an EIS; and (2) an EA or EIS prepared by a contractor, funded by a cooperative services agreement between the petitioner and APHIS.[2] This project is consistent with the Council on Environmental Quality's (CEQ) regulations for implementing NEPA (40 CFR parts 1500–1508), which allow Federal agencies to obtain relevant information from applicants for the purpose of conducting a NEPA analysis and to contract for services by an independent contractor (chosen and directed by the Agency) to prepare environmental analyses and documents that are paid for by the petitioners.

The petitioner-submitted environmental reports should contain information necessary to develop a draft EA or EIS, including, for example, a description of the geographic area that will be affected and potential impacts on the environment, such as effects on water quality and sensitive wildlife species.

Under the contractor-prepared EA or EIS alternative, petitioners will provide funds for the environmental analyses and documents, while APHIS will select and direct the contractor. In addition, with this alternative, analyses and documents may be prepared for the entire NEPA process or only part of the process, *i.e.,* for the draft EA or EIS, for the evaluation of comments, and/or for the final EA or EIS.

APHIS will independently evaluate all information and references in the environmental documents, supplement the information and analysis in the environmental reports as necessary, and make its own evaluation of the environmental issues and the adequacy of the analyses of those issues to ensure that the scope and content of the environmental analyses meet all requirements of CEQ's regulations and APHIS' NEPA implementing regulations (7 CFR part 372).

NEPA compliance is an important Agency responsibility, and the pilot project is designed and intended to

[1] To learn more about the President's Performance Agenda, visit *http://www.performance.gov/.*

[2] APHIS will continue to conduct environmenanalyses and prepare environmental documents for regulated entities that are unable or choose not to participate in the pilot project.

assist APHIS in developing more effective methods for the NEPA process. APHIS intends to create mechanisms for early and frequent interactions between APHIS' Biotechnology Regulatory Services program staff and participants in the pilot project to identify and thoroughly evaluate the potential environmental impacts pertinent to the Agency's NEPA analysis. This pilot will also include mechanisms to identify NEPA-related issues early in the process involving both the petitioners and interested partners. APHIS also intends to use the pilot project to develop guidance for all petitioners that clearly identifies the information needed to initiate and complete the required NEPA analysis.

APHIS will evaluate the overall results of the pilot project, including the effectiveness of using environmental analyses and documents prepared by petitioners (environmental reports) as compared to environmental analyses and documents prepared using an independent contractor (EAs and EISs), and a cost analysis of the two approaches in relationship to the quality and timeliness of the final product.

APHIS is soliciting letters of interest from regulated entities interested in participating in the NEPA Pilot Project; no limit has been set on the number of participants. APHIS anticipates that the pilot project will run for 2 years. However, APHIS is interested in advancing the pilot project in the next few months and therefore encourages interested entities to submit letters of interest as soon as possible. Interested entities may submit letters of interest by mail or e-mail through April 8, 2013 to the person listed under **FOR FURTHER INFORMATION CONTACT**. APHIS will promptly contact all entities that submit letters of interest to discuss their participation in the NEPA Pilot Project.

Authority: 7 U.S.C. 7701–7772 and 7781–7786; 31 U.S.C. 9701; 7 CFR 2.22, 2.80, and 371.3.

Done in Washington, DC, this 1st day of April 2011.

Kevin Shea,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 2011–8329 Filed 4–6–11; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF AGRICULTURE

Farm Service Agency

Information Collection; Certified State Mediation Program

AGENCY: Farm Service Agency, USDA.

ACTION: Notice; request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, the Farm Service Agency (FSA) is seeking comments from all interested individuals and organizations on an extension of a currently approved information collection that supports the Certified State Mediation Program. The information collection is necessary to ensure the grant program is being administered properly. The collection of information by mail, phone, fax, in person, and by the internet is utilized by FSA initially to determine whether the State meets the eligibility criteria to be a recipient of grant funds. Lack of adequate information to make these determinations could result in the improper administration and appropriation of Federal grant funds.

DATES: We will consider comments that we receive by June 6, 2011.

ADDRESSES: We invite you to submit comments on this notice. In your comments, include date, volume, and page number of this issue of the **Federal Register**. You may submit comments by any of the following methods:

- *Mail:* Carol Wagner, Certified State Mediation Program Manager, USDA, FSA, Appeals and Litigation Staff, 1400 Independence Avenue, SW., Ag Stop 0570, Washington, DC 20250–0570.
- *E-mail: Carol.Wagner@wdc.usda.gov.*
- *Fax:* (202) 690–3003.

You may also send comments to the Desk Officer for Agriculture, Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503. Copies of the information collection may be requested by contacting Carol Wagner at the above addresses.

FOR FURTHER INFORMATION CONTACT: Carol Wagner, FSA, Appeals and Litigation Staff, telephone (202) 720–4966.

SUPPLEMENTARY INFORMATION:

Title: Certified State Mediation Program.

OMB Control Number: 0560–0165.

Expiration Date of Approval: August 31, 2011.

Type of Request: Extension.

Abstract: This information is needed for FSA to effectively administer the Certified State Mediation Program in accordance with Subtitles A and B of Title V of the Agricultural Credit Act of 1987 (7 U.S.C. 5106). FSA requires some of the collected information to be reported in a standard manner. Although other institutions, public and private, generally require and collect information similar to that requested by FSA, there is a wide diversity in reporting practices.

The information to be collected includes an application for certification, re-verification for subsequent annual approval, SF–424, SF–424A, and SF–424B Application for Federal Assistance, financial management systems and reporting requirements, and audit reports. The information collection request has not changed since the last OMB approval.

The information requested is reported annually and is necessary for the FSA to determine eligibility and administer the mediation grant program in an equitable and cost-effective manner.

Estimated of Annual Burden: The public reporting burden for this information collection is estimated to average 34 hours per respondent.

Respondents: State Agencies.

Estimated Number of Respondents: 35.

Estimated Number of Responses per Respondent: 5.

Estimated Total Annual of Reponses: 175.

Estimated Total Annual Burden hours: 1190 hours.

We are requesting comments on all aspects of this information collection to help us to:

(1) Evaluate whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agency's estimate of burden including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility and clarity of the information to be collected;

(4) 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.

All comments in response to this notice, including names and addresses when provided, will be a matter of public record. Comments will be summarized and included in the request for OMB approval.

Signed at Washington DC, on April 1, 2011.

Carolyn B. Cooksie,

Acting Administrator, Farm Service Agency.

[FR Doc. 2011–8320 Filed 4–6–11; 8:45 am]

BILLING CODE 3410–05–P

DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

[Docket No. FSIS–2010–0035]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0092]

Update of the 2003 Interagency Quantitative Assessment of the Relative Risk to Public Health From Foodborne Listeria Monocytogenes Among Selected Categories of Ready-to-Eat Foods; Request for Comments, Scientific Data and Information

AGENCY: Food Safety and Inspection Service, USDA; Food and Drug Administration, HHS.

ACTION: Notice; request for comments and for scientific data and information.

SUMMARY: The Food Safety and Inspection Service (FSIS) and the Food and Drug Administration (FDA) are requesting comments and scientific data and information that would assist the agencies in their plan to update a risk assessment on the relationship between foodborne *Listeria monocytogenes* in selected categories of ready-to-eat (RTE) foods and human health. The purpose of the risk assessment is to incorporate newly available scientific data and information into the risk assessment in order to update estimates of the relative risk of illness and death associated with the consumption of different types of RTE foods that may be contaminated with *L. monocytogenes* and to evaluate the relative effectiveness of strategies to reduce or prevent exposure to *L. monocytogenes* from the consumption of RTE foods, including, for example, the impact of changing refrigerated time and temperature storage prior to consumption.

DATES: Submit electronic or written comments and scientific data and information by July 6, 2011.

ADDRESSES: *FSIS:* Submit electronic comments and scientific data and information to *http://www.regulations.gov.* Submit written comments and scientific data and information to the Docket Clerk, U.S. Department of Agriculture, Food Safety and Inspection Service, George Washington Carver Center, 5601 Sunnyside Ave., Mailstop 5474, Beltsville, MD 20705–5464. All submissions must include the Agency name and docket number FSIS–2010–0035.

FDA: Submit electronic comments and scientific data and information to *http://www.regulations.gov.* Submit written comments and scientific data and information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All submissions must include the Agency name and docket number FDA–2011–N–0092.

FOR FURTHER INFORMATION CONTACT: *FSIS:* Janell Kause, Office of Public Health Science, Food Safety and Inspection Service, United States Department of Agriculture, 1400 Independence Ave., Aerospace Maildrop 344, Washington, DC 20250, 202–690–0286; or

FDA: Sherri Dennis, Center for Food Safety and Applied Nutrition (HFS–06), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–1914.

SUPPLEMENTARY INFORMATION:

I. Background

Listeria monocytogenes is a bacterium that is commonly found in the human environment, including food processing environments. After ingesting *L. monocytogenes,* humans can develop listeriosis, a severe foodborne disease with a high case-fatality rate. Listeriosis occurs predominantly in high-risk population subgroups, including pregnant women and their fetuses or neonates, immune-compromised individuals, and the elderly population (defined for the purpose of the risk assessment discussed in this notice as individuals who are 60 years of age or older). Due to the high proportion of serious illnesses and the high case-fatality rate associated with listeriosis, the "Healthy People 2010" goals for national disease prevention and health promotion specified a reduction in the prevalence of foodborne listeriosis by 50 percent as an important objective (Ref. 1). ("Healthy People" is a national health promotion and disease prevention initiative that brings together national, State, and local government agencies; nonprofit, voluntary, and professional organizations; and businesses, communities, and individuals to improve the health and quality of life of all Americans, eliminate disparities in health, and promote good health and quality of life across all life stages (Ref. 2).) However, despite considerable efforts to reduce the number of listeriosis cases during the past decade, the listeriosis prevalence still exceeds the "Healthy People 2010" target of 0.25 cases per 100,000 population (Ref. 3). (Note that then President Clinton's Council on Food Safety, established by Executive Order 13100, August 25, 1998, developed a strategic plan that set public health goals including, by 2005, reducing foodborne illness by 25 percent for some pathogens and for others to the quantitative targets established in "Healthy People 2010." In 2005, FoodNet data showed 0.30 *L. monocytogenes* cases per 100,000 population; the "Healthy People 2005" target was 0.25 *L. monocytogenes* cases per 100,000 population.) In 2009, the prevalence of listeriosis had decreased by only 26 percent compared to the baseline period (1996 to 1998) rate, and reducing the prevalence of listeriosis was retained in the "Healthy People 2020" objectives, with a target of 0.2 cases per 100,000 population (Refs. 3 and 4).

In 2003, FDA and FSIS published a quantitative assessment of the relative risk to public health from foodborne *L. monocytogenes* among 23 selected categories of RTE foods (the 2003 risk assessment) (Ref. 5). This 2003 risk assessment provided estimates for the median number of listeriosis cases attributable to each of 23 RTE food categories on a per-annum and per-serving basis. This allowed for a relative ranking of the 23 food categories based on the associated public health risk and permitted the evaluation of the likely impact of several "what-if" mitigation scenarios.

Since publication of the 2003 risk assessment, the food industry has changed some practices, including by adding growth inhibitors to RTE products. *L. monocytogenes* prevalence in some RTE foods has decreased over the past decade, and a substantial amount of new scientific data has become available for potential inclusion in risk assessments (Refs. 6, 7, and 8). These changes could potentially affect the outcomes of the risk assessment and alter the relative risk rankings of the RTE food categories evaluated in the 2003 risk assessment.

Risk assessments can be used to evaluate potential risk mitigation strategies and can guide, support, and enhance an Agency's risk management policies, outreach efforts, data collection initiatives, and research priorities. To help ensure that risk mitigation strategies, risk management policies, outreach efforts, data collection initiatives, and research priorities aimed at controlling *L. monocytogenes* in RTE foods are directed to those RTE foods that pose the greatest risk, FDA and FSIS have initiated an update to the 2003 risk assessment. The purpose of updating the risk assessment is to incorporate newly available scientific

data and information that reflect changes in *L. monocytogenes* prevalence and industry practices into the risk assessment in order to: (1) Update estimates of the relative risk of listeriosis associated with the consumption of different types of RTE foods that may be contaminated with *L. monocytogenes* and (2) evaluate the relative effectiveness of strategies to reduce or prevent exposure to *L. monocytogenes* from the consumption of RTE foods, including by modeling the effect of changing refrigerated storage times and temperatures. To fill critical data gaps, FDA and FSIS have initiated collaborative efforts with the USDA Agricultural Research Service, academic partners, and private laboratories to survey the presence and quantity of *L. monocytogenes* in selected categories of RTE foods. RTE foods chosen for this survey include: Leafy green vegetables, low-acid cut fruits, smoked seafood, seafood and deli-type salads, soft ripened and semi-soft cheeses, sandwiches, raw milk, deli meats, hot dogs, pâté, and meat spreads. Estimates for other RTE foods to be included in the risk assessment will be updated using scientific data newly available in the literature (if applicable) and information provided in response to this notice.

II. Request for Comments and Scientific Data and Information

FSIS and FDA are requesting technical comments on the approach outlined previously for updating the 2003 risk assessment. FDA and FSIS are also requesting the submission of new data and information relevant to this risk assessment that was not available for inclusion in the previous risk assessment and that may reflect changes in *L. monocytogenes* prevalence and industry practices that have occurred since the previous risk assessment.

The agencies specifically request new data and information concerning, but not limited to, the following factors that may affect the relative risk of listeriosis associated with consumption of the types of RTE foods that were considered in the 2003 risk assessment:

1. *L. monocytogenes* contamination in different RTE foods sampled at retail or in the processing plant, including:

- The frequency of detecting the presence of *L. monocytogenes* in RTE foods (including sample size, number of positives, total number tested for a specified time period, and test method); and
- The number of *L. monocytogenes* cells present per amount (unit volume or weight) of contaminated RTE food (including method used).

2. *L. monocytogenes* survival and growth dynamics in RTE foods, including:

- Data or models on survival and growth of *L. monocytogenes* in specific RTE food matrices, including the potential effects of commensal microflora;
- Data or models on survival and growth of *L. monocytogenes* in the presence or absence of substances that inhibit or retard growth; and
- Data or models on survival and growth of *L. monocytogenes* at different storage temperatures and over different storage times.

3. The relationship between the dose of *L. monocytogenes* ingested with food and the frequency of listeriosis, including:

- The effect of age, health status, or other characteristics of the consumer on the dose-response relationship;
- The effect of food matrix and product formulation on the dose-response relationship;
- The effect of genetic characteristics of the *L. monocytogenes* strain on the dose-response relationship; and
- Any other data pertinent to *L. monocytogenes* dose-response relationships.

4. Current food consumption practices in the United States, including:

- The frequency with which different RTE foods (*e.g.,* deli meats or cheeses manufactured with growth inhibitors) are consumed by population subgroups (*e.g.,* general adult population, pregnant women, the elderly); and
- Serving sizes for different RTE foods.

5. Food production practices in the United States that may impact *L. monocytogenes* prevalence, concentration, survival, or growth in RTE foods, including:

- The absolute or relative frequency of manufacturing different RTE foods with substances that inhibit the growth of *L. monocytogenes* and the types and concentrations of growth inhibitor used;
- The absolute or relative amount of specific types of RTE foods that are prepared, sliced, cut, or repackaged in retail operations as opposed to being sold pre-sliced/pre-cut;
- The absolute or relative amount of different RTE foods manufactured without growth inhibitors that are prepared, sliced, or repackaged at retail;
- The average shelf life of foods that were identified in the 2003 risk assessment (Ref. 4) as supporting *L. monocytogenes* growth;
- The average shelf life of RTE foods that were not explicitly identified in the 2003 risk assessment but that may conceivably support *L. monocytogenes* growth;
- The ability of current production practices to prevent or reduce *L. monocytogenes* contamination in finished product;
- The ability of current operational practices in retail operations to prevent or reduce *L. monocytogenes* contamination in the final product at the time of sale; and
- The ability of current post-processing practices to prevent *L. monocytogenes* cross-contamination after processing.

6. Storage times and temperatures that may affect *L. monocytogenes* growth during transport and storage of foods in the consumer's home.

7. Other comments, including the RTE food categories that should be evaluated in the risk assessment.

III. Request for Comments, Scientific Data and Information

FSIS: Interested persons may submit to FSIS's Docket Clerk (*see* **ADDRESSES**) either electronic or written comments regarding this document. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the FSIS Docket Room between 8:30 a.m. and 4:30 p.m., Monday through Friday.

FDA: Interested persons may submit to FDA's Division of Dockets Management (*see* **ADDRESSES**) either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

IV. References

The following references are on display in the Division of Dockets Management (*see* **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday. We have verified all addresses, but we are not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register.**

1. U.S. Department of Health and Human Services, "Healthy People 2010," Chapter 10, Food Safety, Washington, DC, 2000, *http://www.healthypeople.gov/2010/Document/pdf/Volume1/10Food.pdf*.

2. U.S. Department of Health and Human Services, "Healthy People 2020," HP 2020 Framework, Washington, DC, 2010, available at *http://www.healthy*

people.gov/2020/Consortium/HP2020 Framework.pdf.

3. Anonymous, 2010, "Preliminary FoodNet Data on the Incidence of Infection With Pathogens Transmitted Commonly Through Food—10 States, 2009," *Morbidity and Mortality Weekly Report,* 59: 418–422, available at *http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5914a2.htm.*

4. U.S. Department of Health and Human Services, "Healthy People 2020," HP 2020 FS–1.3, Washington, DC, 2010, available at *http://www.healthypeople.gov/2020/topicsobjectives2020/pdfs/HP2020objectives.pdf.*

5. U.S. Department of Health and Human Services and U.S. Department of Agriculture/Food Safety and Inspection Service, "Quantitative Assessment of Relative Risk to Public Health From Foodborne *L. monocytogenes* Among Selected Categories of RTE Foods," September 2003, available in Docket No. FDA–1999–N–0134 (formerly Docket No. 1999N–1168), vols. 23 through 28, available at *http://www.fda.gov/Food/ScienceResearch/ResearchAreas/RiskAssessmentSafetyAssessment/ucm183966.htm.*

6. Endrikat, S., D. Gallagher, R. Pouillot, H. Hicks Quesenberry, D. Labarre, C. M. Schroeder, and J. Kause, "A Comparative Risk Assessment for *L. monocytogenes* in Prepackaged Versus Retail-Sliced Deli Meat," *Journal of Food Protection,* 73:612–9.

7. U.S. Department of Agriculture, Food Safety and Inspection Service, 2003, 9 CFR part 430, "Control of *Listeria monocytogenes* in Ready-to-Eat Meat and Poultry Products," final rule. **Federal Register,** 68 FR 34208 to 34254.

8. U.S. Department of Agriculture/Food Safety and Inspection Service, "The FSIS Microbiological Testing Program for Ready-to-Eat (RTE) Meat and Poultry Products, 1990–2009," September 2010, available at *http://www.fsis.usda.gov/Science/Micro_Testing_RTE/index.asp.*

Dated: March 25, 2011.

Alfred V. Almanza,

Administrator, FSIS.

Dated: March 31, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–8360 Filed 4–6–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF AGRICULTURE

Forest Service

Chequamegon-Nicolet National Forest, Wisconsin, Lakewood Southeast Project

AGENCY: Forest Service, USDA.

ACTION: Notice of intent to prepare an environmental impact statement.

SUMMARY: The Forest Service will prepare an environmental impact statement (EIS) to document the analysis and disclose the environmental impacts of proposed land management activities and corresponding alternatives within the Lakewood Southeast Project. The purpose of the Lakewood Southeast Project is to implement land management activities that are consistent with direction in the Chequamegon-Nicolet National Forest 2004 Land and Resource Management Plan and respond to the specific needs identified in the project area. The project-specific needs include: Reintroduction of natural regimes, wildlife habitat and stream bank improvement, forest age, forest composition, and stocking.

DATES: Comments concerning the scope of the analysis must be received by May 9, 2011 in order to be useful in preparation of the draft statement. The draft environmental impact statement is expected in May 2011 and the final environmental impact statement is expected August 2011.

ADDRESSES: Send written comments concerning this proposal to Marilee Houtler, *Attn:* Lakewood Southeast Project, Lakewood-Laona Ranger District, 15085 State Road 32, Lakewood, WI 54138. Comments may also be sent via e-mail to *comments-eastern-chequamegon-nicolet-lakewood@fs.fed.us,* or via facsimile to 715–276–3594. Comments received in response to this solicitation, including names and addresses of those who comment, will be part of the public record for this proposed action. Comments submitted anonymously will be accepted and considered; however, anonymous comments will not provide the Agency with the ability to provide the respondent with subsequent environmental documents.

FOR FURTHER INFORMATION CONTACT: Marilee Houtler, NEPA Coordinator at the above address or by phone at 715–276–6333.

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.

SUPPLEMENTARY INFORMATION: The information presented in this notice is included to help the reviewer determine if they are interested in or potentially affected by the proposed land management activities. The information presented in this notice is summarized. Those who wish to provide comments, or are otherwise interested in or affected by the project, are encouraged to obtain additional information from the contact listed above.

Purpose and Need for Action

The current conditions of many forest stands in the project area vary from desired conditions in the Chequamegon-Nicolet National Forest 2004 Land and Resource Management Plan (forest plan). Our information shows some of the more notable gaps between the existing and desired future conditions by management area. Of primary importance is the need for change in: (1) Loss of natural regimes (2) wildlife habitat (3) stream improvement (4) species age structure (5) species composition and (6) stocking densities. The dominant habitat in the Lakewood Southeast Project area is upland conifer forests mixed with other forest communities.

Preliminary analysis of the project area indicates that there are certain conditions that warrant action to accomplish the direction and desired conditions identified in the forest plan.

Proposed Action

Projected project implementation would be spring of 2012. Lakewood Southeast Project is located on National Forest System lands, administered by the Lakewood-Laona Ranger District, east of Mountain, WI. The legal description of the project is Township 31–32 North, Range 17 East. The Forest Service proposes to reintroduce natural regimes in the Northern dry forests and Pine Barrens (mainly fire), improve wildlife habitat (manage openings, improve habitat for Regional Forester Sensitive Species) and stream corridors (adding long lived species), and use timber harvest (selection, clearcut, shelterwood, and thinning) to move toward desired conditions in the forest plan.

Responsible Official

The responsible official for this project is Lakewood-Laona District Ranger, Chequamegon-Nicolet National Forest.

Nature of Decision To Be Made

Decision making will be limited to specific activities relating to the proposed actions. The primary decision to be made will be whether or not to implement the proposed action, no action, another action alternative, or parts of alternatives that respond to the project's purpose and need. This decision would be documented in a record of decision.

Scoping Process

This notice of intent initiates the scoping process, which guides the development of the EIS. The 45-day comment period will start after the publication in the **Federal Register** of the Notice of Availability for the Lakewood Southeast Project Draft EIS. It is important that reviewers provide their comments at such times and in such manner that they are useful to the Agency's preparation of the EIS. Therefore, comments should be provided prior to the close of the comment period and should clearly articulate the reviewer's concerns and contentions. The submission of timely and specific comments can affect a reviewer's ability to participate in subsequent administrative appeal or judicial review.

March 21, 2011.

Paul I.V. Strong,

Forest Supervisor.

[FR Doc. 2011–8270 Filed 4–6–11; 8:45 am]

BILLING CODE 3410–11–P

DEPARTMENT OF AGRICULTURE

Forest Service

Hood/Willamette Resource Advisory Committee; Meeting

AGENCY: Forest Service, USDA.

ACTION: Notice of meeting.

SUMMARY: The Hood/Willamette Resource Advisory Committee will meet in Salem, Oregon. 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 of the meeting is to make recommendations for the 2012 projects.

DATES: The meeting will be held on May 16, 2011, and begin at 9:30 a.m.

ADDRESSES: The meeting will be held at the Salem Office of the Bureau of Land Management Office; 1717 Fabry Road SE; Salem, Oregon; (503) 375–5646. Written comments should be sent to Connie Athman, Mt. Hood National Forest, 16400 Champion Way, Sandy, Oregon 97055. Comments may also be sent via e-mail to *cathman@fs.fed.us,* or via facsimile to 503–668–1413.

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 Mt. Hood National Forest, 16400 Champion Way, Sandy, Oregon 97055.

FOR FURTHER INFORMATION CONTACT: Connie Athman, Designated Federal Official, Mt. Hood National Forest, 16400 Champion Way, Sandy, Oregon 97055; (503) 668–1672; E-mail: *cathman@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 Standard Time, Monday through Friday.

SUPPLEMENTARY INFORMATION: The meeting is open to the public. The following business will be conducted: (1) Recommendations on 2012 Projects; and (2) Public Forum.

The Public Forum is tentatively scheduled to begin at 9:45 a.m. Time allotted for individual presentations will be limited to 4–5 minutes. Written comments are encouraged, particularly if the material cannot be presented within the time limits for the Public Forum. Written comments may be submitted prior to the May 16th meeting by sending them to the Designated Federal Official, Connie Athman at the address given above.

Dated: March 21, 2011.

Kathryn J. Silverman,

Acting Forest Supervisor.

[FR Doc. 2011–8269 Filed 4–6–11; 8:45 am]

BILLING CODE 3410–11–P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[Docket 25–2011]

Foreign-Trade Zone 205—Port Hueneme, California; Application for Reorganization Under Alternative Site Framework

An application has been submitted to the Foreign-Trade Zones (FTZ) Board (the Board) by the Board of Harbor Commissioners of the Oxnard Harbor District, grantee of FTZ 205, requesting authority to reorganize the zone under the alternative site framework (ASF) adopted by the Board (74 FR 1170, 1/12/09 (correction 74 FR 3987, 1/22/09); 75 FR 71069–71070, 11/22/10). The ASF is an option for grantees for the establishment or reorganization of general-purpose zones and can permit significantly greater flexibility in the designation of new "usage-driven" FTZ sites for operators/users located within a grantee's "service area" in the context of the Board's standard 2,000-acre activation limit for a general-purpose zone project. The application was submitted pursuant to the Foreign-Trade Zones Act, as amended (19 U.S.C. 81–81u), and the regulations of the Board (15 CFR part 400). It was formally filed on March 31, 2011.

FTZ 205 was approved by the Board on October 28, 1994 (Board Order 714, 59 FR 55420, 11/07/1994) and expanded on April 28, 1998 (Board Order 978, 63 FR 25819, 05/11/1998).

The current zone project includes the following sites: *Site 1* (771 acres)—Port Hueneme commercial terminal complex (including the adjacent commercial area within the U.S. Naval Construction Battalion Center designated for FTZ use), 333 Ponoma Street; Port Hueneme; *Site 2* (79 acres)—three parcels within the South Oxnard Industrial Park, 5650 Arcturus Avenue and 5601 Edison Road, Oxnard; *Site 3* (22 acres)—908 East 3rd Street, Oxnard; and, *Site 4* (10 acres)—5851 Arcturus Avenue, Oxnard.

The grantee's proposed service area under the ASF would be Ventura County, California, as described in the application. If approved, the grantee would be able to serve sites throughout the service area based on companies' needs for FTZ designation. The proposed service area is within and adjacent to the Port Hueneme Customs and Border Protection port of entry.

The applicant is requesting authority to reorganize its existing zone project to include all of the existing sites as "magnet" sites. No usage-driven sites are being requested at this time. Because the ASF only pertains to establishing or reorganizing a general-purpose zone, the application would have no impact on FTZ 205's authorized subzone.

In accordance with the Board's regulations, Christopher Kemp of the FTZ Staff is designated examiner to evaluate and analyze the facts and information presented in the application and case record and to report findings and recommendations to the Board.

Public comment is invited from interested parties. Submissions (original and 3 copies) shall be addressed to the Board's Executive Secretary at the address below. The closing period for their receipt is June 6, 2011. Rebuttal comments in response to material submitted during the foregoing period may be submitted during the subsequent 15-day period to June 21, 2011.

A copy of the application will be available for public inspection at the Office of the Executive Secretary, Foreign-Trade Zones Board, Room 2111, U.S. Department of Commerce, 1401 Constitution Avenue, NW., Washington, DC 20230–0002, and in the "Reading Room" section of the Board's Web site, which is accessible via *http://www.trade.gov/ftz.* For further information, contact Christopher Kemp at *Christopher.Kemp@trade.gov* or (202) 482–0862.

Dated: March 31, 2011.

Andrew McGilvray,

Executive Secretary.

[FR Doc. 2011–8349 Filed 4–6–11; 8:45 am]

BILLING CODE P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–351–840]

Certain Orange Juice From Brazil: Preliminary Results of Antidumping Duty Administrative Review and Notice of Intent Not To Revoke Antidumping Duty Order in Part

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

SUMMARY: In response to a request by the petitioners and two producers/exporters of the subject merchandise, the Department of Commerce (the Department) is conducting an administrative review of the antidumping duty order on certain orange juice (OJ) from Brazil with respect to four producers/exporters of the subject merchandise to the United States. This is the fourth period of review (POR), covering March 1, 2009, through February 28, 2010.

We have preliminarily determined that sales to the United States have been made below normal value (NV), and, therefore, are subject to antidumping duties. If these preliminary results are adopted in the final results of this review, we will instruct U.S. Customs and Border Protection (CBP) to assess antidumping duties on all appropriate entries.

DATES: *Effective Date:* April 7, 2011.

FOR FURTHER INFORMATION CONTACT: Hector Rodriguez or Blaine Wiltse, 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) 482–0629 or (202) 482–6345, respectively.

SUPPLEMENTARY INFORMATION:

Background

In March 2006, the Department published in the **Federal Register** an antidumping duty order on certain orange juice from Brazil. *See Antidumping Duty Order: Certain Orange Juice from Brazil,* 71 FR 12183 (Mar. 9, 2006) (*OJ Order*). Subsequently, on March 1, 2010, the Department published in the **Federal Register** a notice of opportunity to request an administrative review of the antidumping duty order of certain orange juice from Brazil for the period March 1, 2009, through February 28, 2010. *See Antidumping or Countervailing Duty Order, Finding, or Suspended Investigation; Opportunity to Request Administrative Review,* 75 FR 9162 (Mar. 1, 2010).

In accordance with 19 CFR 351.213(b)(2), in March 2010, the Department received requests to conduct an administrative review of the antidumping duty order on OJ from Brazil from two producers/exporters of the subject merchandise, Fischer S.A. Comercio, Industria, and Agricultura (Fischer) and Sucocitrico Cutrale, S.A. (Cutrale). In Cutrale's request for an administrative review, it also requested revocation of the antidumping duty order with respect to its sales of subject merchandise, pursuant to 19 CFR 351.222(b).

In accordance with 19 CFR 351.213(b)(1), also in March 2010, the petitioners (Florida Citrus Mutual, A. Duda & Sons, Citrus World Inc., and Southern Gardens Citrus Processing Corporation), also requested that the Department conduct an administrative review for Cutrale and Fischer, as well as for two additional producers/exporters: Montecitrus Trading S.A. (Montecitrus) and Coinbra-Frutesp (SA) (Coinbra-Frutesp). In April 2010, the Department initiated an administrative review for all four companies. *See Initiation of Antidumping and Countervailing Duty Administrative Reviews and Request for Revocation in Part,* 75 FR 22107 (Apr. 27, 2010). Also in April 2010, we issued questionnaires to Coinbra-Frutesp, Cutrale, Fischer, and Montecitrus.

In May 2010, we received statements from Coinbra-Frutesp and Montecitrus that they had no shipments of subject merchandise to the United States during the POR.

From May through July 2010, we received responses to section A of the questionnaire (*i.e.,* the section covering general information) from Cutrale and Fischer, as well as responses to sections B and C of the questionnaire (*i.e.,* the sections covering sales in the home market and United States) and section D (*i.e.,* the section covering cost of production (COP)/constructed value (CV)).

From August through November 2010, we issued supplemental sales and cost questionnaires to Cutrale and Fischer. We received responses to these supplemental questionnaires from September through November 2010.

On November 16, 2010, the Department extended the deadline for the preliminary results of this review until no later than March 31, 2010. *See Certain Orange Juice from Brazil: Notice of Extension of Time Limits for the Preliminary Results of Antidumping Duty Administrative Review,* 75 FR 69917 (Nov. 16, 2010).

From December 2010 through March 2011, we issued Cutrale and Fischer additional supplemental sales and cost questionnaires. We received responses to these supplemental questionnaires from January through March 2011.

Finally, in March 2011, we requested that Cutrale provide additional information regarding its indirect selling expenses. Because this information was not received in time for use in the preliminary results, we expect to consider this information in the final results.

Scope of the Order

The scope of this order includes certain orange juice for transport and/or further manufacturing, produced in two different forms: (1) Frozen orange juice in a highly concentrated form, sometimes referred to as frozen concentrated orange juice for manufacture (FCOJM); and (2) pasteurized single-strength orange juice which has not been concentrated, referred to as not-from-concentrate (NFC). At the time of the filing of the petition, there was an existing antidumping duty order on frozen concentrated orange juice (FCOJ) from Brazil. *See Antidumping Duty Order; Frozen Concentrated Orange Juice from Brazil,* 52 FR 16426 (May 5, 1987). Therefore, the scope of this order with regard to FCOJM covers only FCOJM produced and/or exported by those companies which were excluded or revoked from the pre-existing antidumping order on FCOJ from Brazil as of December 27, 2004. Those companies are Cargill Citrus Limitada, Coinbra-Frutesp, Cutrale, Fischer, and Montecitrus.

Excluded from the scope of the order are reconstituted orange juice and frozen concentrated orange juice for retail (FCOJR). Reconstituted orange juice is produced through further manufacture of FCOJM, by adding

water, oils and essences to the orange juice concentrate. FCOJR is concentrated orange juice, typically at 42 Brix, in a frozen state, packed in retail-sized containers ready for sale to consumers. FCOJR, a finished consumer product, is produced through further manufacture of FCOJM, a bulk manufacturer's product.

The subject merchandise is currently classifiable under subheadings 2009.11.00, 2009.12.25, 2009.12.45, and 2009.19.00 of the Harmonized Tariff Schedule of the United States (HTSUS). These HTSUS subheadings are provided for convenience and for customs purposes only and are not dispositive. Rather, the written description of the scope of the order is dispositive.

Determination Not To Revoke Order, in Part

The Department may revoke, in whole or in part, an antidumping duty order upon completion of a review under section 751 of the Tariff Act of 1930, as amended (the Act). While Congress has not specified the procedures that the Department must follow in revoking an order, the Department has developed a procedure for revocation that is described in 19 CFR 351.222. This regulation requires, *inter alia,* that a company requesting revocation must submit the following: (1) A certification that the company has sold the subject merchandise at not less than NV in the current review period and that the company will not sell subject merchandise at less than NV in the future; (2) a certification that the company sold commercial quantities of the subject merchandise to the United States in each of the three years forming the basis of the request; and (3) an agreement to immediate reinstatement of the order if the Department concludes that the company, subsequent to the revocation, sold subject merchandise at less than NV. *See* 19 CFR 351.222(e)(1). Upon receipt of such a request, the Department will consider: (1) Whether the company in question has sold subject merchandise at not less than NV for a period of at least three consecutive years; (2) whether the company has agreed in writing to its immediate reinstatement in the order, as long as any exporter or producer is subject to the order, if the Department concludes that the company, subsequent to the revocation, sold the subject merchandise at less than NV; and (3) whether the continued application of the antidumping duty order is otherwise necessary to offset dumping. *See* 19 CFR 351.222(b)(2)(i).

On March 31, 2010, Cutrale requested revocation of the antidumping duty order with respect to its sales of subject merchandise, pursuant to 19 CFR 351.222(b). This request was accompanied by certification that: (1) Cutrale sold the subject merchandise at not less than NV during the current POR and will not sell the merchandise at less than NV in the future; and (2) it sold subject merchandise to the United States in commercial quantities for a period of at least three consecutive years. Cutrale also agreed to immediate reinstatement of the antidumping duty order, as long as any exporter or producer is subject to the order, if the Department concludes that, subsequent to the revocation, it sold the subject merchandise at less than NV.

In its revocation request, filed in this fourth administrative review, Cutrale argued that the Department found dumping margins below *de minimis* levels in the first administrative review. Although Cutrale acknowledged that the Department found dumping margins in the second administrative review, it argued that the margins were based upon the application of zeroing, which the World Trade Organization (WTO) has found to be inconsistent with international obligations. Cutrale states that there is an ongoing WTO dispute between Brazil and the United States regarding zeroing and that it believes that without zeroing it will have zero dumping margins for all administrative reviews thus far conducted or underway.

After analyzing Cutrale's request for revocation, we preliminarily find that it does not meet all of the criteria under 19 CFR 351.222(b). Pursuant to the regulation, upon receipt of a request for revocation, the Department will consider: (1) Whether the company in question has sold subject merchandise at not less than NV for a period of at least three consecutive years; (2) whether the company has agreed in writing to its immediate reinstatement in the order, as long as any exporter or producer is subject to the order, if the Department concludes that the company, subsequent to the revocation, sold the subject merchandise at less than NV; and (3) whether the continued application of the antidumping duty order is otherwise necessary to offset dumping. *See* 19 CFR 351.222(b)(2)(i).

In this case, our preliminary margin calculation for the fourth administrative review shows that Cutrale did not sell the subject merchandise at less than NV during the current review period. *See* "Preliminary Results of the Review" section below. However, in the second and third administrative reviews, Cutrale received antidumping duty margins above *de minimis. See Certain Orange Juice from Brazil: Final Results of Antidumping Duty Administrative Review,* 74 FR 40167 (Aug. 11, 2009) (*2007–2008 OJ from Brazil*); and *Certain Orange Juice from Brazil: Final Results of Antidumping Duty Administrative Review and Notice of Intent Not To Revoke Antidumping Duty Order in Part,* 75 FR 50999 (Aug. 18, 2010) (*2008–2009 OJ from Brazil*). Accordingly, while the Department preliminarily finds that Cutrale did not sell the subject merchandise at less than NV in this segment of the proceeding, we have found that Cutrale sold the subject merchandise at less than NV in the two most recently-completed administrative reviews (*i.e.,* the second and third administrative reviews).

Cutrale's speculation as to what antidumping margins might have been calculated in prior reviews had the Department used a different methodology does not provide a basis for revocation. The principles of administrative finality apply to these completed reviews. Cutrale did not successfully challenge the final results of the second administrative review in court and, thus, they are final and conclusive. Although Cutrale has challenged the final results of the third administrative review before the Court of International Trade, unless or until there is a final and conclusive court decision invalidating these results, by statute, these results are presumed to be correct. *See Shandong Huarong Gen. Group Corp.* v. *United States,* 122 F.Supp. 2d 143, 148 (CIT 2000) ("By statute, Commerce's administrative review determinations are presumed to be correct and the burden of proving otherwise rests exclusively upon the party challenging such decision.") (citing 28 U.S.C. 2639a(1)). Because the results of the administrative reviews are presumed to be correct for a court action appealing them, they must also be presumed to be correct in the context of a revocation request. Cutrale's filing of an appeal of the final results of the third administrative review to a court does not render the final results incorrect or unlawful.

With respect to Cutrale's argument that Brazil has challenged zeroing before the WTO, we acknowledge that there is an ongoing WTO dispute between Brazil and the United States regarding zeroing. However, this dispute is yet to be resolved by the WTO, including any potential appeals. More importantly, WTO reports do not provide an independent basis for altering the Department's methodology, except to the extent that they are implemented pursuant to a specified statutory scheme. *See Corus Staal BV* v.

Department of Commerce, 395 F.3d 1343, 1347, 1349 (Fed. Cir. 2005), cert denied, 126 S. Ct. 1023, 163 L. Ed. 2d 853 (January 9, 2006). There have been no WTO reports implemented in any fashion that would necessitate any change in the Department's methodology in this administrative review or prior administrative reviews of this antidumping duty order.

Therefore, we preliminarily determine that Cutrale does not qualify for revocation of the order on OJ pursuant to 19 CFR 351.222(b)(2), and thus, that the order with respect to such merchandise should not be revoked.

Preliminary Determination of No Shipments

As noted in the "Background" section above, Coinbra-Frutesp and Montecitrus indicated that they had no shipments of subject merchandise to the United States during the POR. The Department subsequently confirmed with CBP the no-shipment claim made by these two companies. Because the evidence on the record indicates that these companies did not export subject merchandise to the United States during the POR, we preliminarily determine that neither Coinbra-Frutesp nor Montecitrus had any reviewable transactions during the POR.

Since the implementation of the 1997 regulations, our practice concerning no-shipment respondents has been to rescind the administrative review if the respondent certifies that it had no shipments and we have confirmed through our examination of CBP data that there were no shipments of subject merchandise during the POR. *See Antidumping Duties; Countervailing Duties,* 62 FR 27296, 27393 (May 19, 1997). As a result, in such circumstances, we normally instruct CBP to liquidate any entries from the no-shipment company at the deposit rate in effect on the date of entry.

In our May 6, 2003, "automatic assessment" clarification, we explained that, where respondents in an administrative review demonstrate that they had no knowledge of sales through resellers to the United States, we would instruct CBP to liquidate such entries at the all-others rate applicable to the proceeding. *See Antidumping and Countervailing Duty Proceedings: Assessment of Antidumping Duties,* 68 FR 23954 (May 6, 2003) (*Assessment Policy Notice*).

Because "as entered" liquidation instructions do not alleviate the concerns which the May 2003 clarification was intended to address, we find it appropriate in this case to instruct CBP to liquidate any existing entries of merchandise produced by Coinbra-Frutesp or Montecitrus, and exported by other parties, at the all-others rate. *See, e.g., Magnesium Metal From the Russian Federation: Preliminary Results of Antidumping Duty Administrative Review,* 75 FR 26922 (May 13, 2010), unchanged in *Magnesium Metal From the Russian Federation: Final Results of Antidumping Duty Administrative Review,* 75 FR 56989 (Sept. 17, 2010). In addition, the Department finds that it is more consistent with the May 2003 clarification not to rescind the review in part in these circumstances but, rather, to complete the review with respect to Coinbra-Frutesp and Montecitrus and issue appropriate instructions to CBP based on the final results of the review. *See* the "Assessment Rates" section of this notice below.

Comparisons to Normal Value

To determine whether sales of OJ by Cutrale and Fischer to the United States were made at less than NV, we compared constructed export price (CEP) to the NV, as described in the "Constructed Export Price" and "Normal Value" sections of this notice.

Pursuant to section 777A(d)(2) of the Act, we compared the CEPs of individual U.S. transactions to the weighted-average NV of the foreign like product where there were sales made in the ordinary course of trade, as discussed in the "Cost of Production Analysis" section below.

Product Comparisons

In accordance with section 771(16) of the Act, we considered all products produced by Cutrale and Fischer covered by the description in the "Scope of the Order" section, above, to be foreign like products for purposes of determining appropriate product comparisons to U.S. sales. Pursuant to 19 CFR 351.414(e)(2), we compared U.S. sales of OJ to sales of OJ in the home market within the contemporaneous window period, which extends from three months prior to the month of the first U.S. sale until two months after the last U.S. sale. Where there were no sales of identical merchandise in the home market made in the ordinary course of trade to compare to U.S. sales, we compared U.S. sales to sales of the most similar foreign like product made in the ordinary course of trade. In making product comparisons, we matched foreign like products based on the physical characteristics reported by the respondents in the following order of importance: Product type and organic designation. Where there were no sales of identical or similar merchandise, we made product comparisons using CV, as discussed in the "Calculation of Normal Value Based on Constructed Value" section below. *See* section 773(a)(4) of the Act.

Constructed Export Price

In accordance with section 772(b) of the Act, we calculated CEP for those sales where the merchandise was first sold (or agreed to be sold) in the United States before or after the date of importation by or for the account of the producer or exporter, or by a seller affiliated with the producer or exporter, to a purchaser not affiliated with the producer or exporter. In this case, we are treating all of Cutrale's and Fischer's U.S. sales as CEP sales because they were made in the United States by their U.S. affiliates on behalf of the respondents, within the meaning of section 772(b) of the Act.

A. Cutrale

We based CEP on the packed delivered prices to unaffiliated purchasers in the United States. For sales made pursuant to futures contracts, we adjusted the reported gross unit price (*i.e.,* the notice price) to include gains and losses incurred on the futures contract which resulted in the shipment of subject merchandise. Additionally, for certain sales made pursuant to futures contracts which were noticed prior to the POR, but were shipped and invoiced during the POR, we adjusted the reported date of sale for these transactions to base it on the invoice date. We also adjusted the reported data to account for the difference between the reported and actual brix levels, as indicated on the invoice, at which the U.S. product was sold. In a small number of instances where the invoice did not reflect the actual brix level, we used the reported brix data. Where appropriate, we made adjustments for billing adjustments and rebates.

In addition, we made deductions for movement expenses, in accordance with section 772(c)(2)(A) of the Act. These included, where appropriate, foreign inland freight; foreign warehousing expenses; foreign brokerage and handling expenses; ocean freight; U.S. brokerage and handling (offset by customer-specific reimbursements); U.S. customs duties, harbor maintenance fees and merchandise processing fees (offset by U.S. duty drawback and customs duty reimbursements); U.S. inland freight expenses; and U.S. warehousing expenses. We capped reimbursements for brokerage and handling expenses by the amount of brokerage and handling expenses incurred on the subject

merchandise, in accordance with our practice. *See, e.g, Certain Orange Juice from Brazil: Final Results and Partial Rescission of Antidumping Duty Administrative Review,* 73 FR 46584 (Aug. 11, 2008) (*2005–2007 OJ from Brazil*), and accompanying Issues and Decision Memorandum at Comment 7; *2007–2008 OJ from Brazil* at Comment 3; and *2008–2009 OJ from Brazil* at Comment 2. We also capped U.S. customs duty reimbursements, as well as U.S. duty drawback, by the amount of U.S. customs duties incurred on the subject merchandise, in accordance with our practice. *Id.*

In accordance with section 772(d)(1) of the Act and 19 CFR 351.402(b), we deducted those selling expenses associated with economic activities occurring in the United States, including direct selling expenses (*i.e.,* bank charges, commissions, imputed credit expenses, and repacking (offset by pallet and drum revenue)), and indirect selling expenses (including inventory carrying costs and other indirect selling expenses). We capped U.S. pallet revenue and drum revenue by the amount of repacking expenses, in accordance with our practice. *Id.* In addition, we recalculated inventory carrying costs using the manufacturing costs reported in Cutrale's most recent cost response, adjusted as noted in the "Calculation of Cost of Production" section of this notice, below.

Pursuant to section 772(d)(3) of the Act, we further reduced the starting price by an amount for profit to arrive at CEP. In accordance with section 772(f) of the Act, we calculated the CEP profit rate using the expenses incurred by Cutrale and its U.S. affiliate on their sales of the subject merchandise in the United States and the profit associated with those sales.

For further discussion of the changes made to Cutrale's reported U.S. sales data, see the March 31, 2011, memorandum from Blaine Wiltse, Analyst, to the File, entitled "Calculation Adjustments for Sucocitrico Cutrale Ltda. for the Preliminary Results" (Cutrale Sales Calculation Memo).

B. Fischer

We based CEP on the packed delivered prices to unaffiliated purchasers in the United States. In addition, we made deductions for movement expenses, in accordance with section 772(c)(2)(A) of the Act; these included, where appropriate, foreign inland freight expenses; foreign warehousing expenses; foreign brokerage and handling expenses; ocean freight expenses; marine insurance expenses; U.S. brokerage and handling expenses; U.S. customs duties, harbor maintenance fees and merchandise processing fees (offset by U.S. duty drawback); U.S. inland freight expenses; and U.S. warehousing expenses. We capped reimbursements for U.S. customs duties, as well as U.S. duty drawback, by the amount of U.S. customs duties incurred on the subject merchandise, in accordance with our practice. *See 2005–2007 OJ from Brazil* at Comment 7; *2007–2008 OJ from Brazil* at Comment 3, and *2008–2009 OJ from Brazil* at Comment 2. Further, we determined that the international freight expenses provided by Fischer's affiliated freight provider were not at arm's length. Therefore, for all sales shipped by Fischer's affiliate, we assigned the international freight rate charged by Fischer's affiliate to an unaffiliated party to restate them on an arm's-length basis. For further discussion, see the March 31, 2011, memorandum to the file from Hector Rodriguez, Analyst, entitled "Calculations Performed for Fischer S.A. Comercio, Industria, and Agricultura for the Preliminary Results in the 2009–2010 Antidumping Duty Administrative Review of Certain Orange Juice from Brazil" (Fischer Sales Calculation Memo).

In accordance with sections 772(d)(1) of the Act and 19 CFR 351.402(b), we deducted those selling expenses associated with economic activities occurring in the United States, including direct selling expenses (*i.e.,* additional processing expenses, imputed credit expenses, and repacking), and indirect selling expenses (including inventory carrying costs, and other indirect selling expenses). In addition, we recalculated inventory carrying costs using the manufacturing costs reported in Fischer's most recent cost response, adjusted as noted in the "Calculation of Cost of Production" section of this notice, below.

Pursuant to section 772(d)(3) of the Act, we further reduced the starting price by an amount for profit to arrive at CEP. In accordance with section 772(f) of the Act, we calculated the CEP profit rate using the expenses incurred by Fischer and its U.S. affiliate on their sales of the subject merchandise in the United States and the profit associated with those sales.

Normal Value

A. Home Market Viability and Selection of Comparison Markets

In order to determine whether there was a sufficient volume of sales in the home market to serve as a viable basis for calculating NV, we compared the volume of home market sales of the foreign like product to the volume of U.S. sales of the subject merchandise, in accordance with section 773(a)(1)(C) of the Act.

We determined that the aggregate volume of home market sales of the foreign like product for each respondent was sufficient to permit a proper comparison with its U.S. sales of the subject merchandise.

B. Level of Trade

Section 773(a)(1)(B)(i) of the Act states that, to the extent practicable, the Department will calculate NV based on sales at the same level of trade (LOT) as the export price (EP) or CEP. Sales are made at different LOTs if they are made at different marketing stages (or their equivalent). *See* 19 CFR 351.412(c)(2). Substantial differences in selling activities are a necessary, but not sufficient, condition for determining that there is a difference in the stages of marketing. *Id. See also Notice of Final Determination of Sales at Less Than Fair Value: Certain Cut-to-Length Carbon Steel Plate From South Africa,* 62 FR 61731, 61732 (Nov. 19, 1997) (*Plate from South Africa*). In order to determine whether the comparison market sales were at different stages in the marketing process than the U.S. sales, we reviewed the distribution system in each market (*i.e.,* the chain of distribution), including selling functions, class of customer (customer category), and the level of selling expenses for each type of sale.

Pursuant to section 773(a)(1)(B)(i) of the Act, in identifying LOTs for EP and comparison market sales (*i.e.,* NV based on either home market or third country prices),[1] we consider the starting prices before any adjustments. For CEP sales, we consider only the selling activities reflected in the price after the deduction of expenses and profit under section 772(d) of the Act. *See Micron Technology, Inc.* v. *United States,* 243 F.3d 1301, 1314 (Fed. Cir. 2001).

When the Department is unable to match U.S. sales of the foreign like product in the comparison market at the same LOT as the EP or CEP, the Department may compare the U.S. sale to sales at a different LOT in the comparison market. In comparing EP or CEP sales at a different LOT in the comparison market, where available data make it practicable, we make an

[1] Where NV is based on CV, we determine the NV LOT based on the LOT of the sales from which we derive selling, general and administrative (SG&A) expenses, and profit for CV, where possible.

LOT adjustment under section 773(a)(7)(A) of the Act. Finally, for CEP sales only, if the NV LOT is at a more advanced stage of distribution than the CEP LOT and there is no basis for determining whether the difference in LOTs between NV and CEP affects price comparability (*i.e.,* no LOT adjustment was practicable), the Department shall grant a CEP offset, as provided in section 773(a)(7)(B) of the Act. *See Plate from South Africa,* 62 FR at 61732–33.

In this administrative review, we obtained information from each respondent regarding the marketing stages involved in making the reported home market and U.S. sales, including a description of the selling activities performed by each respondent for each channel of distribution. Company-specific LOT findings are summarized below.

1. Cutrale

Cutrale reported that it made CEP sales through one channel of distribution in the United States (*i.e.,* sales via an affiliated reseller) and thus the selling activities it performed did not vary by the type of customer. We examined the selling activities performed for this channel and found that Cutrale performed the following selling functions: order input/processing, freight and delivery, packing, maintaining inventory at the port of exportation, and quality testing.

Selling activities can be generally grouped into four selling function categories for analysis: (1) Sales and marketing; (2) freight and delivery; (3) inventory maintenance and warehousing; and (4) warranty and technical support. *See 2008–2009 OJ from Brazil* at Comment 7 and *Certain Frozen Warmwater Shrimp From India: Preliminary Results and Preliminary Partial Rescission of Antidumping Duty Administrative Review,* 74 FR 9991, 9996 (Mar. 9, 2009), unchanged in *Certain Frozen Warmwater Shrimp from India: Final Results and Partial Rescission of Antidumping Duty Administrative Review,* 74 FR 33409 (July 13, 2009). Based on these selling function categories, we find that Cutrale performed sales and marketing, freight and delivery services, and inventory maintenance and warehousing for U.S. sales. Because all sales in the United States are made through a single distribution channel, we preliminarily determine that there is one LOT in the U.S. market.

With respect to the home market, Cutrale reported that it made sales through one channel of distribution (*i.e.,* direct sales to soft drink manufacturers). We examined the selling activities performed for home market sales and found that Cutrale performed the following selling functions: order input/processing, advertising via sponsorship of a soccer team, freight and delivery, packing, and inventory maintenance at the factory. In addition to these functions, Cutrale also claimed that it offered quality guarantees, engineering services, and after-sales services to home market customers. With respect to engineering services and after-sales services, we disagree that the record supports Cutrale's claims. Rather, the record shows that Cutrale provided no such services other than holding a single meeting with one customer in which certain topics were discussed. Because the specifics of this meeting are business proprietary in nature, they cannot be disclosed here. For further discussion, see the Cutrale Sales Calculation Memo. Accordingly, based on the four selling function categories listed above, we find that Cutrale performed sales and marketing, freight and delivery, inventory maintenance and warehousing, and warranty and technical support for home market sales. Because all home market sales are made through a single distribution channel, we preliminarily determine that there is one LOT in the home market for Cutrale.

Finally, we compared the CEP LOT to the home market LOT and found that the selling functions performed for U.S. and home market customers do not differ significantly. Specifically, we found that the differences were limited to the following activities: (1) Cutrale performed limited advertising in the home market (*i.e.,* the sponsorship of a local soccer team in Brazil); (2) Cutrale entered orders into the company's computer system for home market sales based on orders placed by customers, while it generated sales documents for sales to its U.S. affiliate based on a general shipping schedule; (3) Cutrale provided post-sale services consisting of a single meeting with one customer; and (4) Cutrale provided additional quality testing in the home market which was limited to a small number of basic screenings for each batch of orange juice produced.

According to 19 CFR 351.412(c)(2), the Department will determine that sales are made at different levels of trade if they are made at different marketing stages (or their equivalent). Substantial differences in selling activities are a necessary, but not sufficient, condition for determining that there is a difference in the stage of marketing. Therefore, because we determine that substantial differences in Cutrale's selling activities do not exist across markets, we determine that sales to the U.S. and home markets during the POR were made at the same LOT. As a result, neither a LOT adjustment nor a CEP offset is warranted for Cutrale. This determination is consistent with findings in previous reviews.[2] *See, e.g., 2005–2007 OJ from Brazil* at Comment 5; *2007–2008 OJ from Brazil* at Comment 2; and *2008–2009 OJ from Brazil* at Comment 7.

2. Fischer

Fischer reported that it made CEP sales through one channel of distribution in the United States (*i.e.,* sales via an affiliated reseller) and, thus, the selling activities it performed did not vary by the type of customer. We examined the selling activities performed for this channel and found that Fischer performed the following selling functions: customer contact and price negotiation; order processing; arranging for freight and the provision of customs clearance/brokerage services; and inventory maintenance. Selling activities can be generally grouped into four selling function categories for analysis: (1) Sales and marketing; (2) freight and delivery; (3) inventory maintenance and warehousing; and (4) warranty and technical support. Accordingly, based on these selling function categories, we find that Fischer performed sales and marketing, freight and delivery services, and inventory maintenance and warehousing for U.S. sales. Because all sales in the United States are made through a single distribution channel, we preliminarily determine that there is one LOT in the U.S. market.

With respect to the home market, Fischer reported that it made sales through one channel of distribution and that the selling activities it performed did not vary by the type of customer. We examined the selling activities performed for home market sales, and found that Fischer performed the following selling functions: customer contact and price negotiation; order processing; arranging for freight; cold storage and inventory maintenance; sales and marketing support; and technical assistance. Accordingly, based on the selling function categories listed above, we find that Fischer performed sales and marketing, freight and delivery services, inventory maintenance and warehousing, and

[2] This finding is also consistent with Cutrale's statement that there were no significant differences between the sales activities that it performed during the current POR and those which it performed in both markets during the previous segment of the proceeding. *See* Cutrale's supplemental section A response, submitted on September 8, 2010, at page 3.

warranty and technical support for home market sales. Because all home market sales are made through a single distribution channel, we preliminarily determine that there is one LOT in the home market for Fischer.

Finally, we compared the CEP LOT to the home market LOT and found that the selling functions performed for U.S. and home market customers do not differ significantly. Therefore, we determine that sales to the U.S. and home markets during the POR were made at the same LOT, and as a result, neither a LOT adjustment nor a CEP offset is warranted for Fischer.

C. Affiliated-Party Transactions and Arm's-Length Test

During the POR, Cutrale made sales in the home market to an affiliated party, as defined in section 771(33) of the Act. Consequently, we tested these sales to ensure that they were made at arm's-length prices, in accordance with 19 CFR 351.403(c). To test whether the sales to the affiliate were made at arm's-length prices, we compared the unit prices of sales to the affiliated and unaffiliated customers net of all movement charges, direct selling expenses, and packing expenses. Pursuant to 19 CFR 351.403(c) and in accordance with the Department's practice, where the price to that affiliated party was, on average, within a range of 98 to 102 percent of the price of the same or comparable merchandise sold to the unaffiliated parties at the same LOT, we determined that the sales made to the affiliated party were at arm's-length. *See Antidumping Proceedings: Affiliated Party Sales in the Ordinary Course of Trade,* 67 FR 69186 (Nov. 15, 2002) (establishing that the overall ratio calculated for an affiliate must be between 98 and 102 percent in order for sales to be considered in the ordinary course of trade and used in the NV calculation). Sales to affiliated customers in the home market that were not made at arm's-length prices were excluded from our analysis because we considered these sales to be outside the ordinary course of trade. *See* section 771(15) of the Act and 19 CFR 351.102(b).

D. Cost of Production Analysis

We found that both Cutrale and Fischer made sales below the COP in the 2007–2008 administrative review, the most recently completed segment of this proceeding as of the date of initiation of this review, and such sales were disregarded. *See 2007–2008 OJ from Brazil,* 74 FR at 40167. Thus, in accordance with section 773(b)(2)(A)(ii) of the Act, there are reasonable grounds to believe or suspect that Cutrale and Fischer made home market sales at prices below the cost of producing the merchandise in the current POR.

1. Calculation of Cost of Production

In accordance with section 773(b)(3) of the Act, we calculated the respondents' COPs based on the sum of their costs of materials and conversion for the foreign like product, plus amounts for general and administrative (G&A) expenses and interest expenses (*see* "Test of Comparison Market Sales Prices" section, below, for treatment of home market selling expenses).

The Department relied on the COP data submitted by each respondent in its most recently submitted cost database for the COP calculation, except in the following instances:

a. Cutrale

i. We used Cutrale's home market actual brix level data to adjust Cutrale's home market costs to ensure that these are stated on a pounds-solid basis using actual brix. For further discussion of this adjustment, see the Cutrale Sales Calculation Memo.

ii. We adjusted Cutrale's financial expense ratio by limiting the interest income offset to income earned on short-term investments of its working capital. For further discussion of this adjustment, see the March 31, 2011, Memorandum from Gary Urso, Accountant, to Neal M. Halper, Director Office of Accounting, entitled "Cost of Production and Constructed Value Calculation Adjustments for the Preliminary Results—Sucocitrico Cutrale Ltda."

b. Fischer

i. We revised Fischer's reported per-unit raw material costs to reflect the POR cost of purchases and purchase price adjustments as recorded in Fischer's normal books and records.

ii. We revised Fischer's G&A calculation to include losses on the disposition of fixed assets and the eradication of orange trees.

For further discussion of these adjustments, see the March 31, 2011, Memorandum from Frederick Mines, Accountant, to Neal M. Halper, Director Office of Accounting, entitled "Cost of Production and Constructed Value Calculation Adjustments for the Preliminary Results—Fischer S.A. Comercio, Industria and Agricultura."

2. Test of Comparison Market Sales Prices

On a product-specific basis, we compared the adjusted weighted-average COP to the home market sales prices of the foreign like product, as required under section 773(b) of the Act, in order to determine whether the sales prices were below the COP. For purposes of this comparison, we used COP exclusive of selling and packing expenses. The prices (inclusive of billing adjustments, where appropriate) were exclusive of any applicable movement charges, direct and indirect selling expenses and packing expenses.

3. Results of the COP Test

In determining whether to disregard home market sales made at prices below the COP, we examined, in accordance with sections 773(b)(1)(A) and (B) of the Act: (1) Whether, within an extended period of time, such sales were made in substantial quantities; and (2) whether such sales were made at prices which permitted the recovery of all costs within a reasonable period of time in the normal course of trade. Where less than 20 percent of the respondent's home market sales of a given product are at prices less than the COP, we do not disregard any below-cost sales of that product, because we determine that in such instances the below-cost sales were not made within an extended period of time and in "substantial quantities." Where 20 percent or more of a respondent's sales of a given product are at prices less than the COP, we disregard the below-cost sales when: (1) They were made within an extended period of time in "substantial quantities," in accordance with sections 773(b)(2)(B) and (C) of the Act, and 2) based on our comparison of prices to the weighted-average COPs for the POR, they were at prices which would not permit the recovery of all costs within a reasonable period of time, in accordance with section 773(b)(2)(D) of the Act.

We found that, for certain products, more than 20 percent of Cutrale's and Fischer's home market sales were at prices less than the COP and, in addition, such sales did not provide for the recovery of costs within a reasonable period of time. We therefore excluded these sales from our analysis. We used the remaining sales as the basis for determining NV for Cutrale and Fischer in accordance with section 773(b)(1) of the Act.

E. Calculation of Normal Value Based on Comparison Market Prices

1. Cutrale

For Cutrale, we calculated NV based on ex-factory prices to unaffiliated customers. We made adjustments, where appropriate, to the starting price for billing adjustments, in accordance

with 19 CFR 351.401(c). We also made adjustments, where appropriate, to the starting price for Brazilian taxes, in accordance with section 773(a)(6)(B)(iii) of the Act.

In addition we made deductions pursuant to section 773(a)(6)(C) of the Act for home market credit expenses (offset by interest revenue). We recalculated Cutrale's home market credit expenses to base the calculation on the gross unit price net of taxes and billing adjustments. Where applicable, in accordance with 19 CFR 351.410(e), we offset any commission paid on a U.S. sale by reducing the NV by the amount of home market indirect selling expenses and inventory carrying costs, up to the amount of the U.S. commission. We capped Cutrale's interest revenue by the amount of credit expenses, in accordance with our practice. *See, e.g., 2005–2007 OJ from Brazil* at Comment 7; *2007–2008 OJ from Brazil* at Comment 3, and *2008–2009 OJ from Brazil* at Comment 2. We recalculated home market inventory carrying costs using the manufacturing costs reported in Cutrale's most recent cost response, adjusted as noted in the "Calculation of Cost of Production" section of this notice, above. For further discussion of these adjustments, see the Cutrale Sales Calculation Memo.

We deducted home market packing costs and added U.S. packing costs, where appropriate, in accordance with sections 773(a)(6)(A) and (B) of the Act.

Finally, we made adjustments for differences in costs attributable to differences in the physical characteristics of the merchandise, in accordance with section 773(a)(6)(C)(ii) of the Act and 19 CFR 351.411.

2. Fischer

We calculated NV based on delivered prices to unaffiliated customers. We made adjustments, where appropriate, to the starting price for billing adjustments and other discounts in accordance with 19 CFR 351.401(c). We also made adjustments, where appropriate, to the starting price for Brazilian taxes, in accordance with section 773(a)(6)(B)(iii) of the Act. We made deductions for foreign inland freight expenses and inland insurance expenses, in accordance with section 773(a)(6)(B)(ii) of the Act.

In addition, we made deductions pursuant to section 773(a)(6)(C) of the Act for home market credit expenses (offset by interest revenue). We capped Fischer's interest revenue by the amount of credit expenses, in accordance with our practice. *See, e.g, 2005–2007 OJ from Brazil* at Comment 7; *2007–2008 OJ from Brazil* at Comment 3, and *2008–2009 OJ from Brazil* at Comment 2.

We deducted home market packing costs and added U.S. packing costs, in accordance with sections 773(a)(6)(A) and (B) of the Act.

Finally, we made adjustments for differences in costs attributable to differences in the physical characteristics of the merchandise, in accordance with section 773(a)(6)(C)(ii) of the Act and 19 CFR 351.411.

F. Calculation of Normal Value Based on Constructed Value

Section 773(a)(4) of the Act provides that where NV cannot be based on comparison market sales, NV may be based on CV. Accordingly, for those OJ products for which we could not determine the NV based on comparison-market sales, either because there were no useable sales of a comparable product or all sales of the comparable products failed the COP test, we based NV on CV.

Section 773(e) of the Act provides that CV shall be based on the sum of the cost of materials and fabrication for the imported merchandise, plus amounts for SG&A expenses, profit, and U.S. packing costs. We calculated the cost of materials and fabrication based on the methodology described in the "Calculation of Cost of Production" section, above. We based SG&A and profit for Fischer on the actual amounts incurred and realized by the respondents in connection with the production and sale of the foreign like product in the ordinary course of trade for consumption in the home market, in accordance with section 773(e)(2)(A) of the Act.

For comparisons to CEP, we deducted home market direct selling expenses from CV. *Id.* We also made adjustments, where applicable, for home market indirect selling expenses to offset U.S. commissions. *See* 19 CFR 351.410(e).

Currency Conversion

We made currency conversions into U.S. dollars, in accordance with section 773A of the Act and 19 CFR 351.415, based on the exchange rates in effect on the dates of the U.S. sales as certified by the Federal Reserve Bank.

Preliminary Results of the Review

We preliminarily determine that weighted-average dumping margins exist for the respondents for the period March 1, 2009, through February 28, 2010, as follows:

Manufacturer/exporter	Percent margin
Sucocitrico Cutrale, S.A.	0.41 (*de minimis*)
Fischer S.A. Comercio, Industria, and Agricultura.	3.96
Coinbra-Frutesp (SA)	*
Montecitrus Trading S.A.	*

* No shipments or sales subject to this review.

Disclosure and Public Hearing

The Department will disclose to parties the calculations performed in connection with these preliminary results within five days of the date of publication of this notice. *See* 19 CFR 351.224(b). Pursuant to 19 CFR 351.309, interested parties may submit cases briefs not later than 30 days after the date of publication of this notice. Rebuttal briefs, limited to issues raised in the case briefs, may be filed not later than five days after the time limit for filing the case briefs. Parties who submit case briefs or rebuttal briefs in this proceeding are requested to submit with each argument: (1) A statement of the issue; (2) a brief summary of the argument; and (3) a table of authorities. *See* 19 CFR 351.309(c)(2).

Pursuant to 19 CFR 351.310(c), interested parties who wish to request a hearing, or to participate if one is requested, must submit a written request to the Assistant Secretary for Import Administration, Room 1870, within 30 days of the date of publication of this notice. Requests should contain: (1) The party's name, address and telephone number; (2) the number of participants; and (3) a list of issues to be discussed. *Id.* Issues raised in the hearing will be limited to those raised in the respective case briefs. The Department intends to issue the final results of this administrative review, including the results of its analysis of the issues raised in any written briefs, not later than 120 days after the date of publication of this notice, pursuant to section 751(a)(3)(A) of the Act.

Assessment Rates

Upon completion of the administrative review, the Department shall determine, and CBP shall assess, antidumping duties on all appropriate entries, in accordance with 19 CFR 351.212. The Department will issue appropriate appraisement instructions for the companies subject to this review directly to CBP 15 days after the date of publication of the final results of this review.

We will calculate importer-specific *ad valorem* duty assessment rates based on the ratio of the total amount of

antidumping duties calculated for the examined sales to the total entered value of the sales. We will instruct CBP to assess antidumping duties on all appropriate entries covered by this review if any importer-specific assessment rate calculated in the final results of this review is above *de minimis.* Pursuant to 19 CFR 351.106(c)(2), we will instruct CBP to liquidate without regard to antidumping duties any entries for which the assessment rate is *de minimis. See* 19 CFR 351.106(c)(1). The final results of this review shall be the basis for the assessment of antidumping duties on entries of merchandise covered by the final results of this review and for future deposits of estimated duties, where applicable.

The Department clarified its "automatic assessment" regulation on May 6, 2003. *See Assessment Policy Notice.* This clarification will apply to entries of subject merchandise during the POR produced by companies included in these final results of review for which the reviewed companies did not know that the merchandise they sold to the intermediary (*e.g.,* a reseller, trading company, or exporter) was destined for the United States. In such instances, we will instruct CBP to liquidate unreviewed entries at the all-others rate if there is no rate for the intermediary involved in the transaction. *See Assessment Policy Notice* for a full discussion of this clarification.

Cash Deposit Requirements

The following cash deposit requirements will be effective for all shipments of the subject merchandise entered, or withdrawn from warehouse, for consumption on or after the publication date of the final results of this administrative review, as provided by section 751(a)(2)(C) of the Act: (1) The cash deposit rate for each specific company listed above will be that established in the final results of this review, except if the rate is less than 0.50 percent and, therefore, *de minimis* within the meaning of 19 CFR 351.106(c)(1), in which case the cash deposit rate will be zero; (2) for previously reviewed or investigated companies not participating in this review, the cash deposit rate will continue to be the company-specific rate published for the most recent period; (3) if the exporter is not a firm covered in this review, or the original less than fair value (LTFV) investigation, but the manufacturer is, the cash deposit rate will be the rate established for the most recent period for the manufacturer of the merchandise; and (4) the cash deposit rate for all other manufacturers or exporters of NFC, and for FCOJM produced and/or exported by Cargill Citrus Limitada and Coinbra-Frutesp will continue to be 16.51 percent, the all-others rate made effective by the LTFV investigation. *See OJ Order,* 71 FR at 12184. These deposit requirements, when imposed, shall remain in effect until further notice.

Notification to Importers

This notice also serves as a preliminary reminder to importers of their responsibility under 19 CFR 351.402(f) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this review period. Failure to comply with this requirement could result in the Secretary's presumption that reimbursement of antidumping duties occurred and the subsequent assessment of double antidumping duties.

This administrative review and notice are published in accordance with sections 751(a)(1) and 777(i)(1) of the Act and 19 CFR 351.221.

Dated: March 31, 2011.

Ronald K. Lorentzen,

Deputy Assistant Secretary for Import Administration.

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DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–831]

Garlic From the People's Republic of China: Rescission of Antidumping Duty New Shipper Reviews

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

SUMMARY: On November 12, 2010, the Department of Commerce (Department) published preliminary results for the new shipper reviews (NSRs) of fresh garlic from the People's Republic of China (PRC) covering the period of review (POR) November 1, 2008, through October 31, 2009. *See Fresh Garlic From the People's Republic of China: Preliminary Results of New Shipper Reviews and Preliminary Rescission, in Part,* 75 FR 69415 (November 12, 2010) (*Preliminary Results*). The reviews covered three respondents: Jinxiang Chengda Imp & Exp Co., Ltd. (Chengda), Zhengzhou Huachao Industrial Co., Ltd. (Huachao), and Jinxiang Yuanxin Imp & Exp Co., Ltd. (Yuanxin).

As discussed below, we preliminarily found that Yuanxin's and Huachao's sales were *bona fide* and that these sales were made in the United States at prices below normal value (NV). In addition, we found Chengda's sales to be not *bona fide,* and announced our preliminary intent to rescind Chengda's new shipper review. For the final results of this review, we are finding the sales of all three respondents, Chengda, Huachao, and Yuanxin, to be not *bona fide.* Therefore, because there were no other shipments or entries by these three companies during the POR, we are rescinding these new shipper reviews.

DATES: *Effective Date:* April 7, 2011.

FOR FURTHER INFORMATION CONTACT: Scott Lindsay, AD/CVD Operations, Office 6, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW., Washington, DC 20230; telephone: (202) 482–0780.

SUPPLEMENTARY INFORMATION:

Background

Since the *Preliminary Results,* the following events have occurred. On December 2, 2010, surrogate value information was placed on the record by Huachao. On December 30, 2010, the Department extended the time limit for the final results of this new shipper review. On January 26, 2011, the Department issued a supplemental questionnaire to Yuanxin. On January 27, 2011, the Department issued a supplemental questionnaire to Huachao. On February 4, 2011, the Department issued a letter to Yuanxin concerning the business proprietary designation of the company's Web site address.

On February 4, 2011, the Department issued the briefing schedule for briefs addressing all issues except the *bona fides* of Huachao's and Yuanxin's respective sales. On February 8, 2011, Yuanxin requested an extension to the deadlines as established in the February 4, 2011 briefing schedule. On February 9, 2011, the Department issued an extension of this briefing schedule, with briefs due February 17, 2011, and rebuttal briefs due February 22, 2011. On February 14, 2011, the Department placed information related to Jinxiang Hejia Co., Ltd.'s NSR sale to the United States, from the 2007/2008 NSR, on the record of this review. Huachao and Yuanxin submitted supplemental questionnaire responses on February 14, 2011. Yuanxin also submitted its case brief on February 14, 2011. On February 15, 2011, the Department placed memoranda on the record of this review that included information related to

Yuanxin's domain name registration and the corporate records of the importers and customers of each of the exporters involved in this review. On February 17, 2011, Huachao and Chengda submitted case briefs.

On February 18, 2011, the Department issued the briefing schedule for briefs addressing only the *bona fides* of Huachao's and Yuanxin's respective sales. Additionally, on February 18, 2011, the Fresh Garlic Producers Association and its individual members (Christopher Ranch L.L.C., the Garlic Company, Valley Garlic, and Vessey and Company, Inc.) (collectively, Petitioners) requested an extension of the February 22, 2011 deadline for rebuttal briefs not related to the *bona fides* of Huachao's and Yuanxin's respective sales. On February 22, 2011, the Department granted Petitioners' February 18, 2011 request for an extension to the rebuttal briefs deadline, the new deadline becoming February 25, 2011. On February 24, 2011, Petitioners submitted a rebuttal to Huachao's February 14, 2011 supplemental questionnaire response. On February 25, 2011, Petitioners submitted rebuttal briefs for all three respondents. Also, on February 25, 2011, Petitioners submitted a brief regarding whether Huachao's POR sale was *bona fide.*

On March 1, 2011, Huachao requested an extension to the deadline of the *bona fides* rebuttal briefs as established in the Department's February 18, 2011 briefing schedule. On March 2, 2011, the Department granted Huachao's March 1, 2011 request for an extension, the new deadline for *bona fides* rebuttal briefs becoming March 7, 2011. On March 3, 2011, Huachao submitted a letter requesting that the Department reject Petitioners' February 24, 2011 submission on the grounds that it contained untimely new factual information. Further, Huachao argued that Petitioners' February 25, 2011 case brief also be rejected, as it relies upon information contained in the February 24, 2011 submission. The information in question involves the nature of the United States garlic market and the appropriate benchmark to be used in determining the *bona fide* nature of Huachao's sale. The Department found this information to be relevant to the information provided by Huachao in its supplemental response, which addressed Department questions regarding whether Huachao's sale was *bona fide.* Thus, the Department concluded that Petitioners' submission was timely rebuttal information allowed for under 19 CFR 351.301(c). Finally, on March 7, 2011, Huachao submitted a rebuttal brief to the February 25, 2011 case brief submitted by Petitioners regarding the *bona fides* of its sale.

On March 16, 2011, Department officials met with Chengda's counsel to discuss issues related to the case briefs. *See* Memorandum for the File from Lingjun Wang, Case Analyst, AD/CVD Operations, Office 6, "Meeting with Counsel for the Jinxiang Chengda Import & Export Co., Ltd.: New Shipper Review of the Antidumping Duty Order on Fresh Garlic from China" (March 16, 2011). On March 17, 2011, Department officials met with Petitioners' counsel to discuss issues related to the case briefs. *See* Memorandum for the File from David Lindgren, Case Analyst, AD/CVD Operations, Office 6, "Meeting with Counsel for the Petitioners: New Shipper Review of the Antidumping Duty Order on Fresh Garlic from China" (March 17, 2011).

Scope of the Order

The products covered by the order are all grades of garlic, whole or separated into constituent cloves, whether or not peeled, fresh, chilled, frozen, provisionally preserved, or packed in water or other neutral substance, but not prepared or preserved by the addition of other ingredients or heat processing. The differences between grades are based on color, size, sheathing, and level of decay. The scope of this order does not include the following: (a) garlic that has been mechanically harvested and that is primarily, but not exclusively, destined for non-fresh use; or (b) garlic that has been specially prepared and cultivated prior to planting and then harvested and otherwise prepared for use as seed. The subject merchandise is used principally as a food product and for seasoning. The subject garlic is currently classifiable under subheadings 0703.20.0010, 0703.20.0020, 0703.20.0090, 0710.80.7060, 0710.80.9750, 0711.90.6000, and 2005.90.9700 of the Harmonized Tariff Schedule of the United States (HTSUS). Although the HTSUS subheadings are provided for convenience and customs purposes, our written description of the scope of the order is dispositive. In order to be excluded from the order, garlic entered under the HTSUS subheadings listed above that is (1) mechanically harvested and primarily, but not exclusively, destined for non-fresh use or (2) specially prepared and cultivated prior to planting and then harvested and otherwise prepared for use as seed must be accompanied by declarations to CBP to that effect.

Analyses of Comments Received

In addition to commenting on the *bona fides* of Chengda's and Huachao's U.S. sales (*see Bona Fides Analysis* section below), the parties addressed, in their case and rebuttal briefs, three surrogate valuation issues: (1) What to use as the surrogate value for raw garlic bulbs; (2) which financial statements to use as the surrogate financial ratios; and (3) how to properly calculate the wage rate. Since, as discussed below, we are rescinding these reviews, the Department need not address the parties' comments on these issues pertaining to the calculation of the dumping margin.

Bona Fides Analysis

In conducting an NSR, the Department examines price, quantity, and other circumstances associated with the sale to determine if the sale was based on normal commercial considerations and presents an accurate representation of the company's normal business practices, and provides a future indicator of its future selling practice. *See Shandong Chenhe Int'l Trading Co.* v. *United States,* No. 08–00373, slip op. at 19 (Ct. Int'l Trade Nov. 22, 2010); *see also Tianjin Tiancheng Pharmaceutical Co., Ltd.* v. *United States,* 366 F. Supp. 2d 1246, 1250 (Ct. Int'l Trade 2005); and *Hebei New Donghua Amino Acid Co., Ltd.* v. *United States,* 374 F. Supp. 2d 1333, 1342 (Ct. Int'l Trade 2005). If the Department determines that the price was not based on normal commercial considerations or is atypical of the respondent's normal business practices, including other sales of comparable merchandise, the sale may be considered not *bona fide,* and, as such, cannot serve as a reasonable or reliable basis for calculating a dumping margin.

In the *Preliminary Results,* the Department found Chengda's POR sales to be not *bona fide.* The Department found that Huachao's POR sale, however, was made on a *bona fide* basis, noting that it would continue to examine all factors relating to the *bona fides* of that sale given the Department's concerns regarding the price, quantity, and payment terms of the sale. Likewise, the Department found that Yuanxin's POR sale was also made on a *bona fide* basis, noting that it would continue to examine the *bona fides* of the sale given the Department's concerns regarding the price, quantity, and atypicality of the product and transaction. Based on our continuing analyses of all aspects of the parties' sales, summarized below, and our analyses of supplemental questionnaire

responses, of information and documentation from a prior NSR placed on the record of this review, and of comments made by interested parties, the Department continues to find that Chengda's sales are not *bona fide,* and now finds that the sales of Yuanxin and Huachao are not *bona fide* as well. As such, the sales made by all three parties do not provide reasonable or reliable bases for calculating dumping margins.

Chengda

For the *Preliminary Results,* the Department analyzed the *bona fides* of Chengda's sales and preliminarily found Chengda's sales to the United States to be not *bona fide. See* "*Bona Fide* Nature of the Sale in the Antidumping Duty New Shipper Review of Fresh Garlic from the People's Republic of China (PRC): Jinxiang Chengda Imp & Exp Co., Ltd." (November 1, 2010). Since the *Preliminary Results,* both Chengda and Petitioners have submitted arguments regarding whether Chengda's POR shipment was *bona fide.* Significant portions of these arguments involve discussion of business proprietary information (BPI). Therefore, the Department's summaries of, and positions on, these arguments, in addition to our full analysis of the *bona fides* of Chengda's sales, are included in the memorandum, "Final Results of Antidumping Duty New Shipper Review of Fresh Garlic from the People's Republic of China: *Bona Fides* Analysis of Chengda Imp & Exp Co., Ltd.," issued concurrently with this **Federal Register** notice. Based on the Department's complete analysis of all the information on the record of this review regarding the *bona fides* of Chengda's NSR sales, the Department continues to find Chengda's sales not *bona fide* because (1) Chengda's sale prices are so high that they are atypical, aberrational, commercially unreasonable, and not indicative of future sales, and (2) Chengda's sales quantities are too small to reflect normal commercial practices of the garlic industry.

Huachao

For the *Preliminary Results,* the Department analyzed the *bona fides* of Huachao's sale and preliminarily found Huachao's sale to the United States to be *bona fide,* noting that we would continue to examine all factors relating to the *bona fides* of that sale given the Department's concerns regarding the price, quantity, and payment terms of the sale. *See* "*Bona Fide* Nature of the Sale in the Antidumping Duty New Shipper Review of Fresh Garlic from the People's Republic of China (PRC): Zhengzhou Huachao Industrial Co., Ltd." (November 1, 2010). After the *Preliminary Results,* the Department issued a supplemental questionnaire to Huachao. In addition, Petitioners filed a case brief and Huachao filed a rebuttal brief on whether Huachao's sale should be considered *bona fide.* Significant portions of these arguments involve discussion of BPI. Therefore, the Department's summaries of, and positions on, these arguments, in addition to our full analysis of the *bona fides* of Huachao's sale, are included in the memorandum "Final Results of Antidumping Duty New Shipper Review of Fresh Garlic from the People's Republic of China: *Bona Fides* Analysis of Zhengzhou Huachao Industrial Co., Ltd.," issued concurrently with this **Federal Register** notice. Based on the Department's complete analysis of all the information on the record of this review regarding the *bona fides* of Huachao's NSR sale, the Department finds Huachao's sale to be not *bona fide* because (1) Huachao's sale price is so high as to be commercially unreasonable and not indicative of the garlic industry, (2) Huachao's sales quantity is not commercially reasonable, (3) Huachao's function as the processor of its U.S. sale is atypical of its normal business practice, and (4) there are inconsistencies in the information provided by Huachao's customer in the United States, raising doubts about Huachao's description of the sale's structure.

Yuanxin

In the *Preliminary Results,* the Department found that Yuanxin's POR sale was made on a *bona fide* basis, noting that it would continue to examine the *bona fides* of the sale given the Department's concerns regarding the price, quantity, and atypical nature of the product and transaction. *See* "*Bona Fide* Nature of the Sale in the Antidumping Duty New Shipper Review of Fresh Garlic from the People's Republic of China (PRC): Jinxiang Yuanxin Imp & Exp Co., Ltd." (November 1, 2010). As noted in the background section, after the *Preliminary Results,* the Department issued a supplemental questionnaire to Yuanxin. In addition, new information with respect to the *bona fides* of Yuanxin's sale was placed on the record of this review. *See* the Department's February 14, 2011 memorandum to the file regarding Jinxiang Hejia Co., Ltd.'s NSR and Yuanxin's February 14, 2011 supplemental questionnaire response; *see also* the Department's February 15, 2011 memorandum to the file regarding Yuanxin's domain name registration and the Department's February 15, 2011 memorandum to the file regarding the corporate records of the importers and customers of each of the exporters involved in this review.

Significant portions of the issues involved in Yuanxin's *bona fides* include BPI. Therefore, we have addressed all of the arguments in a separate memorandum as part of our full *bona fides* analysis. *See* "Final Results of Antidumping Duty New Shipper Review of Fresh Garlic from the People's Republic of China: *Bona Fides* Analysis of Jinxiang Yuanxin Imp & Exp Co., Ltd.," issued concurrently with this **Federal Register** notice. Based on the Department's complete analysis of all the information on the record of this review regarding the *bona fides* of Yuanxin's NSR sale, the Department finds Yuanxin's sale to be not *bona fide* because (1) Yuanxin's sale price is so high as to be commercially unreasonable and not indicative of future sales, (2) Yuanxin's sales quantity is not representative of the garlic industry, and (3) the structure of Yuanxin's U.S. sale is of an unusual nature.

Rescission of New Shipper Reviews

For the foregoing reasons, the Department finds that the sales of all three new shippers are not *bona fide* and that these sales do not provide a reasonable or reliable basis for calculating a dumping margin. Because these non-*bona fide* sales were the only sales of subject merchandise during the POR, the Department is rescinding all three new shipper reviews in their entirety.

Notification to Importers

The Department will notify U.S. Customs and Border Protection that bonding is no longer permitted to fulfill security requirements for shipments by Chengda, Huachao, and Yuanxin of fresh garlic from the PRC entered, or withdrawn from warehouse, for consumption in the United States on or after the publication of this rescission notice in the **Federal Register**, and that a cash deposit of $4.71 per kilogram should be collected for all shipments of the subject merchandise entered, or withdrawn from warehouse, for consumption on or after the publication date of this notice, as provided for by section 751(a)(2)(C) of the Act, by Chengda, Huachao, and Yuanxin.

This notice is the only reminder to parties subject to the administrative protective order (APO) of their responsibility concerning the return or destruction of proprietary information

disclosed under the APO in accordance with 19 CFR 351.305(a)(3). Timely written notification of the return or destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and the terms of an APO is a sanctionable violation.

These new shipper reviews and notice are issued and published in accordance with sections 751(a)(2)(B) and 777(i) of the Act and 19 CFR 351.214.

Dated: March 31, 2011.

Ronald K. Lorentzen,

Deputy Assistant Secretary for Import Administration.

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DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–934]

1-Hydroxyethylidene-1, 1-Diphosphonic Acid From the People's Republic of China: Preliminary Results of Antidumping Duty Administrative Review and Intent To Rescind Review in Part

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

SUMMARY: In response to a timely request from Compass Chemical International LLC ("Petitioner"), the Department of Commerce ("Department") is conducting an administrative review of the antidumping duty order on 1-hydroxyethylidene-1, 1-diphosphonic acid ("HEDP") from the People's Republic of China ("PRC"). The period of review ("POR") is April 23, 2009, through March 31, 2010. This administrative review covers two exporters of the subject merchandise that are being individually examined as mandatory respondents.

The Department has preliminarily determined that one mandatory respondent, Jiangsu Jianghai Chemical Group Co., Ltd. ("Jiangsu Jianghai"), did not demonstrate that it is entitled to a separate rate. Therefore, the Department has treated Jiangsu Jianghai as part of the PRC-wide entity. The other mandatory respondent, Changzhou Wujin Fine Chemical Factory Co., Ltd. ("Wujin Fine"), reported that it did not ship subject merchandise to the United States during the POR. Because record evidence does not contradict Wujin Fine's no-shipment claim, the Department intends to rescind the administrative review with respect to this company. If these preliminary results are adopted in the final results of review, the Department will instruct U.S. Customs and Border Protection ("CBP") to assess antidumping duties on entries of subject merchandise during the POR for which the importer-specific assessment rates are above *de minimis.*

Interested parties are invited to comment on these preliminary results. Parties that submit comments are requested to submit with each argument a statement of the issue and a brief summary of the argument. The Department intends to issue the final results of this review no later than 120 days from the date of publication of this notice.

DATES: *Effective Date:* April 7, 2011.

FOR FURTHER INFORMATION CONTACT: Shawn Higgins, AD/CVD Operations, Office 4, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW., Washington, DC 20230; *telephone:* (202) 482–0679.

SUPPLEMENTARY INFORMATION:

Background

On April 28, 2009, the Department published the antidumping duty order on HEDP from the PRC in the **Federal Register**.[1] On April 1, 2010, the Department notified interested parties of their opportunity to request an administrative review of the antidumping duty order on HEDP from the PRC.[2] On April 30, 2010, Petitioner requested that the Department conduct an administrative review of Jiangsu Jianghai and Wujin Fine.[3] On May 28, 2010, the Department published a notice initiating an antidumping duty administrative review of the *Order* covering Jiangsu Jianghai and Wujin Fine during the period April 23, 2009, through March 31, 2010.[4]

The *Initiation Notice* notified parties that they must submit timely separate rate applications or separate rate certifications in order to qualify for a separate rate.[5] The Department did not receive any separate rate applications or separate rate certifications.

On June 7, 2010, the Department issued antidumping questionnaires to Jiangsu Jianghai and Wujin Fine.[6] In June and July 2010, Jiangsu Jianghai and Wujin Fine submitted letters certifying that they did not ship subject merchandise to the United States during the POR.[7] From July through September 2010, the Department requested and received import data and entry documentation from CBP. The Department placed this information on the record of this review and solicited comments from interested parties.[8] Petitioner, Jiangsu Jianghai, and Wujin Fine submitted comments on this import data and entry documentation in August and October 2010.[9] On October 25, 2010, the Department informed Jiangsu Jianghai that record CBP data

[1] *See 1-Hydroxyethylidene-1, 1-Diphosphonic Acid from India and the People's Republic of China: Antidumping Duty Orders,* 74 FR 19197 (April 28, 2009) ("*Order*").

[2] *See Antidumping or Countervailing Duty Order, Finding, or Suspended Investigation; Opportunity To Request Administrative Review,* 75 FR 16426 (April 1, 2010).

[3] *See* Letter from Petitioner to the Secretary of Commerce, "1-Hydroxyethylidene-1, 1-Diphosphonic Acid (HEDP) from The People's Republic of China (PRC): Request for Administrative Review" (April 30, 2010).

[4] *See Initiation of Antidumping and Countervailing Duty Administrative Reviews,* 75 FR 29976 (May 28, 2010) ("*Initiation Notice*").

[5] *Id.,* 75 FR at 29976–77.

[6] *See, e.g.,* Letter from Robert Bolling, Program Manager, AD/CVD Operations, Office 4, to Jiangsu Jianghai, "1-Hydroxyethylidene-1, 1-Diphosphonic Acid from the People's Republic of China: Antidumping Duty Administrative Review of Jiangsu Jianghai Chemical Group Co., Ltd." (June 7, 2010) ("antidumping questionnaire").

[7] *See* Letter from Jiangsu Jianghai to the Secretary of Commerce, "1-Hydroxyethylidene-1, 1-Diphosphonic Acid from the Republic of India and the People's Republic of China; A–570–934; Copy of Certification of No Shipments by Jiangsu Jianghai Chemical Group Co., Ltd." (July 13, 2010); Letter from Wujin Fine to the Secretary of Commerce, "1-Hydroxyethylidene-1, 1-Diphosphonic Acid from the Republic of India and the People's Republic of China; A–570–934; Notification by Changzhou Wujin Fine Chemical Factory Co., Ltd." (June 28, 2010).

[8] *See* Memorandum from Shawn Higgins, International Trade Compliance Analyst, AD/CVD Operations, Office 4, to Interested Parties, "2009–2010 Administrative Review of 1-Hydroxyethylidene-1, 1-Diphosphonic Acid from the People's Republic of China; Placing CBP Data and Entry Documents on the Record" (August 13, 2010); Memorandum from Shawn Higgins, International Trade Compliance Analyst, AD/CVD Operations, Office 4, to Interested Parties, "2009–2010 Administrative Review of 1-Hydroxyethylidene-1, 1-Diphosphonic Acid from the People's Republic of China; Placing CBP Data and Entry Documents on the Record" (September 24, 2010) ("CBP Data and Entry Documents").

[9] *See* Letter from Jiangsu Jianghai to the Secretary of Commerce, "1-Hydroxyethyidene-1, 1-Diphosphonic Acid from the Republic of India and the People's Republic of China; A–570–934; Comments on Customs and Border Protection Data by Jiangsu Jianghai Chemical Group Co., Ltd." (August 19, 2010); Letter from Wujin Fine to the Secretary of Commerce, "1-Hydroxyethyidene-1, 1-Diphosphonic Acid from the Republic of India and the People's Republic of China; A–570–934; Comments on Customs and Border Protection Data by Changzhou Wujin Fine Chemical Factory Co., Ltd." (August 19, 2010); Letter from Jiangsu Jianghai to the Secretary of Commerce, "1-Hydroxyethyidene-1, 1-Diphosphonic Acid from the Republic of India and the People's Republic of China; A–570–934; Comments on Customs and Border Protection Data by Jiangsu Jianghai Chemical Group Co., Ltd." (October 4, 2010); Letter from Petitioner to the Secretary of Commerce, "1-Hydroxyethidene-1, 1-Diphosphonic Acid from the People's Republic of China" (October 4, 2010).

and entry documentation indicated that Jiangsu Jianghai had a shipment of subject merchandise that entered the United States during the POR.[10] Further, the Department explained that it is necessary for Jiangsu Jianghai to provide the information requested by the Department in the antidumping questionnaire because the entry date of Jiangsu Jianghai's shipment was within the POR and there is no record evidence in this review of circumstances that compel the Department to employ an atypical methodology to determine the universe of sales to be examined during this review.[11]

In November and December 2010, Jiangsu Jianghai submitted timely responses to Sections A, C, and D of the antidumping questionnaire.[12] The Department issued a supplementary Sections A and C questionnaire and a supplementary Section D questionnaire to Jiangsu Jianghai on December 9, 2010, and December 17, 2010, respectively.[13] Jiangsu Jianghai neither responded to these supplementary questionnaires nor asked for extensions of time to respond.[14]

In response to the Department's November 12, 2010, letter providing all interested parties with an opportunity to submit comments regarding surrogate country and surrogate value selection,[15] Petitioner filed surrogate country and surrogate value comments in November and December 2010.[16]

On December 1, 2010, the Department extended the time period for completing the preliminary results of this administrative review until March 31, 2011.[17]

Scope of the Order

The merchandise subject to the order includes all grades of aqueous, acidic (non-neutralized) concentrations of 1-hydroxyethylidene-1, 1-diphosphonic acid,[18] also referred to as hydroxethlylidenediphosphonic acid, hydroxyethanediphosphonic acid, acetodiphosphonic acid, and etidronic acid. The CAS (Chemical Abstract Service) registry number for HEDP is 2809–21–4. The merchandise subject to the order is currently classified in the Harmonized Tariff Schedule of the United States ("HTSUS") at subheading 2931.00.9043. It may also enter under HTSUS subheading 2811.19.6090. While HTSUS subheadings are provided for convenience and customs purposes only, the written description of the scope of the order is dispositive.

Intent To Partially Rescind the Administrative Review

As stated above, Jiangsu Jianghai and Wujin Fine submitted letters certifying that they did not ship subject merchandise to the United States during the POR. To test these claims, the Department ran a CBP data query, issued no-shipment inquiries to CBP requesting that it provide any information that contradicted these no-shipment claims, and obtained entry documentation from CBP. After examining this information, the Department has preliminarily determined that Jiangsu Jianghai had a shipment of subject merchandise that entered the United States during the POR.[19] However, because the evidence on the record does not contradict Wujin Fine's no-shipment claim, the Department intends to rescind this administrative review with respect to Wujin Fine, pursuant to 19 CFR 351.213(d)(3).

Non-Market Economy Country Status

In every case conducted by the Department involving the PRC, the PRC has been treated as a non-market economy ("NME") country. In accordance with section 771(18)(C)(i) of the Tariff Act of 1930, as amended (the "Act"), any determination that a foreign country is an NME country shall remain in effect until revoked by the administering authority. None of the parties to this proceeding have contested NME treatment.

Separate Rates

In proceedings involving NME countries, the Department maintains a rebuttable presumption that all companies within the country are subject to government control.[20] In accordance with this presumption, all exporters of subject merchandise in an NME country are assigned a single rate unless an exporter can affirmatively demonstrate its entitlement to a separate, company-specific margin by showing an absence of government control, both in law and in fact, with respect to export activities.[21] To determine whether *de jure* government control exists, the Department examines evidence of: (1) An absence of restrictive stipulations associated with an individual exporter's business and export license; (2) any legislative enactments decentralizing control of companies; or (3) any other formal measures by the government decentralizing control of companies.[22] Evidence supporting *de facto* absence of government control includes: (1) Whether each exporter sets its own export prices independently of the government; (2) whether each exporter has the authority to negotiate and sign contracts and other agreements; (3) whether each exporter has autonomy from the government in making decisions regarding the selection of

[10] *See* Letter from Robert Bolling, Program Manager, AD/CVD Operations, Office 4, to Jiangsu Jianghai, "1-Hydroxyethylidene-1, 1-Diphosphonic Acid from the People's Republic of China: Antidumping Duty Administrative Review of Jiangsu Jianghai Chemical Group Co., Ltd." (October 25, 2010) ("Shipment Letter") at 2.

[11] *Id.*

[12] *See* Memorandum from Jiangsu Jianghai to the Secretary of Commerce, "1-Hydroxyethylidene-1, 1-Diphosphonic Acid from the Republic of India and the People's Republic of China; A–570–934; Section A Response" (November 19, 2010) ("Section A Response"); Memorandum from Jiangsu Jianghai to the Secretary of Commerce, "1-Hydroxyethylidene-1, 1-Diphosphonic Acid from the Republic of India and the People's Republic of China; A–570–934; Section C Response" (December 1, 2010); Memorandum from Jiangsu Jianghai to the Secretary of Commerce, "1-Hydroxyethylidene-1, 1-Diphosphonic Acid from the Republic of India and the People's Republic of China; A–570–934; Section D Response of Jiangsu Jianghai Chemical Group Co., Ltd." (December 9, 2010).

[13] *See* Letter from Robert Bolling, Program Manager, AD/CVD Operations, Office 4, to Jiangsu Jianghai, "Sections A & C Supplemental Questionnaire" (December 9, 2010) ("Sections A & C Supplemental"); Letter from Robert Bolling, Program Manager, AD/CVD Operations, Office 4, to Jiangsu Jianghai, "Section D Supplemental Questionnaire" (December 17, 2010).

[14] *See* Memorandum from Shawn Higgins, International Trade Compliance Analyst, AD/CVD Operations, Office 4, to the File, "Administrative Review of the Antidumping Duty Order on 1-Hydroxyethylidene-1, 1-Diphosphonic Acid from the People's Republic of China: Telephone Conversation With Counsel for Jiangsu Jianghai Chemical Group Co., Ltd." (January 3, 2011) ("Telephone Conversation Memo").

[15] *See* Letter from Robert Bolling, Program Manager, AD/CVD Operations, Office 4, to All Interested Parties, "Administrative Review of the Antidumping Duty Order on 1-Hydroxyethylidene-1, 1-Diphosphonic Acid from the People's Republic of China: Request for Comments on Selection of Surrogate Country and Surrogate Values" (November 12, 2010).

[16] *See* Letter from Petitioner to the Secretary of Commerce, "1-Hydroxyethylidene-1, 1-Diphosphonic Acid from the People's Republic of China" (November 30, 2010); Letter from Petitioner to the Secretary of Commerce, "1-Hydroxyethylidene-1, 1-Diphosphonic Acid from the People's Republic of China" (December 16, 2010).

[17] *See 1-Hydroxyethylidene-1, 1-Diphosphonic Acid From the People's Republic of China: Extension of the Time Limit for the Preliminary Results of the Antidumping Duty Administrative Review,* 75 FR 74684 (December 1, 2010).

[18] $C_2H_8O_7P_2$ or $C(CH_3)(OH)(PO_3H_2)_2$.

[19] *See* Shipment Letter at 2.

[20] *See Sigma Corp.* v. *United States,* 117 F.3d 1401, 1405–06 (Fed. Cir. 1997).

[21] *Id.,* 117 F.3d at 1405.

[22] *See Final Determination of Sales at Less Than Fair Value: Sparklers From the People's Republic of China,* 56 FR 20588, 20589 (May 6, 1991) ("*Sparklers*"); *Qingdao Taifa Group Co., Ltd.* v. *United States,* 710 F. Supp. 2d 1352, 1355–56 (Ct. Int'l Trade 2010) ("*Qingdao Taifa*") (citing *Coal. for the Pres. of Am. Brake Drum and Rotor Aftermarket Mfrs.* v. *United States*, 44 F. Supp. 2d 229, 242 (Ct. Int'l Trade 1999) ("*Brake Drum*")).

management; and (4) whether each exporter can retain the proceeds from its export sales and make independent decisions regarding disposition of profits or financing of losses.[23]

On November 19, 2010, Jiangsu Jianghai submitted its response to Section A of the antidumping questionnaire.[24] Jiangsu Jianghai's submission was incomplete and contained information insufficient to overcome the presumption that Jiangsu Jianghai's export activities are controlled, in law and in fact, by the PRC government. On December 9, 2010, the Department issued Jiangsu Jianghai a supplementary questionnaire that requested Jiangsu Jianghai to correct these deficiencies and provide additional information necessary to determine whether it qualified for a separate rate.[25] On January 3, 2011, the Department received confirmation that Jiangsu Jianghai would not provide the Department with the information requested in the December 9, 2010 supplementary questionnaire.[26] Therefore, by submitting incomplete and unverifiable responses to questions regarding government control of its export activities and not responding to the Department's supplementary questionnaire, Jiangsu Jianghai has prevented the Department from further investigating the facts related to the question of government control and failed to demonstrate an absence of *de jure* and *de facto* government control under the criteria identified in *Sparklers* and *Silicon Carbide*.

Moreover, by submitting incomplete and unverifiable responses to the antidumping questionnaire and not responding to either the Department's December 9, 2010, supplementary Sections A and C questionnaire or its December 17, 2010, supplementary Section D questionnaire, Jiangsu Jianghai did not meet its requirement to fully participate in this administrative review by responding to all information that has been requested by the Department.[27] The Department does not permit respondents to selectively choose which requests to respond to or which information to submit.[28] Jiangsu Jianghai cannot qualify for separate rate status by participating in only limited aspects of this review while simultaneously failing to provide complete and verifiable data with respect to other required elements.[29]

Therefore, the Department has preliminarily determined that Jiangsu Jianghai does not qualify for a separate rate because it has failed to demonstrate an absence of *de jure* and *de facto* government control under the criteria identified in *Sparklers* and *Silicon Carbide* and did not fully participate in this administrative review. Accordingly, the Department is treating Jiangsu Jianghai as part of the PRC-wide entity. Moreover, because Jiangsu Jianghai's responses to the antidumping questionnaire cannot be verified and Jiangsu Jianghai did not remedy the deficiencies noted in the Department's supplementary questionnaires, the Department has, in accordance with sections 782(d) and (e) of the Act, preliminarily determined to disregard all of Jiangsu Jianghai's responses to the antidumping questionnaire.

Use of Facts Available and Adverse Facts Available ("AFA")

Section 776(a) of the Act provides that the Department shall apply "facts otherwise available" if: (1) Necessary information is not on the record, or (2) an interested party or any other person (A) withholds information that has been requested, (B) fails to provide information within the deadlines established, or in the form and manner requested by the Department, subject to subsections (c)(1) and (e) of section 782 of the Act, (C) significantly impedes a proceeding, or (D) provides information that cannot be verified as provided by section 782(i) of the Act.

Further, Section 776(b) of the Act provides that the Department may use an adverse inference in applying the facts otherwise available when a party has failed to cooperate by not acting to the best of its ability to comply with a request for information. Such an adverse inference may include reliance on information derived from the petition, the final determination, a previous administrative review, or other information placed on the record.

Application of Total AFA to the PRC-Wide Entity

In the *Initiation Notice,* the Department stated that if one of the companies for which this review was initiated "does not qualify for a separate rate, all other exporters of {HEDP from the PRC} that have not qualified for a separate rate are deemed to be covered by this review as part of the single PRC entity. * * *" As noted above, Jiangsu Jianghai, one of the companies for which this review was initiated, has not qualified for a separate rate. Therefore, the PRC-wide entity is now under review.

As explained above, Jiangsu Jianghai, as part of the PRC-wide entity, submitted incomplete and unverifiable responses to the antidumping questionnaire and did not respond to either the Department's December 9, 2010, supplementary Sections A and C questionnaire or its December 17, 2010 supplementary Section D questionnaire. For these reasons, the Department has preliminarily determined that the PRC-wide entity (1) withheld information that was requested, (2) failed to provide information within the deadlines established and in the form and manner requested by the Department, (3) significantly impeded this proceeding, and (4) provided information that cannot be verified. Therefore, in accordance with subsections 776(a)(2)(A) through (D) of the Act, the Department has preliminarily based the dumping margin of the PRC-wide entity on the facts otherwise available. Further, because the PRC-wide entity failed to cooperate by not acting to the best of its ability to comply with the Department's requests for information, the Department has preliminarily determined, pursuant to section 776(b) of the Act, to use an inference that is adverse to the interests of the PRC-wide entity in selecting from among the facts otherwise available.

Selection of the AFA Rate

Section 776(b) of the Act and 19 CFR 351.308(c)(1) provide that the Department's adverse inference "may include reliance on information derived from (1) the petition, (2) a final determination in the investigation, (3) any previous review or determination, or (4) any other information placed on the record." In selecting a rate for use as AFA, the Department selects a rate that is sufficiently adverse "as to effectuate the purpose of the facts available rule to induce respondents to provide the Department with complete and accurate

[23] *See Notice of Final Determination of Sales at Less Than Fair Value: Silicon Carbide From the People's Republic of China*, 59 FR 22585, 22586–87 (May 2, 1994) ("*Silicon Carbide,*"); *Qingdao Taifa*, 710 F. Supp. 2d at 1356 (citing *Brake Drum*, 44 F. Supp. 2d at 243).

[24] *See* Section A Response.

[25] *See* Sections A & C Supplemental at Enclosure 1–3.

[26] *See* Telephone Conversation Memo.

[27] *See* antidumping questionnaire at G–1 ("[A]s a respondent, your company must wholly and fully participate in this administrative review. * * * a respondent must respond to all information that has been requested by the Department"); *Wooden Bedroom Furniture from the People's Republic of China: Final Results of Antidumping Duty Administrative Review and New Shipper Reviews,* 74 FR 41374 (August 17, 2009) ("*Furniture*") and accompanying Issues and Decision Memorandum at Comment 32.

[28] *See* antidumping questionnaire at G–1.

[29] *See Furniture,* and accompanying Issues and Decision Memorandum at Comment 32; *see also* antidumping questionnaire at G–1.

information in a timely manner."[30] Furthermore, it is the Department's practice to ensure "that the party does not obtain a more favorable result by failing to cooperate than if it had cooperated fully"[31] and to select "the highest rate on the record of the proceeding"[32] that can be corroborated, to the extent practicable.[33] Therefore, as AFA, the Department has preliminarily assigned the PRC-wide entity a dumping margin of 72.42 percent, which was the margin calculated in the petition, as adjusted by the Department for initiation, and is the highest dumping margin on the record of this proceeding.

Corroboration of Secondary Information

Section 776(c) of the Act provides that, when the Department relies on secondary information rather than on information obtained in the course of an investigation or review, it shall, to the extent practicable, corroborate that information from independent sources that are reasonably at its disposal. Secondary information is defined as information derived from the petition that gave rise to the investigation or review, the final determination concerning the subject merchandise, or any previous review under section 751 of the Act concerning the subject merchandise.[34] "Corroborate" means that the Department will satisfy itself that the secondary information to be used has probative value.[35] To corroborate secondary information, the Department will, to the extent practicable, examine the reliability and relevance of the information to be used.[36] Independent sources used to corroborate such information may include, for example, published price lists, official import statistics and customs data, and information obtained from interested parties during the particular investigation or review.[37]

To corroborate the 72.42 percent petition rate, the Department first revisited its pre-initiation analysis of the information in the petition. During the initiation of the antidumping investigation of HEDP from the PRC, the Department examined evidence supporting the calculations in the petition and the supplemental information provided by Petitioner to determine the probative value of the margins alleged in the petition.[38] During the Department's pre-initiation analysis, it examined the information used as the basis of export price ("EP") and normal value ("NV") in the petition, and the calculations used to derive the alleged margins.[39] Also during its pre-initiation analysis, the Department examined information from various independent sources provided either in the petition or in supplements to the petition, which corroborated key elements of the EP and NV calculations.[40]

To further corroborate the 72.42 percent petition rate, the Department examined the information on the record of this administrative review. Because the Department has, in accordance with section 782(d) of the Act, disregarded all of Jiangsu Jianghai's responses to the antidumping questionnaire, the Department preliminarily determined that the only information on the record of this administrative review that can be used for purposes of corroboration are the entry documents provided by CBP.[41] These entry documents—particularly the commercial invoice for Jiangsu Jianghai's single entry of subject merchandise during the POR—establish that Jiangsu Jianghai's U.S. price approximates the U.S. price in the petition.[42] Therefore, the Department has preliminarily determined that the U.S. price in the petition reflects commercial reality.

For these reasons, the Department has preliminarily determined that the 72.42 percent petition rate has probative value and, therefore, is corroborated to the extent practicable, in accordance with section 776(c) of the Act. Moreover, because the information on the record of this administrative review that can be used for purposes of corroboration approximate the information used as a basis for the petition rate, the Department is satisfied that the 72.42 percent petition rate reflects commercial reality.

Preliminary Results of Review

The Department has preliminarily determined that the following weighted-average dumping margins exist for the period April 23, 2009, through March 31, 2010:

Exporter	Antidumping duty percent margin
PRC-Wide Entity[43]	72.42

Comments

Interested parties may submit written comments no later than 30 days after the date of publication of these preliminary results of review.[44] Rebuttal comments must be limited to the issues raised in the written comments and may be filed no later than 35 days after the date of publication.[45] Parties submitting written comments or rebuttal comments are requested to provide the Department with an additional copy of those comments on CD–ROM. Any interested party may request a hearing within 30 days of publication of these preliminary results.[46] Any hearing, if requested, ordinarily will be held two days after the scheduled date for submission of rebuttal briefs.[47] Parties should confirm by telephone the date, time, and

[30] *See Notice of Final Determination of Sales at Less Than Fair Value: Static Random Access Memory Semiconductors From Taiwan,* 63 FR 8909, 8932 (February 23, 1998).

[31] *See* Statement of Administrative Action accompanying the Uruguay Round Agreements Act, H. Doc. No. 316, 103d Cong., 2d Session at 870 (1994) ("SAA"); *Brake Rotors From the People's Republic of China: Final Results and Partial Rescission of the Seventh Administrative Review; Final Results of the Eleventh New Shipper Review,* 70 FR 69937, 69939 (November 18, 2005).

[32] *See Certain Frozen Warmwater Shrimp from Brazil: Final Results and Partial Rescission of Antidumping Duty Administrative Review,* 73 FR 39940, 39942 (July 11, 2008).

[33] *See Fujian Lianfu Forestry Co., Ltd.* v. *United States,* 638 F. Supp. 2d 1325, 1336 (Ct. Int'l Trade 2009).

[34] *See* SAA at 870.

[35] *Id.*

[36] *See Tapered Roller Bearings and Parts Thereof, Finished and Unfinished From Japan, and Tapered Roller Bearings Four Inches or Less in Outside Diameter, and Components Thereof, From Japan; Preliminary Results of Antidumping Duty Administrative Reviews and Partial Termination of Administrative Reviews,* 61 FR 57391, 57392 (November 6, 1996), unchanged in *Tapered Roller Bearings and Parts Thereof, Finished and Unfinished From Japan, and Tapered Roller Bearings, Four Inches or Less in Outside Diameter, and Components Thereof, From Japan; Final Results of Antidumping Duty Administrative Reviews and Termination in Part,* 62 FR 11825 (March 13, 1997).

[37] *See Notice of Preliminary Determination of Sales at Less Than Fair Value: High and Ultra-High Voltage Ceramic Station Post Insulators from Japan,* 68 FR 35627, 35629 (June 16, 2003), unchanged in *Notice of Final Determination of Sales at Less Than Fair Value: High and Ultra-High Voltage Ceramic Station Post Insulators from Japan,* 68 FR 62560 (November 5, 2003); *Notice of Final Determination of Sales at Less Than Fair Value: Live Swine From Canada,* 70 FR 12181, 12183–84 (March 11, 2005).

[38] *See 1-Hydroxyethylidene-1, 1-Diphosphonic Acid from the Republic of India and the People's Republic of China: Initiation of Antidumping Duty Investigations,* 73 FR 20023, 20025–26 (April 14, 2008) ("*Investigation Initiation*"); *1-Hydroxyethylidene-1, 1-Diphosphonic Acid from the People's Republic of China: Final Determination of Sales at Less Than Fair Value,* 74 FR 10545, 10547 (March 11, 2009) ("*Final Determination*").

[39] *See Investigation Initiation,* 73 FR at 20025–26; *Final Determination,* 74 FR at 10547.

[40] *See Final Determination,* 74 FR at 10547.

[41] *See* CBP Data and Entry Documents at Attachment 1.

[42] *See* Memorandum from Shawn Higgins, International Trade Compliance Analyst, AD/CVD Operations, Office 4, to the File, "1-Hydroxyethylidene-1, 1-Diphosphonic Acid from the People's Republic of China: Corroboration Memorandum for Preliminary Results of Administrative Review" (March 31, 2011).

[43] Jiangsu Jianghai is part of the PRC-wide entity.

[44] *See* 19 CFR 351.309(c)(1)(ii).

[45] *See* 19 CFR 351.309(d).

[46] *See* 19 CFR 351.310(c).

[47] *See* 19 CFR 351.310(d).

location of the hearing two days before the scheduled date.

The Department will issue the final results of this administrative review, which will include the results of its analysis of issues raised in the briefs, within 120 days of publication of these preliminary results, in accordance with 19 CFR 351.213(h)(1), unless the time limit is extended.

Assessment Rates

Pursuant to 19 CFR 351.212, the Department will determine, and CBP shall assess, antidumping duties on all appropriate entries of subject merchandise in accordance with the final results of this review. The Department intends to instruct CBP to liquidate entries containing subject merchandise exported by the PRC-wide entity at the PRC-wide rate the Department determines in the final results of this review. The Department intends to issue appropriate assessment instructions directly to CBP 15 days after publication of the final results of this review.

Cash Deposit Requirements

The following cash deposit requirements will be effective upon publication of the final results of this administrative review for all shipments of the subject merchandise from the PRC entered, or withdrawn from warehouse, for consumption on or after the publication date, as provided for by section 751(a)(2)(C) of the Act: (1) For previously investigated or reviewed PRC and non-PRC exporters not listed above that have separate rates, the cash deposit rate will continue to be the exporter-specific rate published for the most recent period; (2) for all PRC exporters of subject merchandise which have not been found to be entitled to a separate rate, the cash deposit rate will be the PRC-wide rate established in the final results of this review; and (3) for all non-PRC exporters of subject merchandise which have not received their own rate, the cash deposit rate will be the rate applicable to the PRC exporters that supplied that non-PRC exporter. These deposit requirements, when imposed, shall remain in effect until further notice.

Notification to Importers

This notice also serves as a preliminary reminder to importers of their responsibility under 19 CFR 351.402(f) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this review period. Failure to comply with this requirement could result in the Secretary presuming that reimbursement of antidumping duties occurred and, subsequently, the assessment of double antidumping duties.

The Department is issuing and publishing these preliminary results of administrative review in accordance with sections 751(a)(1) and 777(i)(1) of the Act and 19 CFR 351.221(b)(4).

Dated: March 31, 2011.

Ronald K. Lorentzen,

Deputy Assistant Secretary for Import Administration.

[FR Doc. 2011–8347 Filed 4–6–11; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XA358

New England Fishery Management Council (NEFMC); 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) will hold a 3-day meeting on Tuesday through Thursday, April 26–28, 2011, to consider actions affecting New England fisheries in the exclusive economic zone (EEZ).

DATES: The meeting will be held on Tuesday, April 26, 2011 through Thursday, April 28, 2011. The meeting will begin at 9 a.m. on Tuesday, April 26th and at 8:30 a.m. on Wednesday, April 27th and Thursday, April 28th.

ADDRESSES: The meeting will be held at the Mystic Hilton Hotel, 20 Coogan Boulevard, Mystic, CT 06355; telephone: (860) 572–0731; fax: (860) 572–0238.

Council address: New England Fishery Management Council, 50 Water Street, Mill 2, Newburyport, MA 01950; telephone: (978) 465–0492.

FOR FURTHER INFORMATION CONTACT: Paul J. Howard, Executive Director, New England Fishery Management Council; telephone: (978) 465–0492.

SUPPLEMENTARY INFORMATION:

Tuesday, April 26, 2011

Following introductions and any announcements, the Council will receive brief reports from its Chairman and Executive Director, the NOAA Fisheries Regional Administrator (Northeast Region), Northeast Fisheries Science Center and Mid-Atlantic Fishery Management Council liaisons, NOAA General Counsel, representatives of the U.S. Coast Guard and the Atlantic States Marine Fisheries Commission, as well as staff from the Vessel Monitoring Systems Operations and Law Enforcement offices. There also will be a review of any experimental fishery permit applications that have been made available for review since the January Council meeting. The Council will then receive a presentation and discuss one of its 2011 priorities, a proposed NEFMC-sponsored catch shares workshop. The discussion will include consideration and possible approval of a workshop goal and objectives. Prior to a break, Mr. Eric Schwaab, Assistant Administrator for NOAA Fisheries, will address the Council about the agency's management review of fisheries in the Northeast. The focus will be on the relationships among the NEFMC, the Northeast Regional Office, and the Northeast Fisheries Science Center and factors that affect the effectiveness of the three entities to carry out their responsibilities under fisheries law. Following a break, an open public period is scheduled for any interested party who wishes to provide brief comments on issues relevant to Council business but not otherwise listed on the meeting agenda. A representative of the Department of the Interior will summarize that agency's offshore wind initiative, including the Maine, Massachusetts, and Rhode Island Task Force efforts to date. The day will conclude on Tuesday with a report from the Council's Scientific and Statistical Committee (SSC). Items for review and discussion, along with SSC recommendations, include the following: (1) A review of the Massachusetts Fisheries Institute report *Economic and Scientific Conditions in the Mass. Multispecies Groundfishery;* (2) recommendations for a *FSV Bigelow* survey calibration method that would be used to determine skate Allowable Biological Catch (ABC) and the status of the skate complex resource; (3) guidance to the Whiting Plan Development Team on options and methods for determining ABCs for silver, red and offshore hake; and (4) a report on conclusions from a peer review panel that evaluated the NEFMC Habitat Plan Development Team's swept area seabed impact (SASI) model.

Wednesday, April 27, 2011

The second session will begin with a report from the Council's Research Steering Committee about several final cooperative research project reports, including the University of Rhode

Island's "mini-eliminator trawl" project. During the Monkfish Committee report to follow, the Council will receive a briefing on the recent scoping hearings and recommendations from its Monkfish Advisory Panel, each concerning the possible development of a monkfish catch shares program. The committee also will review its discussion about the use of trip limit exemptions in the monkfish cooperative research program. The Northeast Fisheries Science Center staff will summarize its recommendations for 2011–12 observer sea-day allocations. During the afternoon, the Council will discuss and possibly modify an option in the Environmental Impact Statement for Herring Amendment 5 that would require federally-permitted fish dealers to accurately weigh all landings of herring. They also will receive the last of three briefings about ecosystem-based fisheries management by staff of the Northeast Fisheries Science Center. The Habitat Committee will summarize any recommendations from its most recent meeting, and at the end of the day, the Habitat Plan Development Team will provide an overview of the impact of the SASI model peer review on the development of the Council's Habitat Omnibus Amendment.

Thursday, April 28, 2011

The last day of the Council meeting will begin with a presentation about "management area coordination." This will consist of an overview of the relationships between the current groundfish mortality closures and the current and proposed essential fish habitat closures, and their impact on access to fishery resources. The Council will address groundfish management for the remainder of this day. It intends to take final action on Framework Adjustment 46 to the Northeast Multispecies Fishery Management Plan (FMP), which would cap the amount of haddock the herring fleet would be allowed to take as bycatch in that fishery. The Council also may take final action on Amendment 17 to the Multispecies FMP. Amendment 17 would create a mechanism for the operation of NOAA-funded, state-operated permit banks. Other groundfish-related business items include a report on workshop planning for the purpose of examining the last year of sector operations, and a Groundfish Committee recommendation to delay further work on an amendment to consider accumulation limits in the fishery. Any other outstanding business will be discussed after the groundfish agenda items have been completed.

Although other non-emergency issues not contained in this agenda may come before this Council for discussion, those issues may not be the subjects of formal action during this meeting. Council action will be restricted to those issues specifically listed in this notice and any issues arising after publication of this notice that require emergency action under section 305(c) of the Magnuson-Stevens Act, provided that 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 (*see* **ADDRESSES**) at least 5 days prior to the meeting date.

Dated: April 4, 2011.

Tracey L. Thompson,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2011–8343 Filed 4–6–11; 8:45 am]

BILLING CODE 3510–22–P

COMMODITY FUTURES TRADING COMMISSION

Privacy Act of 1974 System of Records Notice

AGENCY: Commodity Futures Trading Commission.

ACTION: Notice; publication of existence and character of a new system of records.

SUMMARY: The Commodity Futures Trading Commission is establishing a system of records under the Privacy Act of 1974 for the online collection of public comments to notices of proposed rulemakings, proposed orders, and other regulatory actions that are required to be published in the **Federal Register**, or applications for registration or designation, approval requests or self-certifications related to financial products or self-regulatory organization rules or rule amendments, petitions for exemption, and other input collected from the public that may not be associated with statutory or regulatory notice and comment requirements.

DATES: Comments should be postmarked by May 17, 2011. This notice will become effective without further notice, on the date which is 60 days from the date given above unless otherwise revised pursuant to comments received.

ADDRESSES: You may submit comments, identified by "Comments Online SORN," by any of the following methods:

- Agency Web site, via its Comments Online process: *http://comments.cftc.gov.* Follow the instructions for submitting comments through the Web site.
- Federal eRulemaking Portal: Comments may be submitted at *http://www.regulations.gov.* Following the instructions for submitting comments.
- Mail: David A. Stawick, Secretary of the Commission, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street, NW., Washington, DC 20581.
- Hand Delivery/Courier: Same as mail above.

Please submit your comments using only one method.

All comments must be submitted in English, or if not, accompanied by an English translation. Comments will be posted as received to *http://www.cftc.gov.* You should submit only information that you wish to make available publicly. If you wish the Commission to consider information that you believe is exempt from disclosure under the Freedom of Information Act, a petition for confidential treatment of the exempt information may be submitted according to the procedures established in § 145.9 of the Commission's regulations, 17 CFR 145.9.

The Commission reserves the right, but shall have no obligation, to review, pre-screen, filter, redact, refuse or remove any or all of a submission from *http://www.cftc.gov* that it may deem to be inappropriate for publication, such as obscene language. All submissions that have been redacted or removed that contain comments on the merits of the notice will be retained in the public comment file and will be considered as required under all applicable laws, and may be accessible under the Freedom of Information Act.

FOR FURTHER INFORMATION CONTACT: Kathy Harman-Stokes, Chief Privacy Officer, *kharman-stokes@cftc.gov,* 202–418–6629, Office of the Executive Director, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street, NW., Washington, DC 20581.

SUPPLEMENTARY INFORMATION:

I. Comments Online

The CFTC is obligated to collect comments on rulemakings and other regulatory action, which it timely publishes on its Web site to provide transparency in the informal rulemaking process under the Administrative Procedure Act ("APA"), 5 U.S.C. 553, and in the regulatory processes established in the Commodity Exchange

Act, 7 U.S.C. 1 *et seq.* The CFTC also may solicit comments or other input from the public that may not be associated with statutory or regulatory notice and comment requirements. Previously, this input was received by the Commission's Office of the Secretary and incorporated into the Commission Correspondence Files, Privacy Act System of Record Notice CFTC–2.

The new "Comments Online" system will collect and store comments and input received by the Commission. Specifically, the system includes a web form on *http://www.cftc.gov* allowing individuals to submit their comments or input, along with their name, organization and contact information. Once submitted, the system stores this information in the Comments Online database. Any comments received by fax, postal mail or email are uploaded by personnel into this database, collecting all comments into one database. The commenter's name, organization and comment or input are automatically published to *http://www.cftc.gov.* The commenter's contact information, or other personal information voluntarily submitted, is not published on the Internet, unless the commenter has incorporated such information into the text of his or her comment.

During an informal rulemaking or other statutory or regulatory notice and comment process, Commission personnel may manually remove a comment from publication if the commenter withdraws his or her comments before the comment period has closed or because the comment contains obscenities or other material deemed inappropriate for publication by the Commission.[1] However, comments that are removed from publication will be retained by the Commission for consideration as required by the APA, or as part of the Commission's documentation of a comment withdrawal in the event that one is requested.

II. The Privacy Act

Under the Privacy Act of 1974, 5 U.S.C. 552a, a "system of records" is defined as any group of records under the control of a federal government agency from which information about individuals is retrieved by name or other personal identifier. The Privacy Act establishes the means by which government agencies must collect, maintain, and use personally identifiable information associated with an individual in a government system of records.

Each government agency is required to publish a notice in the **Federal Register** of a system of records in which the agency identifies and describes each system of records it maintains, the reasons why the agency uses the personally identifying information therein, the routine uses for which the agency will disclose such information outside the agency, and how individuals may exercise their rights under the Privacy Act to determine if the system contains information about them.

III. Notice

SYSTEM NUMBER: CFTC–45

SYSTEM NAME:

Comments Online.

SECURITY CLASSIFICATION:

Unclassified.

SYSTEM LOCATION:

This system is located in the Commission's principal office at Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street, NW., Washington, DC 20581.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Individuals providing comments or other input to the Commission in response to proposed rules, industry filings or other Commission request for comments associated with Commission rules, policies or procedures, whether the individuals provide comments or input directly or through their representatives. Any individuals who may be discussed or identified in the comments or input provided by others to the Commission.

CATEGORIES OF RECORDS IN THE SYSTEM:

Incoming comments or other input to the Commission in response to proposed rules, industry filings or other Commission request for comments associated with Commission rules, policies or procedures, provided to the Commission via the web form on the *http://www.cftc.gov* site, electronic mail, facsimile or postal mail. Comments or input submitted through *http://www.cftc.gov* include the full name of the submitter, an email address and the name of the organization, if an organization is submitting the comments. The commenter may optionally provide job title, mailing address and phone numbers. The comments or input provided may contain other personal information, although the comment submission instructions advise commenters not to include additional personal or confidential information.

This system excludes comments or input for which the Commission has received and either has approved or not yet decided a Freedom of Information Act "request for confidential treatment." Records related to such requests are covered under System of Record Notice CFTC–41, "Requests for Confidential Treatment."

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

44 U.S.C. 3101, Administrative Procedure Act, 5 U.S.C. 553 *et seq.,* the Commodity Exchange Act, 7 U.S.C. 1 *et seq.,* and rules and regulations promulgated thereunder.

PURPOSE(S):

To collect and maintain in an electronic system feedback from the public and industry groups regarding proposed rules and other Commission regulatory actions in accordance with the Administrative Procedure Act ("APA") or other statutory or regulatory provisions, as well as input on Commission activities that may not be associated with notice and comment requirements.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

Comments or input in this system, along with the commenter's name and organization, are published on the *http://www.cftc.gov* site. In the event a commenter has withdrawn a comment before the comment period has closed or the Commission has determined that a comment contains obscenities or other material deemed inappropriate for publication by the Commission, the comment will be removed from publication on the *http://www.cftc.gov* site but will be retained the Comments Online database for consideration as required by the APA or as part of the Commission's documentation of a comment withdrawal if requested.

The Comments Online system also contains the commenter's email address and other personal contact information the commenter may voluntarily provide to the Commission, such as phone number. The email address will be used for the Commission to send the commenter a verification of receipt of

[1] The Commission reserves the right, but has no obligation, to review, pre-screen, filter, redact, refuse or remove any submission or part of a submission that it may deem inappropriate for publication, such as a comment containing obscene language. If an individual wishes to include in his/her comments information that he/she believes may be exempt from disclosure under the Freedom of Information Act, 5 U.S.C. 552, the individual may submit a petition for confidential treatment according to the procedure set forth in CFTC regulations at 17 CFR 145.9 before submitting comments.

the comment. The email address and other contact information may be used by the Commission to contact the commenter with questions about his or her submission. Only the commenter's name and organization are made available with the comment or input on *http://www.cftc.gov*, unless the commenter incorporates other personal information into the text of his or her comment or input.

Also, information in this system may be disclosed in accordance with the blanket routine uses numbered 1 through 19 that appear in the Commission's Privacy Act Systems of Records Notice, 76 FR 5974 (Feb. 2, 2011).

DISCLOSURE TO CONSUMER REPORTING AGENCIES:

None.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESS CONTROLS, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Paper records are stored in file folders, binders, computer disks, and are uploaded into the Comments Online system. Electronic records, including comments or input and personal information provided through the web form on the *http://www.cftc.gov* site, by electronic mail or as uploaded into the Comments Online database, are stored on the Commission's network and other electronic media as needed, such as the eLaw system, desktop applications and back-up media.

RETRIEVABILITY:

By name of the individual providing the comment or input, name of the individual on whose behalf a comment or input is provided, number assigned to the comment or input, or the subject matter, such as the proposed rule or industry filing to which the comment or input pertains. Also, by the name of any individual who is identified or discussed in the text of a comment or other input provided by another party.

ACCESS CONTROLS, SAFEGUARDS:

Records in the Comments Online system, including personal information contained in the database and not published on *http://www.cftc.gov,* are protected from unauthorized access and misuse through various administrative, technical and physical security measures. Technical security measures within CFTC include restrictions on computer access to authorized individuals, required use of strong passwords that are frequently changed, use of encryption for certain data types and transfers, and regular review of security procedures and best practices to enhance security. Physical measures include restrictions on building access to authorized individuals only and maintaining records in lockable offices and filing cabinets.

RETENTION AND DISPOSAL:

The retention and disposal period depends on the nature of the comment or input provided to the Commission. For example, comments that pertain to a Commission proposed rule or industry filing become part of the agency's central files and are kept permanently. Other input to the Commission may be kept for between one and 10 years, depending on the subject matter.

SYSTEM MANAGER(S) AND ADDRESS:

The Commission's Office of the Secretariat, located at the Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street, NW., Washington, DC 20581.

NOTIFICATION PROCEDURE:

Individuals seeking to determine whether this system of records contains information about themselves or seeking access to records about themselves in this system of records, or contesting the content of records about themselves contained in this system of records should address written inquiry to the Office of General Counsel, Paralegal Specialist, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street, NW., Washington, DC 20581. Telephone (202) 418–5011.

RECORD SOURCE CATEGORIES:

Individuals and organizations providing comments or other input to the Commission.

EXEMPTIONS CLAIMED FOR THIS SYSTEM:

None.

Issued in Washington, DC this 4th day of April, 2011, by the Commission.

Sauntia S. Warfield,

Assistant Secretary of the Commission.

[FR Doc. 2011–8346 Filed 4–6–11; 8:45 am]

BILLING CODE 6351–01–P

DEPARTMENT OF EDUCATION

Notice of Proposed Information Collection Requests

AGENCY: Department of Education.

ACTION: Comment request.

SUMMARY: The Department of Education (the Department), in accordance with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)), provides the general public and Federal agencies with an opportunity to comment on proposed and continuing collections of information. This helps the Department assess the impact of its information collection requirements and minimize the reporting burden on the public and helps the public understand the Department's information collection requirements and provide the requested data in the desired format. The Director, Information Collection Clearance Division, Information Management and Privacy Services, Office of Management, invites comments on the proposed information collection requests as required by the Paperwork Reduction Act of 1995.

DATES: Interested persons are invited to submit comments on or before June 6, 2011.

ADDRESSES: Comments regarding burden and/or the collection activity requirements should be electronically mailed to *ICDocketMgr@ed.gov* or mailed to U.S. Department of Education, 400 Maryland Avenue, SW., LBJ, Washington, DC 20202–4537. Please note that written comments received in response to this notice will be considered public records.

SUPPLEMENTARY INFORMATION: Section 3506 of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35) requires that Federal agencies provide interested parties an early opportunity to comment on information collection requests. The Director, Information Collection Clearance Division, Information Management and Privacy Services, Office of Management, publishes this notice containing proposed information collection requests at the beginning of the Departmental review of the information collection. The Department of Education is especially interested in public comment addressing the following issues: (1) Is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology.

Dated: April 4, 2011.

Darrin A. King,

Director, Information Collection Clearance Division, Information Management and Privacy Services, Office of Management.

Office of Planning, Evaluation and Policy Development

Type of Review: New.

Title of Collection: Evaluation of the Education for Homeless Children and Youth Program.

OMB Control Number: Pending.

Agency Form Number(s): N/A.

Frequency of Responses: Once.

Affected Public: State, Local, or Tribal Government, State Educational Agencies or Local Educational Agencies.

Total Estimated Number of Annual Responses: 256.

Total Estimated Number of Annual Burden Hours: 151.

Abstract: The evaluation will survey state coordinators and district liaisons for Education for Homeless Children and Youth (EHCY) Program. The evaluation addresses research questions in the following areas of program implementation: (1) The collection and use of data on homeless children and youth; (2) the expenditure of EHCY Program funds; (3) the policies and services provided by local educational agencies (LEAs) to remove barriers that prevent homeless children and youth from accessing a free, appropriate public education; and (4) the coordination of such efforts at the local level.

Copies of the proposed information collection request may be accessed from *http://edicsweb.ed.gov,* by selecting the "Browse Pending Collections" link and by clicking on link number 4559. When you access the information collection, click on "Download Attachments" to view. Written requests for information should be addressed to U.S. Department of Education, 400 Maryland Avenue, SW., LBJ, Washington, DC 20202–4537. Requests may also be electronically mailed to *ICDocketMgr@ed.gov* or faxed to 202–401–0920. Please specify the complete title of the information collection and OMB Control Number when making your request.

Individuals who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339.

[FR Doc. 2011–8332 Filed 4–6–11; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. IC11–725B–001]

Commission Information Collection Activities (FERC–725B); Comment Request; Submitted for OMB Review

AGENCY: Federal Energy Regulatory Commission, DOE.

ACTION: Notice.

SUMMARY: In compliance with the requirements of section 3507 of the Paperwork Reduction Act of 1995, 44 U.S.C. 3507, the Federal Energy Regulatory Commission (Commission or FERC) has submitted the information collection described below to the Office of Management and Budget (OMB) for review of the information collection requirements. Any interested person may file comments directly with OMB and should address a copy of those comments to the Commission as explained below. The Commission issued a Notice in the **Federal Register** (75 FR 65618, 10/26/2010) requesting public comments. FERC received no comments on the FERC–725B and has made this notation in its submission to OMB. OMB only makes a decision after the 30-day comment period for this notice has expired.

DATES: Comments on the collection of information are due by May 9, 2011.

ADDRESSES: Address comments on the collection of information to the Office of Management and Budget, Office of Information and Regulatory Affairs, Attention: Federal Energy Regulatory Commission Desk Officer. Comments to OMB should be filed electronically, c/o *oira__submission@omb.eop.gov* and include OMB Control Number 1902–0248 for reference. The Desk Officer may be reached by telephone at 202–395–4638.

A copy of the comments should also be sent to: Federal Energy Regulatory Commission, Secretary of the Commission, 888 First Street, NE., Washington, DC 20426. Comments may be filed either on paper or on CD/DVD, and should refer to Docket No. IC11–725B–001. Documents must be prepared in an acceptable filing format and in compliance with Commission submission guidelines at *http://www.ferc.gov/help/submission-guide.asp.* eFiling and eSubscription are not available for Docket No. IC11–725B–001, due to a system issue.

All comments may be viewed, printed or downloaded remotely via the Internet through FERC's homepage using the "eLibrary" link. For user assistance, contact *ferconlinesupport@ferc.gov* or toll-free at (866) 208–3676, or for TTY, contact (202) 502–8659.

FOR FURTHER INFORMATION CONTACT: Ellen Brown may be reached by e-mail at *DataClearance@FERC.gov*, by telephone at (202) 502–8663, and by fax at (202) 273–0873.

SUPPLEMENTARY INFORMATION: The information collected by the FERC–725B, Reliability Standards for Critical Infrastructure Protection (OMB Control No. 1902–0248), is required to implement the statutory provisions of section 215 of the Federal Power Act (FPA) (16 U.S.C. 824o). On January 18, 2008, the Commission issued order 706, approving eight Critical Infrastructure Protection (CIP) Reliability Standards submitted by the North American Electric Reliability Corporation (NERC) for Commission approval.[1]

The CIP Reliability Standards require certain users, owners, and operators of the Bulk-Power System to comply with specific requirements to safeguard critical cyber assets.[2] These standards help protect the nation's Bulk-Power System against potential disruptions from cyber attacks.[3] The CIP Reliability Standards include one actual reporting requirement and several recordkeeping requirements. Specifically, CIP–008–1 requires responsible entities to report cyber security incidents to the Electricity Sector-Information Sharing and Analysis Center (ES–ISAC). In addition, the eight CIP Reliability Standards require responsible entities to develop various policies, plans, programs, and procedures.[4]

The CIP Reliability Standards do not require a responsible entity to report to the Commission, ERO or Regional Entities, the various policies, plans, programs and procedures. However, a showing of the documented policies, plans, programs and procedures is required to demonstrate compliance with the CIP Reliability Standards.

Action: The Commission is requesting a three-year extension of the existing collection with no changes to the requirements.

Burden Statement: The extent of the reporting burden is influenced by the number of identified critical assets and related critical cyber assets pursuant to CIP–002. An entity identifying one or more critical cyber assets, including assets located at remote locations, will likely require more resources to demonstrate compliance with the CIP Reliability Standards compared to an entity that identifies no critical assets. The Commission has developed

[1] CIP–002–1, CIP–003–1, CIP–004–1, CIP–005–1, CIP–006–1, CIP–007–1, CIP–008–1, and CIP–009–1.

[2] In addition, in accordance with section 215(d)(5) of the FPA, the Commission proposed to direct NERC to develop modifications to the CIP Reliability Standards to address specific concerns identified by the Commission.

[3] For a description of the CIP Reliability Standards, *see* the Critical Infrastructure Protection Section on NERC's Web site at *http://www.nerc.com/page.php?cid=2|20.*

[4] The October notice issued in this docket contains more information on the reporting requirements and can be found at *http://elibrary.ferc.gov/idmws/File_list.asp?document_id=13857625.* The full text of the standards can be found on NERC's Web site at *http://www.nerc.com/page.php?cid=2|20.*

estimates using data from NERC's compliance registry as well as a 2009 survey that was conducted by NERC to asses the number of entities reporting Critical Cyber Assets.

Data collection	Number of respondents [5]	Average number of responses per respondent	Average number of burden hours per response [6]	Total annual hours
	(1)	(2)	(3)	(1) x (2) x (3)
FERC–725B:				
Estimate of U.S. Entities that have identified Critical Cyber Assets	345	1	320	110,400
Estimate of U.S. Entities that have not identified Critical Cyber Assets	1,156	1	8	9,248
New U.S. Entities that have to come into compliance with the CIP Standards [7]	*6	1	1,176	7,056
Totals	1,501			126,704

* not included in the 1,501 total because it is assumed that on average, six entities per year will no longer have to comply with the CIP standards.

The total estimated annual cost burden to respondents is:

• Entities that have identified Critical Assets = 110,400 hours@$96 = $10,598,400.

• Entities that have not identified Critical Assets = 9,248 hours@$96 = $887,808.

• Storage Costs for Entities that have identified Critical Assets [8] = 315 Entities@$15.25 = $4,804.

The hourly rate of $96 is the average cost of legal services ($230 per hour), technical employees ($40 per hour) and administrative support ($18 per hour), based on hourly rates from the Bureau of Labor Statistics (BLS) and the 2009 Billing Rates and Practices Survey Report.[9] The $15.25 rate for storage costs for each entity is an estimate based on the average costs to service and store 1 GB of data to demonstrate compliance with the CIP standards.[10]

The reporting burden includes the total time, effort, or financial resources expended to generate, maintain, retain, disclose, or provide the information including: (1) Reviewing instructions; (2) developing, acquiring, installing, and utilizing technology and systems for the purposes of collecting, validating, verifying, processing, maintaining, disclosing and providing information; (3) adjusting the existing ways to comply with any previously applicable instructions and requirements; (4) training personnel to respond to a collection of information; (5) searching data sources; (6) completing and reviewing the collection of information; and (7) transmitting, or otherwise disclosing the information.

Comments are invited on: (1) Whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information will have practical utility; (2) the accuracy of the agency's estimates 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 collections 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, *e.g.* permitting electronic submission of responses.

Dated: March 31, 2011.

Kimberly D. Bose,

Secretary.

[FR Doc. 2011–8248 Filed 4–6–11; 8:45 am]

BILLING CODE 6717–01–P

[5] The NERC Compliance Registry as of 9/28/2010 indicated that 2079 entities were registered for NERC's compliance program. Of these, 2057 were identified as being U.S. entities. Staff concluded that of the 2057 U.S. entities, only 1501 were registered for at least one CIP related function. According to an April 7, 2009 memo to industry, NERC's VP and Chief Security officer noted that only 31% of entities responded to an earlier survey and reported that they had at least one Critical Asset, and only 23% reported having a Critical Cyber Asset. Staff applied the 23% reporting to the 1501 figure to obtain an estimate. The 6 new entities listed here are assumed to match a similar set of 6 entities that would drop out in an existing year. Thus, the net estimate of respondents remains at 1501 per year.

[6] This figure relates to NERC's audit schedule which requires NERC to engage in a compliance Audit once every 3 to 5 years. For simplicity, staff has divided the total number of hours by 3 to reflect the amount of time annually spent preparing documents. Staff assumed that each CIP audit or spot check would require four individuals 6 weeks to prepare and demonstrate compliance with CIP standards for entities that have identified Critical Cyber Assets. Staff estimated that entities that do not have Critical Cyber Assets would still be required to demonstrate compliance with CIP–002, which would require one individual approximately three days to execute.

[7] This category of respondents (with the corresponding burden) was not included in the 60-day public notice due to an oversight by Commission staff.

[8] This cost category was not included in the 60-day public notice due to an oversight by Commission staff.

[9] Bureau of Labor Statistics figures were obtained from *http://www.bls.gov/oes/current/naics2_22.htm,* and 2009 Billing Rates figure were obtained from *http://www.marylandlawyerblog.com/2009/07/average_hourly_rate_for_lawyer.html.* Legal services were based on the national average billing rate (contracting out) from the above report and BLS hourly earnings (in-house personnel). It is assumed that 25% of respondents have in-house legal personnel.

[10] Based on the aggregate cost of an IBM advanced data protection server.

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 2479–011]

Pacific Gas and Electric Company; Notice of Application Accepted for Filing, Soliciting Motions To Intervene and Protests, Ready for Environmental Analysis, and Soliciting Comments, Recommendations, and Preliminary Terms and Conditions

Take notice that the following hydroelectric application has been filed with the Commission and is available for public inspection.

a. *Type of Application:* Subsequent License—Transmission Line Only.

b. *Project No.:* P–2479–011.

c. *Date filed:* February 22, 2011.

d. *Applicant:* Pacific Gas and Electric Company.

e. *Name of Project:* French Meadows Transmission Line Project.

f. *Location:* The French Meadows Transmission Line Project is located in Placer County, California, within the boundaries of the Eldorado and Tahoe National Forests.

g. *Filed Pursuant to:* Federal Power Act 16 U.S.C. 791(a)–825(r).

h. *Applicant Contact:* Forrest Sullivan, Senior Project Manager, Pacific Gas and Electric Company, 5555 Florin Perkins Road, Sacramento, CA, 95826. *Tel:* (916) 386–5580.

i. *FERC Contact:* Mary Greene, (202) 502–8865 or *mary.greene@ferc.gov.*

j. Deadline for filing motions to intervene and protests, comments, recommendations, preliminary terms and conditions, and preliminary prescriptions: 60 days from the issuance date of this notice; reply comments are due 105 days from the issuance date of this notice.

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 is ready for environmental analysis.

l. The Project is connected with The Middle Fork American River Hydroelectric Project, FERC Project No. 2079, owned and operated by the Placer County Water Agency (PCWA). The project consists of a 3-phase, 60-kilovolt (kV), wood-pole transmission line extending 13.27 miles from PCWA's French Meadows powerhouse switchyard to PCWA's Middle Fork powerhouse (feature of Project 2079). The project includes a 3-phase, 60-kV transmission line extending approximately 900 feet from PCWA's Oxbow powerhouse (feature of project No. 2079) to the interconnection at PG&E's Weimar #1 60-kV transmission line. The transmission line right-of-way is 40 feet in width for its entire length. The project also includes a 230-kV tap at PCWA's Ralston powerhouse. The tap is wholly contained within the switchyard at Ralston powerhouse.

The French Meadows 60-kV transmission line is entirely within the boundaries of the Eldorado National Forest, and the Oxbow 60-kV tap is entirely within the boundaries of the Tahoe National Forest. The combined length of the two 60-kV transmission lines on National Forest System lands is 6.58 miles: 6.42 miles in the Eldorado National Forest and 0.16 mile in the Tahoe National Forest. Approximately 6.69 miles of the French Meadows 60-kV transmission line are located on private lands within the boundary of the Eldorado National Forest. The Oxbow tap is located entirely on National Forest System lands.

PG&E is not proposing to modify the existing project and does not plan any changes to the operation or maintenance of the transmission line.

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 email 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," or "PRELIMINARY TERMS AND CONDITIONS;" (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. Revisions to the schedule may be made as appropriate.

Milestone	Target date
Filing of recommendations, preliminary terms and conditions, and preliminary fishway prescriptions.	May 31, 2011.
Commission issues EA	September 28, 2011.
Comments on EA or EIS.	November 14, 2011.
Modified terms and conditions.	January 13, 2012.

p. Final amendments to the application must be filed with the Commission no later than 30 days from the issuance date of this notice.

Dated: April 1, 2011.

Kimberly D. Bose,

Secretary.

[FR Doc. 2011–8301 Filed 4–6–11; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 12715–003]

Fairlawn Hydroelectric Company, LLC; 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:* Original Major License.

b. *Project No.:* 12715–003.

c. *Date filed:* December 23, 2010.

d. *Applicant:* Fairlawn Hydroelectric Company, LLC.

e. *Name of Project:* Jennings Randolph Hydroelectric Project.

f. *Location:* The proposed project would be located at the U.S. Army Corps of Engineers' (Corps) Jennings Randolph dam located on the North Branch Potomac River in Garrett County, Maryland and Mineral County, West Virginia. The project would occupy 5.0 acres of federal land managed by the Corps.

g. *Filed Pursuant to:* Federal Power Act, 16 U.S.C. 791 (a)–825(r).

h. *Applicant Contact:* Clifford Phillips, Fairlawn Hydroelectric Company, LLC, 150 North Miller Road, Suite 450 C, Fairlawn, OH 44333; Telephone (330) 869–8451.

i. *FERC Contact:* Allyson Conner, (202) 502–6082 or *allyson.conner@ferc.gov.*

j. *Deadline for filing motions to intervene and protests, comments, recommendations, preliminary terms and conditions, and preliminary prescriptions:* 60 days from the issuance date of this notice; reply comments are due 105 days from the issuance date of this notice.

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 Project Description:* The proposed Jennings Randolph Project would use the existing U.S. Army Corps of Engineers' Jennings Randolph dam and reservoir and consist of the following proposed features: (1) A 10-foot-diameter, 530-foot-long underwater multi-level intake structure with 24 intake ports to be built on the upstream face of the dam; (2) a 10-foot-diameter, 1,400-foot-long lined tunnel through the dam; (3) a 10-foot-diameter, 1,100-foot-long penstock; (4) the penstock would bifurcate into 96-inch-diameter and 66-inch-diameter penstocks at the entrance to the powerhouse; (5) a powerhouse approximately 54 feet long, 54 feet wide, and 40 feet high that would contain two generating units with a total capacity of 14.0 megawatts; (6) a 40-foot-long tailrace; (7) a 0.74-mile-long, 25-kilovolt partially buried transmission line; (8) a substation; and (9) new compacted gravel access roads to be constructed to the powerhouse and along the transmission line to the project's substation. The proposed project would have an estimated average annual generation of 56,000 megawatt-hours and would discharge approximately 650 feet downstream of the Corps' existing discharge.

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 of 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. Revisions to the schedule may be made as appropriate.

Milestone	Target date
Filing of recommendations, preliminary terms and conditions, and preliminary fishway prescriptions.	May 31, 2011.
Commission issues Single EA.	September 28, 2011.
Comments on EA	October 28, 2011.
Modified terms and conditions.	December 27, 2011.

p. Final amendments to the application must be filed with the Commission no later than 30 days from the issuance date of this notice.

q. A license applicant must file no later than 60 days following the date of issuance of the notice of acceptance and ready for environmental analysis provided for in 5.22: (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.

r. Any qualified applicant desiring to file a competing application must submit to the Commission, on or before the specified intervention deadline date, a competing development application, or a notice of intent to file such an application. Submission of a timely notice of intent allows an interested person to file the competing development application no later than 120 days after the specified intervention deadline date. Applications for preliminary permits will not be accepted in response to this notice.

A notice of intent must specify the exact name, business address, and telephone number of the prospective applicant, and must include an unequivocal statement of intent to submit a development application. A notice of intent must be served on the applicant(s) named in this public notice.

Dated: April 1, 2011.

Kimberly D. Bose,

Secretary.

[FR Doc. 2011–8302 Filed 4–6–11; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 2232–589]

Duke Energy Carolinas, LLC; Notice of Application for Amendment of License and Soliciting Comments, Motions To Intervene, and Protests

Take notice that the following hydroelectric application has been filed with the Commission and is available for public inspection:

a. *Application Type:* Non-project use of project lands and waters.

b. *Project No:* 2232–589.

c. *Date Filed:* March 2, 2011.

d. *Applicant:* Duke Energy Carolinas, LLC.

e. *Name of Project:* Catawba-Wateree Hydroelectric Project.

f. *Location:* The proposed non-project use would be located on Fishing Creek Lake, Lancaster County, South Carolina.

g. *Filed Pursuant to:* Federal Power Act, 16 U.S.C. 791a–825r.

h. *Applicant Contact:* Mr. Kelvin K. Reagan, Manager Lake Services, P.O. Box 1006, Charlotte, NC 28201–1006, (704) 382–9386.

i. *FERC Contact:* Mr. William Doran, (202) 502–6795, *william.doran@ferc.gov.*

j. *Deadline for filing comments, motions to intervene, and protest:* April 30, 2011.

All documents may be filed electronically via the Internet. *See,* 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site at *http://www.ferc.gov/docs-filing/efiling.asp.* If unable to be filed electronically, documents may be paper-filed. To paper-file, an original and seven copies should be mailed to: Secretary, Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426. Commenter's 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. Please include the project number (P–2232–589) on any comments, motions, or recommendations filed.

k. *Description of Request:* Duke Energy Carolinas, LLC requests Commission authorization to lease to Craft development, LLC, 9.510 acres of project lands on Fishing Creek Lake for a true public-use marina (Edgewater Public Marina) for use by the general public, and four residential marinas (Edgewater Community Docks) for use by the residents of Edgewater development. The true public-use and residential marinas will accommodate 156 and 185 boat slips respectively for a total of 341 slips and 24 cluster docks. The true public-use marina also includes: two courtesy docks, fuel service, put-in well, and will require 522.4 cubic yards of dredging activity.

l. *Locations of the Application:* A copy of the application is available for inspection and reproduction at the Commission's Public Reference Room, located at 888 First Street, NE., Room 2A, Washington, DC 20426, or by calling (202) 502–8371. This filing may also be viewed on the Commission's Web site at *http://www.ferc.gov* using the "eLibrary" link. Enter the docket number excluding the last three digits in the docket number field to access the document. You may also register online at *http://www.ferc.gov/docs-filing/esubscription.asp* to be notified via e-mail of new filings and issuances related to this or other pending projects. For assistance, call 1–866–208–3676 or e-mail *FERCOnlineSupport@ferc.gov,* for TTY, call (202) 502–8659. A copy is also available for inspection and reproduction at the address in item (h) above.

m. Individuals desiring to be included on the Commission's mailing list should so indicate by writing to the Secretary of the Commission.

n. *Comments, Protests, or Motions to Intervene:* 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.

o. *Filing and Service of Responsive Documents:* Any filing must (1) bear in all capital letters the title "COMMENTS", "PROTEST", or "MOTION TO INTERVENE" as applicable; (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, motions to intervene, or protests 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. If an intervener 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. 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.

Dated: March 31, 2011.

Kimberly D. Bose,

Secretary.

[FR Doc. 2011–8250 Filed 4–6–11; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP11–142–000]

Tennessee Gas Pipeline Company; Notice of Application

Take notice that on March 18, 2011, Tennessee Gas Pipeline Company (Tennessee), 1001 Louisiana Street, Houston, Texas 77002, filed an application in Docket No. CP11–142–000 pursuant to section 7(b) of the Natural Gas Act (NGA) and Part 157 of the Commission's regulations, requesting authorization to abandon in place and by removal certain inactive supply pipelines, associated meters, and appurtenances located primarily in the East and West Cameron areas in federal offshore waters of the Outer Continental Shelf, Louisiana, referred to as the Southwest Leg Abandonment Project. The facilities to be abandoned include approximately 64.5 miles of 30-inch, 10.5 miles of 24-inch, 13.5 miles of 16-inch and 2.5 miles of 10-inch supply pipelines, as well as related meters and associated appurtenances. Tennessee states that the subject facilities have been out of service due to damage received by Hurricane Ike in September 2008, all as more fully set forth in the application which is on file with the Commission and open to public inspection. The filing is available for review at the Commission in the Public Reference Room or may be viewed on the Commission's Web site web 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 at *FERCOnlineSupport@ferc.gov* or call toll-free, (886) 208–3676 or TTY, (202) 502–8659.

Any questions concerning this application may be directed to Thomas G. Joyce, Manager, Certificates, Tennessee Gas Pipeline Company, 1001 Louisiana Street, Houston, Texas 77002, by telephone at (713) 420–3299, by facsimile at (713) 420–1473, or by e-mail at *tom.joyce@elpaso.com*; Susan T. Halbach, Senior Counsel, Tennessee Gas Pipeline Company, 1001 Louisiana Street, Houston, Texas 77002, by telephone at (713) 420–5751, by facsimile at (713) 420–1601, or by e-mail at *susan.halbach@elpaso.com*; or Debbie Kalisek, Regulatory Analyst, Tennessee Gas Pipeline Company, 1001 Louisiana Street, Houston, Texas 77002, by telephone at (713) 420–3292, by facsimile at (713) 420–1473, or by e-mail at *debbie.kalisek@elpaso.com*.

There are two ways to become involved in the Commission's review of this project. First, any person wishing to obtain legal status by becoming a party to the proceedings for this project should, on or before the comment date stated below file with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, a motion to intervene in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 385.214 or 385.211) and the Regulations under the NGA (18 CFR 157.10). A person obtaining party status will be placed on the service list maintained by the Secretary of the Commission and will receive copies of all documents filed by the applicant and by all other parties. A party must submit 14 copies of filings made in the proceeding with the Commission and must mail a copy to the applicant and to every other party. Only parties to the proceeding can ask for court review of Commission orders in the proceeding.

However, a person does not have to intervene in order to have comments considered. The second way to participate is by filing with the Secretary of the Commission, as soon as possible, an original and two copies of comments in support of or in opposition to this project. The Commission will consider these comments in determining the appropriate action to be taken, but the filing of a comment alone will not serve to make the filer a party to the proceeding. The Commission's rules require that persons filing comments in opposition to the project provide copies of their protests only to the party or parties directly involved in the protest.

Protests and interventions may be filed electronically via the Internet in lieu of paper; see, 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site under the "e-Filing" link. The Commission strongly encourages electronic filings.

Comment Date: April 21, 2010.

Dated: March 31, 2011.

Kimberly D. Bose,

Secretary.

[FR Doc. 2011–8247 Filed 4–6–11; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 13–023]

Green Island Power Authority; Notice of Authorization for Continued Project Operation

On March 2, 2009 Green Island Power Authority, licensee for the Green Island Hydroelectric Project, filed an Application for a New License pursuant to the Federal Power Act (FPA) and the Commission's regulations thereunder. The Green Island Hydroelectric Project is on the Hudson River in Albany County, New York.

The license for Project No. 13 was issued for a period ending March 2, 2011. Section 15(a)(1) of the FPA, 16 U.S.C. 808(a)(1), requires the Commission, at the expiration of a license term, to issue from year-to-year an annual license to the then licensee under the terms and conditions of the prior license until a new license is issued, or the project is otherwise disposed of as provided in section 15 or any other applicable section of the FPA. If the project's prior license waived the applicability of section 15 of the FPA, then, based on section 9(b) of the Administrative Procedure Act, 5 U.S.C. 558(c), and as set forth at 18 CFR 16.21(a), if the licensee of such project has filed an application for a subsequent license, the licensee may continue to operate the project in accordance with the terms and conditions of the license after the minor or minor part license expires, until the Commission acts on its application. If the licensee of such a project has not filed an application for a subsequent license, then it may be required, pursuant to 18 CFR 16.21(b), to continue project operations until the Commission issues someone else a

license for the project or otherwise orders disposition of the project.

If the project is subject to section 15 of the FPA, notice is hereby given that an annual license for Project No. 13 is issued to the Green Island Power Authority for a period effective March 3, 2011 through March 2, 2012, or until the issuance of a new license for the project or other disposition under the FPA, whichever comes first. If issuance of a new license (or other disposition) does not take place on or before March 2, 2012, notice is hereby given that, pursuant to 18 CFR 16.18(c), an annual license under section 15(a)(1) of the FPA is renewed automatically without further order or notice by the Commission, unless the Commission orders otherwise.

If the project is not subject to section 15 of the FPA, notice is hereby given that Green Island Power Authority is authorized to continue operation of the Green Island Hydroelectric Project, until such time as the Commission acts on its application for a subsequent license.

Dated: March 31, 2011.

Kimberly D. Bose,

Secretary.

[FR Doc. 2011–8249 Filed 4–6–11; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. PR11–71–001; Docket No. PR11–72–001; Docket No. PR11–73–001; Not Consolidated]

Southcross Gulf Coast Transmission Ltd.; Southcross Mississippi Pipeline, L.P.; Southcross CCNG Transmission Ltd.; Notice of Baseline Filings

Take notice that on March 29, 2011, the applicants listed above submitted a revised baseline filing of their Statement of Operating Conditions for services provided under section 311 of the Natural Gas Policy Act of 1978 ("NGPA").

Any person desiring to participate in this rate proceeding must file a motion to intervene or to protest this filing must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a notice of intervention or motion to intervene, as appropriate. Such notices, motions, or protests must be filed on or before the date as indicated below. Anyone filing an intervention or protest must serve a copy of that document on the Applicant. Anyone filing an intervention or protest on or before the intervention or protest date need not serve motions to intervene or protests on persons other than the Applicant.

The Commission encourages electronic submission of protests and interventions in lieu of paper using the "eFiling" link at *http://www.ferc.gov.* Persons unable to file electronically should submit an original and 7 copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426.

This filing is accessible 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 Tuesday, April 12, 2011.

Dated: April 1, 2011.

Kimberly D. Bose,

Secretary.

[FR Doc. 2011–8300 Filed 4–6–11; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

Take notice that the Commission received the following electric corporate filings:

Docket Numbers: EC11–57–000.

Applicants: Morgan Stanley Capital Group Inc., Mitsubishi UFJ Financial Group, Inc.

Description: Joint Application for Authorization under section 203 of the Federal Power Act of MS Utilities and MUFG.

Filed Date: 03/29/2011.

Accession Number: 20110329–5152.

Comment Date: 5 p.m. Eastern Time on Tuesday, April 19, 2011.

Docket Numbers: EC11–58–000.

Applicants: Penta Wind Holding, LLC.

Description: Penta Wind Holding, LLC Application for Approval under section 203 of the Federal Power Act and Request for Expedited Action.

Filed Date: 03/29/2011.

Accession Number: 20110329–5153.

Comment Date: 5 p.m. Eastern Time on Tuesday, April 19, 2011.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER11–2224–004.

Applicants: New York Independent System Operator, Inc.

Description: New York Independent System Operator, Inc. submits tariff filing per 35: Compliance Filing—ICAP Demand Curve Tariff Revisions to be effective 12/31/9998.

Filed Date: 03/29/2011.

Accession Number: 20110329–5142.

Comment Date: 5 p.m. Eastern Time on Tuesday, April 19, 2011.

Docket Numbers: ER11–2224–004.

Applicants: New York Independent System Operator, Inc.

Description: New York Independent System Operator, Inc. submits tariff filing per: Supplement to NYISO 3/29/11 ICAP Demand Curve Filing to be effective N/A.

Filed Date: 03/30/2011.

Accession Number: 20110330–5026.

Comment Date: 5 p.m. Eastern Time on Wednesday, April 20, 2011.

Docket Numbers: ER11–2528–001.

Applicants: Southwest Power Pool, Inc.

Description: Southwest Power Pool, Inc. submits tariff filing per 35.17(b): Response to Request for Additional Information (North Buffalo Wind GIA) to be effective 12/10/2010.

Filed Date: 03/29/2011.

Accession Number: 20110329–5109.

Comment Date: 5 p.m. Eastern Time on Tuesday, April 19, 2011.

Docket Numbers: ER11–2541–001.

Applicants: Louisville Gas and Electric Company.

Description: Louisville Gas and Electric Company submits tariff filing per 35: Att C Compliance Filing 3/29/11 to be effective 4/1/2011.

Filed Date: 03/29/2011.

Accession Number: 20110329–5049.

Comment Date: 5 p.m. Eastern Time on Tuesday, April 19, 2011.

Docket Numbers: ER11–3026–001.

Applicants: Aspen Merchant Energy, LP.

Description: Aspen Merchant Energy, LP submits tariff filing per 35.17(b): Supplemental Market Based Rate Filing for Aspen Merchant Energy LP to be effective 3/28/2011.

Filed Date: 03/29/2011.

Accession Number: 20110329–5067.

Comment Date: 5 p.m. Eastern Time on Tuesday, April 19, 2011.

Docket Numbers: ER11–3220–000.
Applicants: Consolidated Edison Company of New York, Inc.
Description: Consolidated Edison Company of New York, Inc. submits tariff filing per 35.13(a)(1): RY2 WDS OATT change to be effective 4/1/2011.
Filed Date: 03/30/2011.
Accession Number: 20110330–5000.
Comment Date: 5 p.m. Eastern Time on Wednesday, April 20, 2011.

Docket Numbers: ER11–3221–000.
Applicants: Louisville Gas and Electric Company.
Description: Louisville Gas and Electric Company submits tariff filing per 35.13(a)(2)(iii): LGE and KU Joint Rate Schedule FERC No 506 to be effective 5/30/2011.
Filed Date: 03/30/2011.
Accession Number: 20110330–5014.
Comment Date: 5 p.m. Eastern Time on Wednesday, April 20, 2011.

Docket Numbers: ER11–3222.–000.
Applicants: Florida Power Corporation.
Description: Notice of Cancellation of Interchange Agreement with Big Rivers Electric Corp. by Florida Power Corporation.
Filed Date: 03/30/2011.
Accession Number: 20110330–5033.
Comment Date: 5 p.m. Eastern Time on Wednesday, April 20, 2011.

Take notice that the Commission received the following electric securities filings:

Docket Numbers: ES11–12–000.
Applicants: PJM Interconnection L.L.C.
Description: Supplemental Request of PJM Interconnection L.L.C.
Filed Date: 03/30/2011.
Accession Number: 20110330–5034.
Comment Date: 5 p.m. Eastern Time on Monday, April 4, 2011.

Any person desiring to intervene or to protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214) on or before 5 p.m. Eastern time on the specified comment date. It is not necessary to separately intervene again in a subdocket related to a compliance filing if you have previously intervened in the same docket. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant. In reference to filings initiating a new proceeding, interventions or protests submitted on or before the comment deadline need not be served on persons other than the Applicant.

As it relates to any qualifying facility filings, the notices of self-certification [or self-recertification] listed above, do not institute a proceeding regarding qualifying facility status. A notice of self-certification [or self-recertification] simply provides notification that the entity making the filing has determined the facility named in the notice meets the applicable criteria to be a qualifying facility. Intervention and/or protest do not lie in dockets that are qualifying facility self-certifications or self-recertifications. Any person seeking to challenge such qualifying facility status may do so by filing a motion pursuant to 18 CFR 292.207(d)(iii). Intervention and protests may be filed in response to notices of qualifying facility dockets other than self-certifications and self-recertifications.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov.* To facilitate electronic service, persons with Internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically should submit an original and 14 copies of the intervention or protest to the Federal Energy Regulatory Commission, 888 First St., NE., Washington, DC 20426.

The filings in the above proceedings are accessible in the Commission's eLibrary system by clicking on the appropriate link in the above list. They are also available for review in the Commission's Public Reference Room in Washington, DC. There is an eSubscription link on the Web site that enables subscribers to receive e-mail notification when a document is added to a subscribed dockets(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: March 30, 2011.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2011–8262 Filed 4–6–11; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings No. 2

Take notice that the Commission has received the following Natural Gas Pipeline Rate and Refund Report filings:

Docket Numbers: RP11–1785–001.
Applicants: Dominion Cove Point LNG, LP.
Description: Dominion Cove Point LNG, LP submits tariff filing per 154.203: DCP—February 18, 2011 Non-Conforming Service Agreement Compliance to be effective N/A.
Filed Date: 03/25/2011.
Accession Number: 20110325–5056.
Comment Date: 5 p.m. Eastern Time on Wednesday, April 6, 2011.

Docket Numbers: RP11–1786–001.
Applicants: Dominion Transmission, Inc.
Description: Dominion Transmission, Inc. submits tariff filing per 154.203: DTI—February 18, 2011 Non-Conforming Service Agreements Compliance to be effective N/A.
Filed Date: 03/25/2011.
Accession Number: 20110325–5057.
Comment Date: 5 p.m. Eastern Time on Wednesday, April 6, 2011.

Any person desiring to protest this filing must file in accordance with Rule 211 of the Commission's Rules of Practice and Procedure (18 CFR 385.211). Protests to this filing will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Such protests must be filed on or before 5 p.m. Eastern time on the specified comment date. Anyone filing a protest must serve a copy of that document on all the parties to the proceeding.

The Commission encourages electronic submission of protests in lieu of paper using the "eFiling" link at *http://www.ferc.gov.* Persons unable to file electronically should submit an original and 14 copies of the protest to the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426.

This filing is accessible on-line at *http://www.ferc.gov,* using the "eLibrary" link and is available for review in the Commission's Public Reference Room in Washington, DC. There is an "eSubscription" link on the Web site that enables subscribers to receive e-mail notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please e-mail *FERCOnlineSupport@ferc.gov,* or call

(866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: March 28, 2011.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2011–8264 Filed 4–6–11; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #2

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER11–2649–001.

Applicants: 3C Solar LLC.

Description: Supplemental Information Regarding Petition for Order Accepting Market-Based Rate Tariff for Filing and Granting Waivers and Blanket Approvals of 3C Solar LLC.

Filed Date: 03/31/2011.

Accession Number: 20110331–5238.

Comment Date: 5 p.m. Eastern Time on Monday, April 11, 2011.

Docket Numbers: ER11–3238–000.

Applicants: PJM Interconnection, L.L.C.

Description: PJM Interconnection, L.L.C. submits tariff filing per 35.13(a)(2)(iii): Interconnection Service Agreements in Connection with the ATSI Integration to be effective 6/1/2011.

Filed Date: 03/31/2011.

Accession Number: 20110331–5062.

Comment Date: 5 p.m. Eastern Time on Thursday, April 21, 2011.

Docket Numbers: ER11–3239–000.

Applicants: Alabama Power Company.

Description: Alabama Power Company submits tariff filing per 35.13(a)(2)(iii): SWE (Black Warrior) NITSA Amendment Filing to be effective 1/1/2011.

Filed Date: 03/31/2011.

Accession Number: 20110331–5069.

Comment Date: 5 p.m. Eastern Time on Thursday, April 21, 2011.

Docket Numbers: ER11–3240–000.

Applicants: Hardwood Energy, LLC.

Description: Hardwood Energy, LLC submits tariff filing per 35.1: Hardwood Energy FERC Electric Tariff to be effective 3/31/2011.

Filed Date: 03/31/2011.

Accession Number: 20110331–5097.

Comment Date: 5 p.m. Eastern Time on Thursday, April 21, 2011.

Docket Numbers: ER11–3241–000.

Applicants: Southwest Power Pool, Inc.

Description: Southwest Power Pool, Inc. submits tariff filing per 35.13(a)(2)(iii): 2166 Westar Energy, Inc. NITSA NOA to be effective 3/1/2011.

Filed Date: 03/31/2011.

Accession Number: 20110331–5135.

Comment Date: 5 p.m. Eastern Time on Thursday, April 21, 2011.

Docket Numbers: ER11–3242–000.

Applicants: Florida Power & Light Company.

Description: Florida Power & Light Company submits tariff filing per 35: FPL Revision to Attachment C Pursuant to Order No. 676–E to be effective 3/31/2011.

Filed Date: 03/31/2011.

Accession Number: 20110331–5139.

Comment Date: 5 p.m. Eastern Time on Thursday, April 21, 2011.

Docket Numbers: ER11–3243–000.

Applicants: Southwest Power Pool, Inc.

Description: Southwest Power Pool, Inc. submits tariff filing per 35.13(a)(2)(iii): 2183 Kansas Municipal Energy Agency NITSA NOA to be effective 3/1/2011.

Filed Date: 03/31/2011.

Accession Number: 20110331–5146.

Comment Date: 5 p.m. Eastern Time on Thursday, April 21, 2011.

Docket Numbers: ER11–3244–000.

Applicants: Florida Power Corporation.

Description: Notice of Cancellation of Rate Schedule No. 196 of Florida Power Corporation.

Filed Date: 03/31/2011.

Accession Number: 20110331–5149.

Comment Date: 5 p.m. Eastern Time on Thursday, April 21, 2011.

Docket Numbers: ER11–3245–000.

Applicants: Florida Power Corporation.

Description: Notice of Cancellation of Rate Schedule No. 195 of Florida Power Corporation.

Filed Date: 03/31/2011.

Accession Number: 20110331–5150.

Comment Date: 5 p.m. Eastern Time on Thursday, April 21, 2011.

Docket Numbers: ER11–3246–000.

Applicants: Florida Power Corporation.

Description: Notice of Cancellation of Rate Schedule No. 118 of Florida Power Corporation.

Filed Date: 03/31/2011.

Accession Number: 20110331–5151.

Comment Date: 5 p.m. Eastern Time on Thursday, April 21, 2011.

Docket Numbers: ER11–3247–000.

Applicants: Midwest Independent Transmission System Operator, Inc.

Description: Midwest Independent Transmission System Operator, Inc. submits tariff filing per 35.13(a)(2)(iii): F096 FCA to be effective 4/1/2011.

Filed Date: 03/31/2011.

Accession Number: 20110331–5158.

Comment Date: 5 p.m. Eastern Time on Thursday, April 21, 2011.

Docket Numbers: ER11–3248–000.

Applicants: Southern California Edison Company.

Description: Southern California Edison Company submits tariff filing per 35.13(a)(2)(iii): 2011 TACBAA Update to be effective 6/1/2011.

Filed Date: 03/31/2011.

Accession Number: 20110331–5159.

Comment Date: 5 p.m. Eastern Time on Thursday, April 21, 2011.

Docket Numbers: ER11–3249–000.

Applicants: PJM Interconnection, L.L.C.

Description: PJM Interconnection, L.L.C. submits tariff filing per 35.13(a)(2)(iii): Queue No. V1–024–V1–025 Interim ISA Original Service Agreement No. 2850 to be effective 3/4/2011.

Filed Date: 03/31/2011.

Accession Number: 20110331–5179.

Comment Date: 5 p.m. Eastern Time on Thursday, April 21, 2011.

Docket Numbers: ER11–3250–000.

Applicants: PJM Interconnection, L.L.C.

Description: PJM Interconnection, L.L.C. submits tariff filing per 35.13(a)(2)(iii): Revisions to add Schedule 16–A Linden VFT Facility Imports into PJM's Tariff to be effective 6/1/2011.

Filed Date: 03/31/2011.

Accession Number: 20110331–5183.

Comment Date: 5 p.m. Eastern Time on Thursday, April 21, 2011.

Docket Numbers: ER11–3251–000.

Applicants: Midwest Independent Transmission System Operator, Inc.

Description: Midwest Independent Transmission System Operator, Inc. submits tariff filing per 35.13(a)(2)(iii): 3–31–2011 ATSI Withdrawal to be effective 6/1/2011.

Filed Date: 03/31/2011.

Accession Number: 20110331–5184.

Comment Date: 5 p.m. Eastern Time on Thursday, April 21, 2011.

Docket Numbers: ER11–3252–000.

Applicants: Consolidated Edison Company of New York, Inc.

Description: Consolidated Edison Company of New York, Inc. submits tariff filing per 35.13(a)(2)(iii): Cancellation of DRS to be effective 4/1/2011.

Filed Date: 03/31/2011.

Accession Number: 20110331–5187.

Comment Date: 5 p.m. Eastern Time on Thursday, April 21, 2011.

Docket Numbers: ER11–3253–000.

Applicants: Turner Energy, LLC.
Description: Turner Energy, LLC submits tariff filing per 35.1: Turner Energy FERC Electric Tariff to be effective 3/31/2011.
Filed Date: 03/31/2011.
Accession Number: 20110331–5196.
Comment Date: 5 p.m. Eastern Time on Thursday, April 21, 2011.

Take notice that the Commission received the following open access transmission tariff filings:

Docket Numbers: OA09–16–002.
Applicants: Northeast Utilities Service Company.
Description: Report/Form of Northeast Utilities Service Company Annual Refund Report—Order 890 Requirement.
Filed Date: 03/31/2011.
Accession Number: 20110331–5125.
Comment Date: 5 p.m. Eastern Time on Thursday, April 21, 2011.

Any person desiring to intervene or to protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214) on or before 5 p.m. Eastern time on the specified comment date. It is not necessary to separately intervene again in a subdocket related to a compliance filing if you have previously intervened in the same docket. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant. In reference to filings initiating a new proceeding, interventions or protests submitted on or before the comment deadline need not be served on persons other than the Applicant.

As it relates to any qualifying facility filings, the notices of self-certification [or self-recertification] listed above, do not institute a proceeding regarding qualifying facility status. A notice of self-certification [or self-recertification] simply provides notification that the entity making the filing has determined the facility named in the notice meets the applicable criteria to be a qualifying facility. Intervention and/or protest do not lie in dockets that are qualifying facility self-certifications or self-recertifications. Any person seeking to challenge such qualifying facility status may do so by filing a motion pursuant to 18 CFR 292.207(d)(iii). Intervention and protests may be filed in response to notices of qualifying facility dockets other than self-certifications and self-recertifications.

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.

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The filings in the above proceedings are accessible in the Commission's eLibrary system by clicking on the appropriate link in the above list. They are also available for review in the Commission's Public Reference Room in Washington, DC. There is an eSubscription link on the Web site that enables subscribers to receive e-mail notification when a document is added to a subscribed dockets(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: March 31, 2011.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2011–8266 Filed 4–6–11; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings

Take notice that the Commission has received the following Natural Gas Pipeline Rate and Refund Report filings:

Docket Numbers: RP11–1866–000
Applicants: Empire Pipeline, Inc.
Description: Empire Pipeline, Inc. submits tariff filing per 154.203: Deferred State Income Tax Balance to be effective N/A.
Filed Date: 03/02/2011
Accession Number: 20110302–5089
Comment Date: 5 p.m. Eastern Time on Friday, April, 1, 2011

Docket Numbers: RP11–1905–000
Applicants: Texas Gas Transmission, LLC
Description: Texas Gas Transmission, LLC submits tariff filing per 154.204: 3–28–11 ProLiance Negotiated Rate Agreement Filing to be effective 4/1/2011.
Filed Date: 03/28/2011
Accession Number: 20110328–5062
Comment Date: 5 p.m. Eastern Time on Monday, April 11, 2011

Docket Numbers: RP11–1906–000
Applicants: Texas Gas Transmission, LLC
Description: Texas Gas Transmission, LLC submits tariff filing per 154.204: 3–28–11 TVA Negotiated Rate Agreement Filing to be effective 4/1/2011.
Filed Date: 03/28/2011
Accession Number: 20110328–5063
Comment Date: 5 p.m. Eastern Time on Monday, April 11, 2011

Docket Numbers: RP11–1907–000
Applicants: Gulf South Pipeline Company, LP
Description: Gulf South Pipeline Company, LP submits tariff filing per 154.204: QEP Amendment to Negotiated Rate Agreement to be effective 4/1/2011.
Filed Date: 03/28/2011
Accession Number: 20110328–5088
Comment Date: 5 p.m. Eastern Time on Monday, April 11, 2011

Docket Numbers: RP11–1908–000
Applicants: Columbia Gulf Transmission Company
Description: Columbia Gulf Transmission Company submits tariff filing per 154.204: Negotiated Rate Service Agreement—Chevron, PXP, McMoran to be effective 5/1/2011.
Filed Date: 03/28/2011
Accession Number: 20110328–5105
Comment Date: 5 p.m. Eastern Time on Monday, April 11, 2011

Docket Numbers: RP11–1909–000
Applicants: Transcontinental Gas Pipe Line Company,
Description: Transcontinental Gas Pipe Line Company, LLC submits tariff filing per 154.204: GT&C Section 25 Monthly Imbalance Resolution to be effective 7/1/2011.
Filed Date: 03/28/2011
Accession Number: 20110328–5108
Comment Date: 5 p.m. Eastern Time on Monday, April 11, 2011

Docket Numbers: RP11–1910–000
Applicants: Rockies Express Pipeline LLC
Description: Rockies Express Pipeline LLC submits tariff filing per 154.204: Negotiated Rate 03–29–11 BP to be effective 4/1/2011.
Filed Date: 03/29/2011
Accession Number: 20110329–5031
Comment Date: 5 p.m. Eastern Time on Monday, April 11, 2011

Docket Numbers: RP11–1911–000
Applicants: Texas Eastern Transmission, LP
Description: Texas Eastern Transmission, LP submits tariff filing per 154.204: NJR negotiated rate, to be effective 4/1/2011.

Filed Date: 03/29/2011
Accession Number: 20110329–5037
Comment Date: 5 p.m. Eastern Time on Monday, April 11, 2011

Docket Numbers: RP11–1912–000
Applicants: Trunkline Gas Company, LLC
Description: Trunkline Gas Company, LLC submits tariff filing per 154.204: Negotiated Rates Filing-7 to be effective 4/1/2011.
Filed Date: 03/29/2011
Accession Number: 20110329–5041
Comment Date: 5 p.m. Eastern Time on Monday, April 11, 2011

Docket Numbers: RP11–1913–000
Applicants: Texas Gas Transmission, LLC
Description: Texas Gas Transmission, LLC submits tariff filing per 154.204: Time Limitations Filing to be effective 4/28/2011.
Filed Date: 03/29/2011
Accession Number: 20110329–5065
Comment Date: 5 p.m. Eastern Time on Monday, April 11, 2011

Docket Numbers: RP11–1914–000
Applicants: Gulf South Pipeline Company, LP
Description: Gulf South Pipeline Company, LP submits tariff filing per 154.204: Open Season Agreements Filing to be effective 4/1/2011.
Filed Date: 03/29/2011
Accession Number: 20110329–5077
Comment Date: 5 p.m. Eastern Time on Monday, April 11, 2011

Docket Numbers: RP11–1915–000
Applicants: Gulf South Pipeline Company, LP
Description: Gulf South Pipeline Company, LP submits tariff filing per 154.204: Pivotal to Sequent Cap Rel Negotiated Rate Agreement Filing to be effective 4/1/2011.
Filed Date: 03/29/2011
Accession Number: 20110329–5078
Comment Date: 5 p.m. Eastern Time on Monday, April 11, 2011

Docket Numbers: RP11–1916–000
Applicants: Gulf South Pipeline Company, LP
Description: Gulf South Pipeline Company, LP submits tariff filing per 154.204: QEP 36601 Amendment to Negotiated Rate Agreement to be effective 4/1/2011.
Filed Date: 03/29/2011
Accession Number: 20110329–5079
Comment Date: 5 p.m. Eastern Time on Monday, April 11, 2011

Any person desiring to intervene or to protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214) on or before 5 p.m. Eastern time on the specified comment date. It is not necessary to separately intervene again in a subdocket related to a compliance filing if you have previously intervened in the same docket. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant. In reference to filings initiating a new proceeding, interventions or protests submitted on or before the comment deadline need not be served on persons other than the Applicant.

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Dated: March 29, 2011.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2011–8265 Filed 4–6–11; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings No. 1

Take notice that the Commission has received the following Natural Gas Pipeline Rate and Refund Report filings:

Docket Numbers: RP11–1899–000.
Applicants: CenterPoint Energy Gas Transmission Company, LLC.
Description: CenterPoint Energy Gas Transmission Company, LLC submits tariff filing per 154.403(d)(2): CEGT LLC—FUEL TRACKER—to be effective 5/1/2011.
Filed Date: 03/25/2011.
Accession Number: 20110325–5067.
Comment Date: 5 p.m. Eastern Time on Wednesday, April 6, 2011.

Docket Numbers: RP11–1900–000.
Applicants: Midcontinent Express Pipeline LLC.
Description: Midcontinent Express Pipeline LLC submits tariff filing per 154.204: Tenaska Negotiated Rate Filing to be effective 4/1/2011.
Filed Date: 03/25/2011.
Accession Number: 20110325–5076.
Comment Date: 5 p.m. Eastern Time on Wednesday, April 6, 2011.

Docket Numbers: RP11–1901–000.
Applicants: Midwestern Gas Transmission Company.
Description: Midwestern Gas Transmission Company submits tariff filing per 154.203: Compliance NCA Chevron to be effective 2/1/2011.
Filed Date: 03/25/2011.
Accession Number: 20110325–5100.
Comment Date: 5 p.m. Eastern Time on Wednesday, April 6, 2011.

Docket Numbers: RP11–1902–000.
Applicants: ANR Pipeline Company.
Description: ANR Pipeline Company submits tariff filing per 154.601: Non-Conforming Agreement with Negotiated Rates to be effective 4/1/2011.
Filed Date: 03/25/2011.
Accession Number: 20110325–5132.
Comment Date: 5 p.m. Eastern Time on Wednesday, April 6, 2011.

Docket Numbers: RP11–1903–000.
Applicants: Midwestern Gas Transmission Company.
Description: Midwestern Gas Transmission Company submits tariff filing per 154.204: Chevron U.S.A. Inc. FA0910 to be effective 4/1/2011.
Filed Date: 03/28/2011.
Accession Number: 20110328–5005.
Comment Date: 5 p.m. Eastern Time on Monday, April 11, 2011.

Docket Numbers: RP11–1904–000.
Applicants: Kinder Morgan Illinois Pipeline LLC.
Description: Penalty Revenue Crediting Report of Kinder Morgan Illinois Pipeline LLC.
Filed Date: 03/25/2011.
Accession Number: 20110325–5151.
Comment Date: 5 p.m. Eastern Time on Wednesday, April 6, 2011.

Any person desiring to intervene or to protest in any of the above proceedings

must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214) on or before 5 p.m. Eastern time on the specified comment date. It is not necessary to separately intervene again in a subdocket related to a compliance filing if you have previously intervened in the same docket. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant. In reference to filings initiating a new proceeding, interventions or protests submitted on or before the comment deadline need not be served on persons other than the Applicant.

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The filings in the above proceedings are accessible in the Commission's eLibrary system by clicking on the appropriate link in the above list. They are also available for review in the Commission's Public Reference Room in Washington, DC. There is an eSubscription link on the Web site that enables subscribers to receive e-mail notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please e-mail *FERCOnlineSupport@ferc.gov.* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: March 28, 2011.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2011–8263 Filed 4–6–11; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER09–1549–003; *ER10–426–004; ER09–172–007; ER09–173–007; ER06–1355–007; ER09–174–006; ER11–2201–001*

Applicants: First Wind Energy Marketing, LLC

Description: Supplemental Information to Triennial Market-Based Rate Update Filings of First Wind Energy, LLC.

Filed Date: 03/31/2011

Accession Number: 20110331–5330

Comment Date: 5 p.m. Eastern Time on Thursday, April 21, 2011

Docket Numbers: ER10–1508–002

Applicants: Tampa Electric Company

Description: Tampa Electric Company submits tariff filing per 35: Compliance Filing—Available Transfer Capability (ATC) to be effective 3/30/2011.

Filed Date: 03/31/2011

Accession Number: 20110331–5268

Comment Date: 5 p.m. Eastern Time on Thursday, April 21, 2011

Docket Numbers: ER10–3168–001

Applicants: ArcLight Energy Marketing, LLC

Description: ArcLight Energy Marketing, LLC Notice of Non-Material Change in Status.

Filed Date: 03/31/2011

Accession Number: 20110331–5258

Comment Date: 5 p.m. Eastern Time on Thursday, April 21, 2011

Docket Numbers: ER11–2046–002

Applicants: MATEP LLC

Description: MATEP LLC submits tariff filing per 35: MATEP Second Substitute MBR Tariff to be effective 3/2/2011.

Filed Date: 03/31/2011

Accession Number: 20110331–5310

Comment Date: 5 p.m. Eastern Time on Thursday, April 21, 2011

Docket Numbers: ER11–2530–002

Applicants: Pacific Gas and Electric Company

Description: Pacific Gas and Electric Company submits tariff filing per 35: Errata to Correct Compliance Filing: SVP IA to be effective 2/28/2011.

Filed Date: 03/31/2011

Accession Number: 20110331–5318

Comment Date: 5 p.m. Eastern Time on Thursday, April 21, 2011

Docket Numbers: ER11–2588–002

Applicants: Power Receivable Finance, LLC

Description: Power Receivable Finance, LLC submits tariff filing per 35: PRF Second Substitute MBR Tariff to be effective 2/28/2011.

Filed Date: 03/31/2011

Accession Number: 20110331–5311

Comment Date: 5 p.m. Eastern Time on Thursday, April 21, 2011

Docket Numbers: ER11–2715–001

Applicants: Interstate Power and Light Company

Description: Interstate Power and Light Company submits tariff filing per 35.17(b): IPL O & T Agreement—Updated Exhibits 1, 2 and 5 to be effective 3/21/2011.

Filed Date: 03/31/2011

Accession Number: 20110331–5316

Comment Date: 5 p.m. Eastern Time on Thursday, April 21, 2011

Docket Numbers: ER11–3254–000

Applicants: Nevada Power Company

Description: Nevada Power Company submits tariff filing per 35.15: Rate Schedule No. 52 Cancellation to be effective 6/1/2011.

Filed Date: 03/31/2011

Accession Number: 20110331–5221

Comment Date: 5 p.m. Eastern Time on Thursday, April 21, 2011

Docket Numbers: ER11–3255–000

Applicants: Westar Energy, Inc.

Description: Westar Energy, Inc. submits tariff filing per 35.13(a)(2)(iii): KEPCo, Changes to Attachment F to be effective 6/1/2011.

Filed Date: 03/31/2011

Accession Number: 20110331–5225

Comment Date: 5 p.m. Eastern Time on Thursday, April 21, 2011

Docket Numbers: ER11–3256–000

Applicants: Midwest Independent Transmission System Operator, Inc., ALLETE, Inc.

Description: Midwest Independent Transmission System Operator, Inc. submits tariff filing per 35.13(a)(2)(iii): Allete-Bison LGIAs filing to be effective 4/1/2011.

Filed Date: 03/31/2011

Accession Number: 20110331–5249

Comment Date: 5 p.m. Eastern Time on Thursday, April 21, 2011

Docket Numbers: ER11–3257–000

Applicants: Southwest Power Pool, Inc.

Description: Southwest Power Pool, Inc. submits tariff filing per 35.13(a)(2)(iii): 1822R2 Kanas Power Pool NITSA and NOAS to be effective 3/1/2011.

Filed Date: 03/31/2011

Accession Number: 20110331–5257

Comment Date: 5 p.m. Eastern Time on Thursday, April 21, 2011

Docket Numbers: ER11–3258–000

Applicants: New England Power Company

Description: New England Power Company submits tariff filing per 35.1: Construction Service Agreement between NEP and Peabody Municipal Light Plant to be effective 3/31/2011.

Filed Date: 03/31/2011

Accession Number: 20110331–5266

Comment Date: 5 p.m. Eastern Time on Thursday, April 21, 2011

Docket Numbers: ER11–3259–000

Applicants: Westar Energy, Inc.

Description: Westar Energy, Inc. submits tariff filing per 35.13(a)(2)(iii): Missouri Joint Municipal Electric Utility Commission Balancing Area Services to be effective 3/1/2011.

Filed Date: 03/31/2011

Accession Number: 20110331–5314

Comment Date: 5 p.m. Eastern Time on Thursday, April 21, 2011

Docket Numbers: ER11–3260–000

Applicants: New England Power Pool Participants Committee

Description: New England Power Pool Participants Committee submits tariff filing per 35.13(a)(2)(iii): April 2011 Membership Filing to be effective 3/1/2011.

Filed Date: 03/31/2011

Accession Number: 20110331–5321

Comment Date: 5 p.m. Eastern Time on Thursday, April 21, 2011

Docket Numbers: ER11–3261–000

Applicants: Southwest Power Pool, Inc.

Description: Southwest Power Pool, Inc. submits tariff filing per 35.13(a)(2)(iii): 1066R3 Northeast Texas Electric Coop. NITSA NOA to be effective 3/1/2011.

Filed Date: 03/31/2011

Accession Number: 20110331–5324

Comment Date: 5 p.m. Eastern Time on Thursday, April 21, 2011

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As it relates to any qualifying facility filings, the notices of self-certification [or self-recertification] listed above, do not institute a proceeding regarding qualifying facility status. A notice of self-certification [or self-recertification] simply provides notification that the entity making the filing has determined the facility named in the notice meets the applicable criteria to be a qualifying facility. Intervention and/or protest do not lie in dockets that are qualifying facility self-certifications or self-recertifications. Any person seeking to challenge such qualifying facility status may do so by filing a motion pursuant to 18 CFR 292.207(d)(iii). Intervention and protests may be filed in response to notices of qualifying facility dockets other than self-certifications and self-recertifications.

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Dated: April 01, 2011.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2011–8371 Filed 4–6–11; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #2

Take notice that the Commission received the following electric corporate filings:

Docket Numbers: EC11–56–000.

Applicants: Plains End, LLC, Rathdrum Power, LLC, Plains End II, LLC

Description: Application for Authorization for Disposition of Jurisdictional Facilities and Rquest for Expedited Action of Plains End, LLC, *et al.*

Filed Date: 03/29/2011.

Accession Number: 20110329–5116.

Comment Date: 5 p.m. Eastern Time on Tuesday, April 19, 2011.

Take notice that the Commission received the following exempt wholesale generator filings:

Docket Numbers: EG11–73–000.

Applicants: Blue Canyon Windpower VI LLC.

Description: Notice of Self-Certification of Exempt Wholesale Generator Status of Blue Canyon Windpower VI LLC.

Filed Date: 03/29/2011.

Accession Number: 20110329–5105.

Comment Date: 5 p.m. Eastern Time on Tuesday, April 19, 2011.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER11–3206–000.

Applicants: NorthWestern Corporation.

Description: NorthWestern Corporation submits tariff filing per 35.13(a)(2)(iii): Service Agreement No. 578—Butte Silver Bow EPC Agreement to be effective 4/1/2011.

Filed Date: 03/29/2011.

Accession Number: 20110329–5000.

Comment Date: 5 p.m. Eastern Time on Tuesday, April 19, 2011.

Docket Numbers: ER11–3209–000.

Applicants: Hammond Belgrade Energy, LLC.

Description: Hammond Belgrade Energy, LLC submits tariff filing per 35.1: Hammond Belgrade FERC Electric Tariff to be effective 3/29/2011.

Filed Date: 03/29/2011.

Accession Number: 20110329–5057.

Comment Date: 5 p.m. Eastern Time on Tuesday, April 19, 2011.

Docket Numbers: ER11–3210–000.

Applicants: ISO New England Inc.

Description: ISO New England Inc. submits tariff filing per 35.13(a)(2)(iii): Revisions to Correct Tariff Records to be effective 3/16/2011.

Filed Date: 03/29/2011.
Accession Number: 20110329–5075.
Comment Date: 5 p.m. Eastern Time on Tuesday, April 19, 2011.

Docket Numbers: ER11–3211–000.
Applicants: Pacific Gas and Electric Company.
Description: Pacific Gas and Electric Company submits tariff filing per 35.13(a)(2)(iii): PWRPA Amended Appendix B to IA and WDT Service Agreements to be effective 3/30/2011.
Filed Date: 03/29/2011.
Accession Number: 20110329–5080.
Comment Date: 5 p.m. Eastern Time on Tuesday, April 19, 2011.

Docket Numbers: ER11–3212–000.
Applicants: XO Energy NY. LP.
Description: XO Energy NY. LP submits tariff filing per 35.12: XO Energy NY, LP Application for Market-based Rates to be effective 3/29/2011.
Filed Date: 03/29/2011.
Accession Number: 20110329–5097.
Comment Date: 5 p.m. Eastern Time on Tuesday, April 19, 2011.

Docket Numbers: ER11–3213–000.
Applicants: XO Energy MA, LP.
Description: XO Energy MA, LP submits tariff filing per 35.12: XO Energy MA, LP Application for Market-based Rates to be effective 3/29/2011.
Filed Date: 03/29/2011.
Accession Number: 20110329–5118.
Comment Date: 5 p.m. Eastern Time on Tuesday, April 19, 2011.

Docket Numbers: ER11–3214–000.
Applicants: XO Energy MW, LP.
Description: XO Energy MW, LP submits tariff filing per 35.12: XO Energy MW, LP Application for Market-based Rates to be effective 3/29/2011.
Filed Date: 03/29/2011.
Accession Number: 20110329–5119.
Comment Date: 5 p.m. Eastern Time on Tuesday, April 19, 2011.

Docket Numbers: ER11–3215–000.
Applicants: Monterey CA, LLC.
Description: Monterey CA, LLC submits tariff filing per 35.12: Monterey CA, LLC Application for Market-based Rates to be effective 3/29/2011.
Filed Date: 03/29/2011.
Accession Number: 20110329–5120.
Comment Date: 5 p.m. Eastern Time on Tuesday, April 19, 2011.

Docket Numbers: ER11–3216–000.
Applicants: Monterey MA, LLC.
Description: Monterey MA, LLC submits tariff filing per 35.12: Monterey MA, LLC Application for Market-based Rates to be effective 3/29/2011.
Filed Date: 03/29/2011.
Accession Number: 20110329–5122.
Comment Date: 5 p.m. Eastern Time on Tuesday, April 19, 2011.

Docket Numbers: ER11–3217–000.
Applicants: Shipyard Energy, LLC.
Description: Shipyard Energy, LLC submits tariff filing per 35.1: Shipyard Energy FERC Electric Tariff to be effective 3/29/2011.
Filed Date: 03/29/2011.
Accession Number: 20110329–5124.
Comment Date: 5 p.m. Eastern Time on Tuesday, April 19, 2011.

Docket Numbers: ER11–3218–000.
Applicants: Monterey MW, LLC.
Description: Monterey MW, LLC submits tariff filing per 35.12: Monterey MW, LLC Application for Market-based Rates to be effective 3/29/2011.
Filed Date: 03/29/2011.
Accession Number: 20110329–5125.
Comment Date: 5 p.m. Eastern Time on Tuesday, April 19, 2011.

Docket Numbers: ER11–3219–000.
Applicants: Monterey NY, LLC.
Description: Monterey NY, LLC submits tariff filing per 35.12: Monterey NY, LLC Application for Market-based Rates to be effective 3/29/2011.
Filed Date: 03/29/2011.
Accession Number: 20110329–5127.
Comment Date: 5 p.m. Eastern Time on Tuesday, April 19, 2011.

Take notice that the Commission received the following electric reliability filings:

Docket Numbers: RD09–7–003; *RD10–6–001.*
Applicants: North American Electric Reliability Corp.
Description: Compliance Filing of the North American Electric Reliability Corporation in Response to January 20, 2011 Order on Violation Risk Factors and Violation Severity Levels for CIP Reliability Standards in Docket No. RD10–6, *et al.*
Filed Date: 03/21/2011.
Accession Number: 20110321–5061.
Comment Date: 5 p.m. Eastern Time on Monday, April 11, 2011.

Any person desiring to intervene or to protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214) on or before 5 p.m. Eastern time on the specified comment date. It is not necessary to separately intervene again in a subdocket related to a compliance filing if you have previously intervened in the same docket. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant. In reference to filings initiating a new proceeding, interventions or protests submitted on or before the comment deadline need not be served on persons other than the Applicant.

As it relates to any qualifying facility filings, the notices of self-certification [or self-recertification] listed above, do not institute a proceeding regarding qualifying facility status. A notice of self-certification [or self-recertification] simply provides notification that the entity making the filing has determined the facility named in the notice meets the applicable criteria to be a qualifying facility. Intervention and/or protest do not lie in dockets that are qualifying facility self-certifications or self-recertifications. Any person seeking to challenge such qualifying facility status may do so by filing a motion pursuant to 18 CFR 292.207(d)(iii). Intervention and protests may be filed in response to notices of qualifying facility dockets other than self-certifications and self-recertifications.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov.* To facilitate electronic service, persons with Internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically should submit an original and 14 copies of the intervention or protest to the Federal Energy Regulatory Commission, 888 First St., NE., Washington, DC 20426.

The filings in the above proceedings are accessible in the Commission's eLibrary system by clicking on the appropriate link in the above list. They are also available for review in the Commission's Public Reference Room in Washington, DC. There is an eSubscription link on the Web site that enables subscribers to receive e-mail notification when a document is added to a subscribed dockets(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: March 29, 2011.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2011–8322 Filed 4–6–11; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER10–2500–001.
Applicants: Arizona Public Service Company.
Description: Arizona Public Service Company submits tariff filing per 35: Compliance filing to conform Attachment M of APS's OATT to be effective 8/31/2010.
Filed Date: 01/27/2011.
Accession Number: 20110127–5146.
Comment Date: 5 p.m. Eastern Time on Tuesday, April 5, 2011.

Docket Numbers: ER11–2224–003.
Applicants: New York Independent System Operator, Inc.
Description: New York Independent System Operator, Inc. submits tariff filing per 35: Compliance Filing to State Currently Effective ICAP Demand Curves to be effective 4/21/2011.
Filed Date: 03/28/2011.
Accession Number: 20110328–5173.
Comment Date: 5 p.m. Eastern Time on Thursday, March 31, 2011.

Docket Numbers: ER11–3161–001.
Applicants: NorthWestern Corporation.
Description: NorthWestern Corporation submits tariff filing per 35.17(b): Resubmittal of Service Agreements/LGIAs with Martinsdale to be effective 9/10/2009.
Filed Date: 03/28/2011.
Accession Number: 20110328–5174.
Comment Date: 5 p.m. Eastern Time on Monday, April 18, 2011.

Docket Numbers: ER11–3203–000.
Applicants: PJM Interconnection, L.L.C.
Description: PJM Interconnection, L.L.C. submits tariff filing per 35.13(a)(2)(iii): S55 Interim ISA Original Service Agreement No. 2800 to be effective 2/25/2010.
Filed Date: 03/28/2011.
Accession Number: 20110328–5137.
Comment Date: 5 p.m. Eastern Time on Monday, April 18, 2011.

Docket Numbers: ER11–3204–000.
Applicants: Consolidated Edison Company of New York, Inc.
Description: Consolidated Edison Company of New York, Inc. submits tariff filing per 35.13(a)(1): Rate Year 2 amendments PASNY/EDDS to be effective 4/1/2011.
Filed Date: 03/28/2011.
Accession Number: 20110328–5158.
Comment Date: 5 p.m. Eastern Time on Monday, April 18, 2011.

Docket Numbers: ER11–3205–000.
Applicants: PJM Interconnection, L.L.C.
Description: PJM Interconnection, L.L.C. submits tariff filing per 35.13(a)(2)(iii): W2–014 ? Interim ISA Original Service Agreement No. 2797 to be effective 2/25/2011.
Filed Date: 03/28/2011.
Accession Number: 20110328–5172.
Comment Date: 5 p.m. Eastern Time on Monday, April 18, 2011.

Docket Numbers: ER11–3207–000.
Applicants: PJM Interconnection, L.L.C.
Description: PJM Interconnection, L.L.C. submits Notice of Cancellation of Original Service Agreement No. 2397 with Zion Energy LLC and Commonwealth Edison Company.
Filed Date: 03/28/2011.
Accession Number: 20110328–5178.
Comment Date: 5 p.m. Eastern Time on Monday, April 18, 2011.

Docket Numbers: ER11–3208–000.
Applicants: PJM Interconnection, L.L.C.
Description: PJM Interconnection, L.L.C. submits Notice of Cancellation of Original Service Agreement No. 2640 with Zion Energy LLC and Commonwealth Edison Company.
Filed Date: 03/28/2011.
Accession Number: 20110328–5179.
Comment Date: 5 p.m. Eastern Time on Monday, April 18, 2011.

Any person desiring to intervene or to protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214) on or before 5 p.m. Eastern time on the specified comment date. It is not necessary to separately intervene again in a subdocket related to a compliance filing if you have previously intervened in the same docket. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant. In reference to filings initiating a new proceeding, interventions or protests submitted on or before the comment deadline need not be served on persons other than the Applicant.

As it relates to any qualifying facility filings, the notices of self-certification [or self-recertification] listed above, do not institute a proceeding regarding qualifying facility status. A notice of self-certification [or self-recertification] simply provides notification that the entity making the filing has determined the facility named in the notice meets the applicable criteria to be a qualifying facility. Intervention and/or protest do not lie in dockets that are qualifying facility self-certifications or self-recertifications. Any person seeking to challenge such qualifying facility status may do so by filing a motion pursuant to 18 CFR 292.207(d)(iii). Intervention and protests may be filed in response to notices of qualifying facility dockets other than self-certifications and self-recertifications.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov.* To facilitate electronic service, persons with Internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically should submit an original and 14 copies of the intervention or protest to the Federal Energy Regulatory Commission, 888 First St., NE., Washington, DC 20426.

The filings in the above proceedings are accessible in the Commission's eLibrary system by clicking on the appropriate link in the above list. They are also available for review in the Commission's Public Reference Room in Washington, DC. There is an eSubscription link on the Web site that enables subscribers to receive e-mail notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please e-mail *FERCOnlineSupport@ferc.gov.* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: March 29, 2011.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2011–8321 Filed 4–6–11; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER09–1534–002; ER11–2405–001.
Applicants: Southern California Edison Company.

Description: Southern California Edison Company's Refund Report, in Compliance with the Commission's February 11, 2011, Issued Letter Order.

Filed Date: 03/30/2011.

Accession Number: 20110330–5059.

Comment Date: 5 p.m. Eastern Time on Wednesday, April 20, 2011.

Docket Numbers: ER11–1991–002.

Applicants: Midwest Independent Transmission System Operator, Inc.

Description: Midwest Independent Transmission System Operator, Inc. submits tariff filing per 35: 03–30–11 DIR 30-day Compliance to be effective 3/1/2011.

Filed Date: 03/30/2011.

Accession Number: 20110330–5199.

Comment Date: 5 p.m. Eastern Time on Wednesday, April 20, 2011.

Docket Numbers: ER11–2887–001.

Applicants: PacifiCorp.

Description: PacifiCorp submits tariff filing per 35.17(b): BPA AC Intertie Agreement Amended Filing to be effective 4/17/2011.

Filed Date: 03/30/2011.

Accession Number: 20110330–5226.

Comment Date: 5 p.m. Eastern Time on Wednesday, April 20, 2011.

Docket Numbers: ER11–3117–001.

Applicants: Lively Grove Energy Partners, LLC.

Description: Lively Grove Energy Partners, LLC submits tariff filing per 35.17(b): Amendment Filing to MBR Tariff to be effective 5/31/2011.

Filed Date: 03/30/2011.

Accession Number: 20110330–5064.

Comment Date: 5 p.m. Eastern Time on Wednesday, April 13, 2011.

Docket Numbers: ER11–3117–001.

Applicants: Lively Grove Energy Partners, LLC.

Description: Supplemental Information of Lively Grove Energy Partners, LLC under ER11–3117, Only the date of Transmittal Letter should be changed from March 30, 2010 to March 30, 2011.

Filed Date: 03/30/2011.

Accession Number: 20110330–5243.

Comment Date: 5 p.m. Eastern Time on Wednesday, April 13, 2011.

Docket Numbers: ER11–3223–000.

Applicants: Central Maine Power Company.

Description: Central Maine Power Company submits tariff filing per 35.13(a)(2)(iii): Central Maine Power Company—Sparhawk Mill Assoc. LLC Interconnection Agreement to be effective 3/1/2011.

Filed Date: 03/30/2011.

Accession Number: 20110330–5036.

Comment Date: 5 p.m. Eastern Time on Wednesday, April 20, 2011.

Docket Numbers: ER11–3224–000.

Applicants: Westar Energy, Inc.

Description: Westar Energy, Inc. submits tariff filing per 35.13(a)(2)(iii): Midwest Energy, Inc. Participation Power Agreement to be effective 6/1/2011.

Filed Date: 03/30/2011.

Accession Number: 20110330–5046.

Comment Date: 5 p.m. Eastern Time on Wednesday, April 20, 2011.

Docket Numbers: ER11–3225–000.

Applicants: Midwest Independent Transmission System Operator, Inc.

Description: Midwest Independent Transmission System Operator, Inc. submits tariff filing per 35: 03–30–11 Attachment C to be effective 4/1/2011.

Filed Date: 03/30/2011.

Accession Number: 20110330–5047.

Comment Date: 5 p.m. Eastern Time on Wednesday, April 20, 2011.

Docket Numbers: ER11–3226–000.

Applicants: KCP&L Greater Missouri Operations Company.

Description: KCP&L Greater Missouri Operations Company submits tariff filing per 35.13(a)(2)(iii): Depreciation Update Filing to be effective 6/4/2011.

Filed Date: 03/30/2011.

Accession Number: 20110330–5073.

Comment Date: 5 p.m. Eastern Time on Wednesday, April 20, 2011.

Docket Numbers: ER11–3227–000.

Applicants: American Transmission Systems, Incorporation, PJM Interconnection, L.L.C.

Description: American Transmission Systems, Incorporated submits tariff filing per 35.13(a)(2)(iii): First Energy Serv Co. Interconnection Agreements re ATSI Integration into PJM to be effective 6/1/2011.

Filed Date: 03/30/2011.

Accession Number: 20110330–5083.

Comment Date: 5 p.m. Eastern Time on Wednesday, April 20, 2011.

Docket Numbers: ER11–3228–000.

Applicants: Southwestern Public Service Company.

Description: Southwestern Public Service Company submits tariff filing per 35.13(a)(2)(iii): 3–30–11_RS132 SPS–GSEC to be effective 7/16/2010.

Filed Date: 03/30/2011.

Accession Number: 20110330–5101.

Comment Date: 5 p.m. Eastern Time on Wednesday, April 20, 2011.

Docket Numbers: ER11–3229–000.

Applicants: Alcoa Power Generating Inc.

Description: Alcoa Power Generating Inc. submits tariff filing per 35.13(a)(2)(iii): APGI Order No. 676–E OATT Revisions to be effective 4/1/2011.

Filed Date: 03/30/2011.

Accession Number: 20110330–5102.

Comment Date: 5 p.m. Eastern Time on Wednesday, April 20, 2011.

Docket Numbers: ER11–3230–000.

Applicants: Southwest Power Pool, Inc.

Description: Southwest Power Pool, Inc. submits tariff filing per 35.13(a)(2)(iii): 1693R1 Western Trail Wind Project I LLC LGIA to be effective 2/28/2011.

Filed Date: 03/30/2011.

Accession Number: 20110330–5103.

Comment Date: 5 p.m. Eastern Time on Wednesday, April 20, 2011.

Docket Numbers: ER11–3231–000.

Applicants: Trans Bay Cable LLC.

Description: Trans Bay Cable LLC submits tariff filing per 35.1: Schedule Rate to be effective 3/30/2011.

Filed Date: 03/30/2011.

Accession Number: 20110330–5113.

Comment Date: 5 p.m. Eastern Time on Wednesday, April 20, 2011.

Docket Numbers: ER11–3232–000.

Applicants: Florida Power Corporation.

Description: Notice of Cancellation of Interchange Agreement with LG&E Energy Marketing by Florida Power Corporation.

Filed Date: 03/30/2011.

Accession Number: 20110330–5115.

Comment Date: 5 p.m. Eastern Time on Wednesday, April 20, 2011.

Docket Numbers: ER11–3233–000.

Applicants: Westar Energy, Inc.

Description: Westar Energy, Inc. submits tariff filing per 35.13(a)(2)(iii): Cost-Based Rate Schedule to be effective 6/1/2011.

Filed Date: 03/30/2011.

Accession Number: 20110330–5123.

Comment Date: 5 p.m. Eastern Time on Wednesday, April 20, 2011.

Docket Numbers: ER11–3234–000.

Applicants: Northern States Power Company, a Minnesota.

Description: Northern States Power Company, a Minnesota corporation submits tariff filing per 35.13(a)(2)(iii): 20110330_InterchangeAgreement to be effective 1/1/2011.

Filed Date: 03/30/2011.

Accession Number: 20110330–5152.

Comment Date: 5 p.m. Eastern Time on Wednesday, April 20, 2011.

Docket Numbers: ER11–3235–000.

Applicants: Northern States Power Company, a Wisconsin.

Description: Northern States Power Company, a Wisconsin corporation submits tariff filing per 35.13(a)(2)(iii): 20110330_InterchangeAgreement to be effective 1/1/2011.

Filed Date: 03/30/2011.

Accession Number: 20110330–5155.

Comment Date: 5 p.m. Eastern Time on Wednesday, April 20, 2011.

Docket Numbers: ER11–3236–000.

Applicants: New York Independent System Operator, Inc.

Description: New York Independent System Operator, Inc. submits tariff filing per 35.13(a)(2)(iii): NYISO Filing to Revise BPCG Calculation and Request for Waiver to be effective 6/1/2011.

Filed Date: 03/30/2011.

Accession Number: 20110330–5184.

Comment Date: 5 p.m. Eastern Time on Wednesday, April 20, 2011.

Docket Numbers: ER11–3237–000.

Applicants: Wisconsin Electric Power Company.

Description: Wisconsin Electric Power Company submits tariff filing per 35.12: Wisconsin Electric Formula Rate Wholesale Sales Tariff Service Agreement No 2 to be effective 6/1/2011. Filing Type: 20.

Filed Date: 03/30/2011.

Accession Number: 20110330–5201.

Comment Date: 5 p.m. Eastern Time on Wednesday, April 20, 2011.

Take notice that the Commission received the following open access transmission tariff filings:

Docket Numbers: OA07–32–011.

Applicants: Entergy Services, Inc.

Description: Informational report of Entergy Services, Inc.

Filed Date: 03/30/2011.

Accession Number: 20110330–5241.

Comment Date: 5 p.m. Eastern Time on Wednesday, April 20, 2011.

Any person desiring to intervene or to protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214) on or before 5 p.m. Eastern time on the specified comment date. It is not necessary to separately intervene again in a subdocket related to a compliance filing if you have previously intervened in the same docket. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant. In reference to filings initiating a new proceeding, interventions or protests submitted on or before the comment deadline need not be served on persons other than the Applicant.

As it relates to any qualifying facility filings, the notices of self-certification [or self-recertification] listed above, do not institute a proceeding regarding qualifying facility status. A notice of self-certification [or self-recertification] simply provides notification that the entity making the filing has determined the facility named in the notice meets the applicable criteria to be a qualifying facility. Intervention and/or protest do not lie in dockets that are qualifying facility self-certifications or self-recertifications. Any person seeking to challenge such qualifying facility status may do so by filing a motion pursuant to 18 CFR 292.207(d)(iii). Intervention and protests may be filed in response to notices of qualifying facility dockets other than self-certifications and self-recertifications.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov.* To facilitate electronic service, persons with Internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically should submit an original and 14 copies of the intervention or protest to the Federal Energy Regulatory Commission, 888 First St., NE., Washington, DC 20426.

The filings in the above proceedings are accessible in the Commission's eLibrary system by clicking on the appropriate link in the above list. They are also available for review in the Commission's Public Reference Room in Washington, DC. There is an eSubscription link on the Web site that enables subscribers to receive e-mail notification when a document is added to a subscribed dockets(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: March 31, 2011.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2011–8251 Filed 4–6–11; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP10–448–000]

Dominion Transmission, Inc.; Notice of Availability of the Environmental Assessment for the Proposed Appalachian Gateway Project

The staff of the Federal Energy Regulatory Commission (FERC or Commission) has prepared an environmental assessment (EA) for the Appalachian Gateway Project proposed by Dominion Transmission, Inc. (Dominion) in the above-referenced docket. Dominion requests authorization to construct and operate the Appalachian Gateway Project including 110 miles of 20- through 30-inch-diameter pipeline (26.3 miles in West Virginia and 74.9 miles in Pennsylvania) along with associated minor pipeline and support facilities, and additional compression, which would increase Dominion's authorized capacity for the transportation of natural gas by about 484 million cubic feet per day.

The EA assesses the potential environmental effects of the construction and operation of the Appalachian Gateway Project in accordance with the requirements of the National Environmental Policy Act of 1969 (NEPA). The FERC staff concludes that approval of the proposed project, with appropriate mitigating measures, would not constitute a major Federal action significantly affecting the quality of the human environment.

The proposed Appalachian Gateway Project includes the following facilities:

Pipeline Facilities

- the 5.3 miles, 20-inch-diameter TL–570, EXT. 1 pipeline in Kanawha County, West Virginia;
- the 6 mile, 24-inch-diameter TL–492, EXT. 5 pipeline in Greene County, Pennsylvania;
- the 42.3 mile 30-inch-diameter TL–590 pipeline in Marshall and Greene Counties, Pennsylvania;
- the 54.2 mile, 24-inch-diameter TL–591 pipeline in Greene, Washington, Allegheny, and Westmoreland Counties, Pennsylvania;
- the 0.5 mile, 16 inch-diameter TL–596 pipeline in Wetzel County, West Virginia;
- the 0.1 mile, 10-inch-diameter TL–597 pipeline in Wetzel County, West Virginia;
- the 0.3 mile, 16-inch-diameter TL–598 pipeline in Harrison County, West Virginia;
- the 0.4 mile, 16-inch-diamter TL–599 pipeline in Harrison County, West Virginia;

Compressor Station Facilities

- the new 4,735 horsepower (hp) Chelyan Compressor Station in County, West Virginia;
- the new 3,550 hp Lewis Wetzel Compressor Station in Wetzel County, West Virginia;
- the new 1,775 hp Morrison Compressor Station in Harrison County, West Virginia;

• the new 6,130 hp Burch Ridge Compressor Station in Mashall County, West Virginia;
• modify the existing Pepper Compressor Station with the addition of 1,665 hp of new compression;
• modify the existing reciprocating engine at the Schutte Compressor Station in Doddridge County, West Virginia by replacing the cylinder liners;

Ancillary Facilities

• the TL–591 Metering and Regulation (M&R) Station, in Westmoreland County, Pennsylvania;
• the Crayne M&R Station in Green County, Pennsylvania; and
• pig launchers, receivers and mainline valves along the pipelines.

The EA has been placed in the public files of the FERC and is available for public viewing on the FERC's Web site at *http://www.ferc.gov* using the eLibrary link. A limited number of copies of the EA are available for distribution and public inspection at: Federal Energy Regulatory Commission, Public Reference Room, 888 First Street, NE., Room 2A, Washington, DC 20426. (202) 502–8371.

Copies of the EA have been mailed to Federal, State, and local government representatives and agencies; elected officials; Native American Tribes; potentially affected landowners and other interested individuals and groups; and newspapers in the project area; and parties to this proceeding.

Any person wishing to comment on the EA may do so. Your comments should focus on the potential environmental effects, reasonable alternatives, and measures to avoid or lessen environmental impacts. The more specific your comments, the more useful they will be. To ensure that your comments are properly recorded and considered prior to a Commission decision on the proposal, it is important that the FERC receives your comments in Washington, DC on or before May 6, 2011.

For your convenience, there are three methods you can use to submit your comments to the Commission. In all instances, please reference the project docket number (CP10–448–000) with your submission. The Commission encourages electronic filing of comments and has dedicated eFiling expert staff available to assist you at (202) 502–8258 or *efiling@ferc.gov*.

(1) You may file your comments electronically by using the eComment feature, which is located on the Commission's Web site at *http://www.ferc.gov* under the link to *Documents and Filings.* An eComment is an easy method for interested persons to submit brief, text-only comments on a project;

(2) You may file your comments electronically by using the eFiling feature, which is located on the Commission's Web site at *http://www.ferc.gov* under the link to *Documents and Filings.* With eFiling, you can provide comments in a variety of formats by attaching them as a file with your submission. New eFiling users must first create an account by clicking on "*eRegister*." You will be asked to select the type of filing you are making. A comment on a particular project is considered a "Comment on a Filing"; or

(3) You may file a paper copy of your comments at the following address: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street, NE., Room 1A, Washington, DC 20426.

Although your comments will be considered by the Commission, simply filing comments will not serve to make the commenter a party to the proceeding. Any person seeking to become a party to the proceeding must file a motion to intervene pursuant to Rule 214 of the Commission's Rules of Practice and Procedures (18 CFR 385.214).[1] Only intervenors have the right to seek rehearing of the Commission's decision.

Affected landowners and parties with environmental concerns may be granted intervenor status upon showing good cause by stating that they have a clear and direct interest in this proceeding which would not be adequately represented by any other parties. You do not need intervenor status to have your comments considered.

Additional information about the project is available from the Commission's Office of External Affairs, at (866) 208–FERC or on the FERC Web site (*http://www.ferc.gov*) using the eLibrary link. Click on the eLibrary link, click on "General Search" and enter the docket number excluding the last three digits in the Docket Number field (*i.e.,* CP10–448). Be sure you have selected an appropriate date range. For assistance, please contact FERC Online Support at *FercOnlineSupport@ferc.gov* or toll free at (866) 208–3676, or for TTY, contact (202) 502–8659. The eLibrary link also provides access to the texts of formal documents issued by the Commission, such as orders, notices, and rulemakings.

In addition, the Commission offers a free service called eSubscription which allows you to keep track of all formal issuances and submittals in specific dockets. This can reduce the amount of time you spend researching proceedings by automatically providing you with notification of these filings, document summaries, and direct links to the documents. Go to *http://www.ferc.gov/esubscribenow.htm.*

Dated: March 31, 2011.

Kimberly D. Bose,

Secretary.

[FR Doc. 2011–8246 Filed 4–6–11; 8:45 am]

BILLING CODE 6717–01–P

[1] Interventions may also be filed electronically via the Internet in lieu of paper. See the previous discussion on filing comments electronically.

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ID–6528–000]

Truax, Hal D.; Notice of Filing

Take notice that on April 1, 2011, Hal D. Truax submitted for filing, an application for authority to hold interlocking positions, pursuant to section 305(b) of the Federal Power Act, 16 U.S.C. 825d (b) (2008), part 45 of Title 18 of the Code of Federal Regulations, 18 CFR part 45, and Commission Order No. 664, 112 FERC ¶ 61,298 (2005).

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 April 21, 2011.

Dated: April 1, 2011.

Kimberly D. Bose,

Secretary.

[FR Doc. 2011–8304 Filed 4–6–11; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER11–3214–000]

XO Energy MW, LP; 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 XO Energy MW, LP'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 April 19, 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: March 30, 2011.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2011–8256 Filed 4–6–11; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER11–3212–000]

XO Energy NY, LP; 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 XO Energy NY, LP'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 April 19, 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: March 30, 2011.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2011–8259 Filed 4–6–11; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER11–3188–000]

Stream Energy Maryland, 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 Stream Energy Maryland, 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 April 19, 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: March 30, 2011.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2011–8258 Filed 4–6–11; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER11–3215–000]

Monterey CA, 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 Monterey CA, 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 April 19, 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: March 30, 2011.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2011–8255 Filed 4–6–11; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER11–3186–000]

Southern California Telephone Company; 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 Southern California Telephone Company'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 April 19, 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: March 30, 2011.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2011–8260 Filed 4–6–11; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER11–3218–000]

Monterey MW, 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 Monterey MW, 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 April 19, 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: March 30, 2011.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2011–8253 Filed 4–6–11; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER11–3219–000]

Monterey NY, 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 Monterey NY, 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 April 19, 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: March 30, 2011.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2011–8252 Filed 4–6–11; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER11–3216–000]

Monterey MA, 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 Monterey MA, 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 April 19, 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: March 30, 2011.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2011–8254 Filed 4–6–11; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER11–3187–000]

SBR 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 SBR 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 April 19, 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: March 30, 2011.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2011–8261 Filed 4–6–11; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER11–3213–000]

XO Energy MA, LP; 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 XO Energy MA, LP'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 April 19, 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: March 30, 2011.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2011–8257 Filed 4–6–11; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 14109–000]

Oregon Winds Hydro, LLC; Notice of Preliminary Permit Application Accepted for Filing and Soliciting Comments, Motions To Intervene, and Competing Applications

On March 11, 2011, Oregon Winds Hydro, LLC filed an application for a preliminary permit, pursuant to section 4(f) of the Federal Power Act (FPA), proposing to study the feasibility of the Oregon Winds Pumped Storage Project to be located on the John Day River, near Condon, Gilliam County, Oregon. The sole purpose of a preliminary permit, if issued, is to grant the permit holder priority to file a license application during the permit term. A preliminary permit does not authorize the permit holder to perform any land-disturbing activities or otherwise enter upon lands or waters owned by others without the owners' express permission.

The proposed project will consist of the following: (1) An upper reservoir with a total storage capacity of 12,000 acre-feet at a normal maximum operating elevation of 2,480 feet mean sea level (msl); (2) a 60-foot-high, 9,120-foot-long upper embankment, Ring Dam; (3) a 200-foot-long, 19.2-foot-diameter concrete-lined low-pressure tunnel; (4) a lower reservoir with a total/usable storage capacity of 12,330 acre-feet at 1,240 feet msl; (5) a 6,500-foot-long, 19.2-foot-diameter concrete and steel-lined high-pressure tunnel; (6) an underground power house located 800 feet southwest of the lower reservoir; (7) a 13-mile-long, 230-kilovolt (kV) transmission line extending from the project substation to the point of interconnection with an existing overhead 500-kV transmission line. The estimated annual generation of the Oregon Winds Pumped Storage Project would be 1,533 gigawatt-hours.

Applicant Contact: Mr. Matthew Shapiro, CEO, Gridflex Energy, LCC; 1210 W. Franklin Street, Ste. 2; Boise, ID 83702; phone: (208) 246–9925.

FERC Contact: Ian Smith; phone: (202) 502–8943.

Deadline for filing comments, motions to intervene, competing applications (without notices of intent), or notices of intent to file competing applications: 60 days from the issuance of this notice. Competing applications and notices of intent must meet the requirements of 18 CFR 4.36. Comments, motions to intervene, notices of intent, and competing applications may be filed electronically via the Internet. See 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site *http://www.ferc.gov/docs-filing/efiling.asp.* Commenters can submit brief comments up to 6,000 characters, without prior registration, using the eComment system at *http://www.ferc.gov/docs-filing/ecomment.asp.* You must include your name and contact information at the end of your comments. For assistance, please contact FERC Online Support at *FERCOnlineSupport@ferc.gov* 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.

More information about this project, including a copy of the application, can be viewed or printed on the "eLibrary" link of Commission's Web site at *http://www.ferc.gov/docs-filing/elibrary.asp.* Enter the docket number (P–14109–000) in the docket number field to access the document. For assistance, contact FERC Online Support.

Dated: April 1, 2011.

Kimberly D. Bose,

Secretary.

[FR Doc. 2011–8303 Filed 4–6–11; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. TS11–2–000]

City Utility Commission of the City of Owensboro, Kentucky; Notice of Request for Waiver or Exemption

Take notice that on March 18, 2011, The City Utility Commission of the City of Owensboro, Kentucky, filed a petition for waiver or exemption of any reciprocity-based standards of conduct or open access same-time information system (OASIS) requirements under Order No. 888, FERC Stats. & Regs. ¶ 31,036 (1996), Order No. 890, FERC Stats. & Regs. ¶ 31,241 (2007), or Order No. 717, 125 FERC ¶ 61,064 (2008).

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 April 18, 2011.

Dated: March 31, 2011.

Kimberly D. Bose,

Secretary.

[FR Doc. 2011–8245 Filed 4–6–11; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Notice of Staff Attendance at Southwest Power Pool Markets Operations Policy Committee Meeting

The Federal Energy Regulatory Commission hereby gives notice that members of its staff may attend the meeting of the Southwest Power Pool, Inc. (SPP) Markets Operations Policy Committee (MOPC), as noted below. Their attendance is part of the Commission's ongoing outreach efforts.

SPP MOPC

April 12, 2011 (8 a.m.–5 p.m.), April 13, 2011 (8 a.m.–3 p.m.), Doubletree Hotel, 616 West 7th Street, Tulsa, OK 74127, 800–838–7914.

The discussions may address matters at issue in the following proceedings:

Docket No. ER06–451, *Southwest Power Pool, Inc.*
Docket No. ER08–1419, *Southwest Power Pool, Inc.*
Docket No. ER09–659, *Southwest Power Pool, Inc.*
Docket No. ER09–1050, *Southwest Power Pool, Inc.*
Docket No. OA08–104, *Southwest Power Pool, Inc.*
Docket No. ER10–696, *Southwest Power Pool, Inc.*
Docket No. ER10–941, *Southwest Power Pool, Inc.*
Docket No. ER10–1069, *Southwest Power Pool, Inc.*
Docket No. ER10–1254, *Southwest Power Pool, Inc.*
Docket No. ER10–1269, *Southwest Power Pool, Inc.*
Docket No. ER10–1697, *Southwest Power Pool, Inc.*
Docket No. ER10–2244, *Southwest Power Pool, Inc.*
Docket No. ER11–13, *Southwest Power Pool, Inc.*
Docket No. ER11–2303, *Southwest Power Pool, Inc.*
Docket No. ER11–2428, *Southwest Power Pool, Inc.*
Docket No. ER11–2528, *Southwest Power Pool, Inc.*
Docket No. ER11–2711, *Southwest Power Pool, Inc.*
Docket No. ER11–2719, *Southwest Power Pool, Inc.*
Docket No. ER11–2725, *Southwest Power Pool, Inc.*
Docket No. ER11–2736, *Southwest Power Pool, Inc.*
Docket No. ER11–2758, *Southwest Power Pool, Inc.*
Docket No. ER11–2781, *Southwest Power Pool, Inc.*
Docket No. ER11–2783, *Southwest Power Pool, Inc.*
Docket No. ER11–2787, *Southwest Power Pool, Inc.*
Docket No. ER11–2828, *Southwest Power Pool, Inc.*
Docket No. ER11–2837, *Southwest Power Pool, Inc.*
Docket No. ER11–2861, *Southwest Power Pool, Inc.*
Docket No. ER11–2881, *Southwest Power Pool, Inc.*
Docket No. ER11–2916, *Southwest Power Pool, Inc.*

These meetings are open to the public.

For more information, contact Patrick Clarey, Office of Energy Market Regulation, Federal Energy Regulatory Commission at (317) 249–5937 or *patrick.clarey@ferc.gov*.

Dated: April 1, 2011.

Kimberly D. Bose,

Secretary.

[FR Doc. 2011–8305 Filed 4–6–11; 8:45 am]

BILLING CODE 6717–01–P

EXPORT-IMPORT BANK OF THE U.S.

[Public Notice 2011–0052]

Agency Information Collection Activities: Final Collection; Comment Request

AGENCY: Export-Import Bank of the U.S.

ACTION: Submission for OMB review and comments request.

Form Title: Letter of Interest Application (EIB 95–09).

SUMMARY: The Export-Import Bank of the United States (Ex-Im Bank), as a part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal Agencies to comment on the proposed information collection, as required by the Paperwork Reduction Act of 1995.

Our customers will be able to submit this form on paper or electronically. The information collected will allow Ex-Im Bank to determine the applicability of a proposed export transaction for receipt of an indication of a willingness to consider financing medium- and long-term guarantee, direct loan and insurance programs.

Form can be viewed at *http://www.exim.gov/pub/pending/EIB95_09.pdf.*

DATES: Comments should be received on or before May 9, 2011 to be assured of consideration.

ADDRESSES: Comments may be submitted electronically on *http://www.regulations.gov* by mail to Office of Information and Regulatory Affairs, 725 17th Street, NW., Washington, DC 20038 attn: OMB 3048–0005.

SUPPLEMENTARY INFORMATION:

Titles and Form Number: EIB 95–09. Letter of Interest Application.

OMB Number: 3048–0005.

Type of Review: Regular.

Need and Use: Ex-Im Bank's Letter of Interest (LI) is a pre-export tool to help get financing off to a quick start. The LI is an indication of Ex-Im's willingness to consider financing for a given export transaction. LIs are used during the bidding or negotiating stage of an export sale or before going on a marketing trip.

Ex-Im Bank uses the requested information to determine the applicability of the proposed export transaction for receipt of this indication of willingness to consider financing.

Affected Public: This form affects entities involved in the export of U.S goods and services.

Annual Number of Respondents: 400.

Estimated Time per Respondent: 0.5 hours.

Government Annual Burden Hours: 200.

Frequency of Reporting or Use: On occasion.

Sharon A. Whitt,

Agency Clearance Officer.

[FR Doc. 2011–8287 Filed 4–6–11; 8:45 am]

BILLING CODE 6690–01–P

FEDERAL COMMUNICATIONS COMMISSION

[DA 11–390]

Video Programming and Accessibility Advisory Committee; Announcement of Date of Next Meeting

AGENCY: Federal Communications Commission.

ACTION: Notice.

SUMMARY: This document announces the next meeting of the Video Programming Accessibility Advisory Committee ("Committee" or "VPAAC"). The meeting will address the provision of closed captioning of Internet programming previously captioned on television, video description of television programming, accessible emergency information for people with vision disabilities delivered over video programming, video programming devices that can render closed captioning and video description, and accessible user interfaces, menus, and programming guides on video programming devices.

DATES: The Committee's next meeting will take place on Thursday, May 5, 2011, 9 a.m. to 5 p.m. at the headquarters of the Federal Communications Commission ("Commission").

ADDRESSES: Federal Communications Commission, 445 12th Street, SW., Washington, DC 20554.

FOR FURTHER INFORMATION CONTACT: Pam Gregory, Consumer and Governmental Affairs Bureau, 202–418–2498 (voice), 202–418–1169 (TTY), or *Pam.Gregory@fcc.gov* (e-mail); or Alison Neplokh, Media Bureau, 202–418–1083, *Alison.Neplokh@fcc.gov* (e-mail).

SUPPLEMENTARY INFORMATION: On December 7, 2010, in document DA–2320, Chairman Julius Genachowski announced the establishment and appointment of members of the VPAAC, following a nominations period that closed on November 1, 2010. This Committee is established in accordance with the Twenty-First Century Communications and Video Accessibility Act of 2010, Public Law 111–260 ("CVAA"). The purpose of the VPAAC is to develop recommendations on closed captioning of Internet

programming previously captioned on television; the compatibility between video programming delivered using Internet protocol and devices capable of receiving and displaying such programming in order to facilitate access to captioning, video description and emergency information; video description and accessible emergency information on television programming delivered using Internet protocol or digital broadcast television; accessible user interfaces on video programming devices; and accessible programming guides and menus. Within six (6) months of its first meeting, the VPAAC shall submit recommendations concerning the provision of closed captions for Internet-delivered video programming and the ability of video devices to pass through or render closed captions contained on Internet-based video programming. By April 8, 2012, the VPAAC shall submit recommendations on the remaining issues listed above.

Open captioning and sign language interpreters will be provided. Other reasonable accommodations for people with disabilities are available upon request. Please include a description of the accommodation you will need and tell us how to contact you if we need more information. Make your request as early as possible. Last minute requests will be accepted, but may be impossible to fill. Send an e-mail to *fcc504@fcc.gov* or call the Consumer and Governmental Affairs Bureau at 202–418–0530 (voice), 202–418–0432 (TTY).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 and Governmental Affairs Bureau at (202) 418–0530 (voice), (202) 418–0432 (TTY).

Federal Communications Commission.

Karen Peltz Strauss,

Deputy Chief, Consumer and Governmental Affairs Bureau.

[FR Doc. 2011–8211 Filed 4–6–11; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

[DA 11–553]

Emergency Access Advisory Committee; Announcement of Date of Next Meeting

AGENCY: Federal Communications Commission.

ACTION: Notice.

SUMMARY: This document announces the date of the Emergency Access Advisory Committee's ("Committee or EAAC") next meeting. The Committee will address the status of the national survey of persons with disability and seniors to learn about preferences for emergency calling when 9–1–1 call centers have the capacity to communicate with callers via voice, data, text and video under the Next Generation 9–1–1. The Committee will discuss options for reporting out the results of the national survey.

DATES: The Committee's next meeting will take place on Friday, April 8, 2011, 10:30 a.m. to 4:30 p.m. (EST), at the headquarters of the Federal Communications Commission (FCC).

ADDRESSES: Federal Communications Commission, 445 12th Street, SW., Washington, DC 20554.

FOR FURTHER INFORMATION CONTACT: Cheryl King, Consumer and Governmental Affairs Bureau, (202) 418–2284 (voice) or (202) 418–0416 (TTY), (*e-mail*): *Cheryl.King@fcc.gov;* and/or Patrick Donovan, Public Safety and Homeland Security Bureau, (202) 418–2413 (voice), (*e-mail*): *Patrick.Donovan@fcc.gov.*

SUPPLEMENTARY INFORMATION: On December 7, 2010, in document DA 10–2318, Chairman Julius Genachowski announced the establishment and appointment of members and Co-Chairpersons of the EAAC, an advisory committee required by the Twenty-first Century Communications and Video Accessibility Act of 2010, Public Law 111–260 (CVAA), which directs that an advisory committee be established, for the purpose of achieving equal access to emergency services by individuals with disabilities as part of our nation's migration to a national Internet protocol-enabled emergency network, also known as the next generation 9–1–1 system ("NG9–1–1").

The purpose of the EAAC is to determine the most effective and efficient technologies and methods by which to enable access to NG9–1–1 emergency services by individuals with disabilities. In order to fulfill this mission, the CVAA directs that within one year after the EAAC's members are appointed, the Committee shall conduct a national survey, with the input of groups represented by the Committee's membership, after which the Committee shall develop and submit to the Commission recommendations to implement such technologies and methods.

The meeting site is fully accessible to people using wheelchairs or other mobility aids. Sign language interpreters, open captioning, and assistive listening devices will be provided on site. Other reasonable accommodations for people with disabilities are available upon request. In your request, include a description of the accommodation you will need and a way we can contact you if we need more information. Last minute requests will be accepted, but may be impossible to fill. Send an e-mail to: *fcc504@fcc.gov* or call the Consumer and Governmental Affairs Bureau at 202–418–0530 (voice), 202–418–0432 (TTY).

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 and Governmental Affairs Bureau at 202–418–0530 (voice), 202–418–0432 (TTY).

Federal Communications Commission.

Karen Peltz Strauss,

Deputy Chief, Consumer and Governmental Affairs Bureau.

[FR Doc. 2011–8319 Filed 4–6–11; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

FCC To Hold Open Commission Meeting, Thursday, April 7, 2011

March 31, 2011.

The Federal Communications Commission will hold an Open Meeting on the subjects listed below on Thursday, April 7, 2011, which is scheduled to commence at 10:30 a.m. in Room TW–C305, at 445 12th Street, SW., Washington, DC.

Item No.	Bureau	Subject
1	Wireline Competition	*Title:* Implementation of Section 224 of the Act (WC Docket No. 07–245); A National Broadband Plan for Our Future (GN Docket No. 09–51).

Item No.	Bureau	Subject
		Summary: The Commission will consider an Order that reforms the Commission's access, rates, and enforcement rules for utility pole attachments, reducing barriers to deployment and availability of broadband and other wireline and wireless services, and promoting competition.
2	Wireline Competition and Wireless Telecommunications.	*Title:* Acceleration of Broadband Deployment: Expanding the Reach and Reducing the Cost of Broadband Deployment by Improving Policies Regarding Government Rights of Way and Wireless Facilities Siting. *Summary:* The Commission will consider a Notice of Inquiry seeking comment on key challenges and best practices in expanding the reach and reducing the cost of broadband deployment, including by improving policies for access to government rights of way and wireless facility siting requirements.
3	Wireless Telecommunications	*Title:* Reexamination of Roaming Obligations of Commercial Mobile Radio Service Providers and Other Providers of Mobile Data Services (WT Docket No. 05–265). *Summary:* The Commission will consider a Second Report and Order that adopts a rule requiring 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.
4	Public Safety and Homeland Security	*Title:* Reliability and Continuity of Communications Networks, Including Broadband Technologies; Effects on Broadband Communications Networks of Damage or Failure of Network Equipment or Severe Overload (PS Docket No. 10–92); Independent Panel Reviewing the Impact of Hurricane Katrina on Communications Networks (EB Docket No. 06–119). *Summary:* The Commission will consider a Notice of Inquiry seeking comment on existing reliability standards for communications networks, including broadband networks, and ways to further strengthen the reliability and continuity of communications networks to avoid disruptions of service during major emergencies, such as large-scale natural and manmade disasters.
5	Wireless Telecommunications	*Title:* Amending Parts 1, 2, 22, 24, 27, 90 and 95 of the Commission's Rules to Improve Wireless Coverage Through the Use of Signal Boosters. *Summary:* The Commission will consider a Notice of Proposed Rulemaking that will help to fill gaps in wireless coverage and expand broadband in rural and difficult-to-serve areas, while protecting wireless networks from harm.
6	Consumer & Governmental Affairs	*Title:* Structure and Practices of the Video Relay Service Program (CG Docket No. 10–51). *Summary:* The Commission will consider a Report and Order that will adopt rules to detect and prevent fraud and abuse in the provision of video relay service ("VRS"). Also, a Further Notice of Proposed Rulemaking Proposes to require all VRS providers to obtain certification from the FCC under new, tighter certification procedures in order to receive compensation from the TRS Fund.

The meeting site is fully accessible to people using wheelchairs or other mobility aids. Sign language interpreters, open captioning, and assistive listening devices will be provided on site. Other reasonable accommodations for people with disabilities are available upon request. In your request, include a description of the accommodation you will need and a way we can contact you if we need more information. Last minute requests will be accepted, but may be impossible to fill. Send an e-mail to: *fcc504@fcc.gov* or call the Consumer & Governmental Affairs Bureau at 202–418–0530 (voice), 202–418–0432 (tty).

Additional information concerning this meeting may be obtained from Audrey Spivack or David Fiske, Office of Media Relations, (202) 418–0500; TTY 1–888–835–5322. Audio/Video coverage of the meeting will be broadcast live with open captioning over the Internet from the FCC Live Web page at *http://www.fcc.gov/live.*

For a fee this meeting can be viewed live over George Mason University's Capitol Connection. The Capitol Connection also will carry the meeting live via the Internet. To purchase these services call (703) 993–3100 or go to *http://www.capitolconnection.gmu.edu.*

Copies of materials adopted at this meeting can be purchased from the FCC's duplicating contractor, Best Copy and Printing, Inc. (202) 488–5300; Fax (202) 488–5563; TTY (202) 488–5562. These copies are available in paper format and alternative media, including large print/type; digital disk; and audio and video tape. Best Copy and Printing, Inc. may be reached by e-mail at *FCC@BCPIWEB.com.*

Federal Communications Commission.

Bulah P. Wheeler,

Deputy Manager.

[FR Doc. 2011–8216 Filed 4–6–11; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL DEPOSIT INSURANCE CORPORATION

Sunshine Act Meeting

Pursuant to the provisions of the "Government in the Sunshine Act" (5 U.S.C. 552b), notice is hereby given that the Federal Deposit Insurance Corporation's Board of Directors will meet in open session at 10 a.m. on Tuesday, April 12, 2011, to consider the following matters:

Summary Agenda: No substantive discussion of the following items is anticipated. These matters will be resolved with a single vote unless a member of the Board of Directors requests that an item be moved to the discussion agenda.

Disposition of minutes of previous Board of Directors' Meetings.

Summary reports, status reports, reports of the Office of Inspector General, and reports of actions taken pursuant to authority delegated by the Board of Directors.

Memorandum and resolution re: Proposed Rule Reflecting Repeal of Prohibition on Paying Interest on Demand Deposits.

Discussion Agenda

Memorandum and resolution re: Margin and Capital Requirements for Certain Swap Dealers and Major

Swap Participants: Notice of Proposed Rulemaking to Implement Sections 731 and 764 of the Dodd-Frank Act.

Memorandum and resolution re: Proposed Assessment Rate Adjustment Guidelines for Large and Highly Complex Institutions.

Memorandum re: Update of Projected Deposit Insurance Fund Losses, Income, and Reserve Ratios for the Restoration Plan.

The meeting will be held in the Board Room on the sixth floor of the FDIC Building located at 550 17th Street, NW., Washington, DC.

This Board meeting will be Webcast live via the Internet and subsequently made available on-demand approximately one week after the event. Visit *http://www.vodium.com/goto/fdic/boardmeetings.asp* to view the event. If you need any technical assistance, please visit our Video Help page at: *http://www.fdic.gov/video.html.*

The FDIC will provide attendees with auxiliary aids (*e.g.,* sign language interpretation) required for this meeting. Those attendees needing such assistance should call 703–562–2404 (Voice) or 703–649–4354 (Video Phone) to make necessary arrangements.

Requests for further information concerning the meeting may be directed to Mr. Robert E. Feldman, Executive Secretary of the Corporation, at 202–898–7043.

Dated: April 5, 2011.

Robert E. Feldman,

Executive Secretary, Federal Deposit Insurance Corporation.

[FR Doc. 2011–8471 Filed 4–5–11; 4:15 pm]

BILLING CODE 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 April 22, 2011.

A. Federal Reserve Bank of Kansas City (Dennis Denney, Assistant Vice President), 1 Memorial Drive, Kansas City, Missouri 64198–0001:

1. *Paul R. Boeding and Marilyn E. Boeding,* both of Seneca, Kansas; to acquire control of Baileyville Bancshares, Inc., and thereby indirectly acquire control of Baileyville State Bank, both in Seneca, Kansas.

2. *Todd L. Sutherland,* Lawrence, Kansas, individually and as trustee of the Todd L. Sutherland 2005 Revocable Trust; to acquire control of Lawrence Financial Corporation, and thereby indirectly acquire control of The University National Bank of Lawrence, both in Lawrence, Kansas.

Board of Governors of the Federal Reserve System, April 4, 2011.

Robert deV. Frierson,

Deputy Secretary of the Board.

[FR Doc. 2011–8289 Filed 4–6–11; 8:45 am]

BILLING CODE 6210–01–P

FEDERAL TRADE COMMISSION

Agency Information Collection Activities: Proposed Collection; Comment Request; Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery

AGENCY: Division of Consumer and Business Education, Federal Trade Commission ("FTC" or "Commission").

ACTION: 30-day notice of submission of information collection approval from the Office of Management and Budget ("OMB") and request for comments.

SUMMARY: As part of a Federal Government-wide effort to streamline the process to seek feedback from the public on service delivery, the FTC is submitting a Generic Information Collection Request (Generic ICR): "Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery" to OMB for approval under the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*).

DATES: Comments must be submitted by May 9, 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 "FTC Generic Clearance ICR, Project No. P035201" on your comment, and file your comment online at *https://ftcpublic.commentworks.com/ftc/genericclearance* 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: To request additional information, please contact Nicole Vincent at 202–326–2372.

SUPPLEMENTARY INFORMATION:

Title: Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery.

Abstract: The information collection activity will garner qualitative customer and stakeholder feedback in an efficient, timely manner, in accordance with the Administration's commitment to improving service delivery. By qualitative feedback we mean information that provides useful insights on perceptions and opinions, but are not statistical surveys that yield quantitative results that can be generalized to the population of study. This feedback will provide insights into customer or stakeholder perceptions, experiences and expectations, provide an early warning of issues with service, or focus attention on areas where communication, training or changes in operations might improve delivery of products or services. These collections will allow for ongoing, collaborative and actionable communications between the Agency and its customers and stakeholders. It will also allow feedback to contribute directly to the improvement of program management.

Feedback collected under this generic clearance will provide useful information, but it will not yield data that can be generalized to the overall population. This type of generic clearance for qualitative information will not be used for quantitative information collections that are designed to yield reliably actionable results, such as monitoring trends over time or documenting program performance. Such data uses require more rigorous designs that address: the target population to which generalizations will be made, the sampling frame, the sample design (including stratification and clustering), the precision requirements or power calculations that justify the proposed sample size, the expected response rate, methods for assessing potential non-response bias, the protocols for data collection, and any testing procedures that were or will be undertaken prior fielding the study. Depending on the degree of influence the results are likely

to have, such collections may still be eligible for submission for other generic mechanisms that are designed to yield quantitative results.

The FTC received no comments in response to the 60-day notice published in the **Federal Register** on December 22, 2010 (75 FR 80542).

Below are the FTC's projected average annual estimates for the next three years: [1]

Current Actions: New collection of information.

Type of Review: New collection.

Affected Public: Individuals and Households, Businesses and Organizations, State, Local or Tribal Government.

Average Expected Annual Number of Activities: 3.

Respondents: 1,656.

Frequency of Response: Once per request.

Annual Responses: 1,656.

Average Minutes per Response: 23 (rounded to nearest whole minute).

Burden Hours: 631.

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.

Request for Comments

You can file a comment online or on paper. For the FTC to consider your comment, we must receive it on or before May 9, 2011. Write "FTC Generic Clearance ICR, Project No. P035201" 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.shtm.* 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).[2] 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/genericclearance* 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 "FTC Generic Clearance ICR, Project No. P035201" 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.

Comments on any proposed information collection requirements subject to review under the PRA should additionally be submitted to OMB. If sent by U.S. mail, they should be addressed to Office of Information and Regulatory Affairs, Office of Management and Budget, Attention: Desk Officer for the Federal Trade Commission, New Executive Office Building, Docket Library, Room 10102, 725 17th Street, NW.,Washington, DC 20503. Comments sent to OMB by U.S. postal mail, however, are subject to delays due to heightened security precautions. Thus, comments instead should be sent by facsimile to (202) 395–5167.

Visit the Commission Website 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 May 9, 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.*

Willard K. Tom,

General Counsel.

[FR Doc. 2011–8326 Filed 4–6–11; 8:45 am]

BILLING CODE 6750–01–P

[1] The 60-day notice included the following estimate of the aggregate burden hours for this generic clearance federal-wide:

Average Expected Annual Number of Activities: 25,000.

Average Number of Respondents per Activity: 200.

Annual Responses: 5,000,000.

Frequency of Response: Once per request.

Average Minutes per Response: 30.

Burden Hours: 2,500,000.

[2] In particular, the written request for confidential treatment that accompanies the comment must include the factual and legal basis for the request, and must identify the specific portions of the comment to be withheld from the public record. *See* FTC Rule 4.9(c), 16 CFR 4.9(c).

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Assistant Secretary for Planning and Evaluation; Medicare Program; Meeting of the Technical Advisory Panel on Medicare Trustee Reports

AGENCY: Assistant Secretary for Planning and Evaluation, HHS.

ACTION: Notice of meeting.

SUMMARY: This notice announces public meetings of the Technical Advisory Panel on Medicare Trustee Reports (Panel). Notice of these meetings is given under the Federal Advisory Committee Act (5 U.S.C. App. 2, section 10(a)(1) and (a)(2)). The Panel will discuss the short-term (10 year) projection methods and assumptions in projecting Medicare health spending and may make recommendations to the Medicare Trustees on how the Trustees might more accurately estimate health spending in the short run. The Panel's discussion is expected to be very technical in nature and will focus on the actuarial and economic assumptions and methods by which Trustees might more accurately measure health spending. Although panelists are not limited in the topics they may discuss, the Panel is not expected to discuss or recommend changes in current or future

Medicare provider payment rates or coverage policy.

Meeting Date: April 12, 2011, 9 a.m. to 5 p.m. e.t.

ADDRESSES: The meetings will be held at HHS headquarters at 200 Independence Ave., SW., Washington, DC 20201, Room 425A.

Comments: The meeting will allocate time on the agenda to hear public comments at the end of the meeting. In lieu of oral comments, formal written comments may be submitted for the record to Donald T. Oellerich, OASPE, 200 Independence Ave., SW., 20201, Room 405F. Those submitting written comments should identify themselves and any relevant organizational affiliations.

FOR FURTHER INFORMATION CONTACT: Donald T. Oellerich (202) 690–8410, *Don.oellerich@hhs.gov.* **Note:** Although the meeting is open to the public, procedures governing security procedures and the entrance to Federal buildings may change without notice. Those wishing to attend the meeting must call or e-mail Dr. Oellerich by Thursday April 7, 2011, so that their name may be put on a list of expected attendees and forwarded to the security officers at HHS Headquarters.

SUPPLEMENTARY INFORMATION:

Topics of the Meeting: The Panel is specifically charged with discussing and possibly making recommendations to the Medicare Trustees on how the Trustees might more accurately estimate health spending in the United States. The discussion is expected to focus on highly technical aspects of estimation involving economics and actuarial science. Panelists are not restricted, however, in the topics that they choose to discuss.

Procedure and Agenda: This meeting is open to the public. The Panel will likely hear presentations by HHS staff presentations regarding short range projection methods and assumptions. After any presentations, the Panel will deliberate openly on the topic. Interested persons may observe the deliberations, but the Panel will not hear public comments during this time. The Panel will also allow an open public session for any attendee to address issues specific to the topic.

Authority: 42 U.S.C. 217a; Section 222 of the Public Health Services Act, as amended. The panel is governed by provisions of Public Law 92–463, as amended (5 U.S.C. Appendix 2), which sets forth standards for the formation and use of advisory committees.

Dated: March 29, 2011.

Sherry Glied,

Assistant Secretary for Planning and Evaluation.

[FR Doc. 2011–8359 Filed 4–6–11; 8:45 am]

BILLING CODE P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Office of the Assistant Secretary for Planning and Evaluation; Statement of Organization, Functions and Delegations of Authority

Part A (Office of the Secretary), Statement of Organization, Functions, and Delegations of Authority of the Department of Health and Human Services (HHS) is being amended at Chapter AE, Office of the Assistant Secretary for Planning and Evaluation (ASPE) as last amended at 67 FR 61341–42 dated September 30, 2002 and most recently at 73 FR 19977, dated April 16, 2010. This reorganization is to realign the functions of ASPE to reflect the current structure and areas of focus. The changes are as follows:

I. Under Section AE.20 Functions, delete Paragraph D, Office of Disability, Aging and Long-Term Care Policy (AEW), in its entirety and replace with the following:

D. The Office of Disability, Aging and Long-Term Care Policy is responsible for the development, coordination, research and evaluation of HHS policies and programs that support the independence, productivity, health and well being of children, working age adults, and older persons with disabilities. The office is also responsible for policy coordination and research to promote the economic and social well-being of older Americans. The Office coordinates its work with aging and disability-related agencies and programs throughout the government, including the Departments of Justice, Labor, Education, Transportation, Housing and Urban Development, the Social Security Administration and the Office of National Drug Control Policy.

1. The Division of Disability and Aging Policy is responsible for policy development, coordination, research and evaluation of policies and programs focusing on persons with disabilities and older Americans (Older Americans Act). Activities related to the Older Americans Act are carried out in coordination with the Office of the Assistant Secretary for Aging. This includes measuring and evaluating the impact of programs authorized by the Older Americans Act. The Division is also responsible for supporting the development and coordination of crosscutting disability and aging data and policies within the Department and other federal agencies. Areas of focus include assessing the interaction between the health, disability, and economic well-being of persons of all ages with disabilities including the prevalence of disability and disabling conditions; describing the socio-demographic characteristics of relevant populations; determining service use, income, employment, and program participation patterns; and coordinating the development of disability and aging data and policies that affect the characteristics, circumstances and needs of older Americans and disabled populations. The Division's responsibilities include long-range planning, budget and economic analysis, program analysis, review of regulations and reports on legislation, review and conduct of research and evaluation activities, and information dissemination.

2. The Division of Long-Term Care Policy is responsible for coordination, development, research and evaluation of HHS policies and programs which address the long-term care and personal assistance needs of people of all ages with functional impairments and disabilities. The Division is the focal point for policy development and analysis related to the long-term care services components of the Affordable Care Act as well as Medicare, Medicaid, and including nursing facility services, community residential services, personal assistance services, home health and rehabilitation services, and the integration of acute, post-acute and long-term care services. The Division's responsibilities include long-range planning, budget and economic analysis, program analysis, review of regulations and reports on legislation, review and conduct of research and evaluation activities, and information dissemination.

3. The Division of Behavioral Health and Intellectual Disabilities Policy is responsible for analysis, coordination, research and evaluation of policies related to individuals with severe intellectual disabilities, severe addictions and/or severe and persistent mental illness. The Division's responsibilities include long-range planning, budget and economic analysis, data development and analysis, program analysis, review of regulations and reports on legislation, review and conduct of research and evaluation activities, and information

dissemination. The Division is the focal point for policy development and analysis related to financing, access/delivery, organization and quality of Intellectual Disabilities and Serious and Persistent Mental Illnesses services, including those financed by Medicaid, Medicare, SAMHSA, Administration on Developmental Disabilities and HRSA. The Division works closely with other offices in ASPE because the two vulnerable populations that are its focus are users of both human services and health services.

II. Delegations of Authority: All delegations and redelegations of authority made to officials and employees of affected organizational components will continue in them or their successors pending further redelegation, provided they are consistent with this reorganization.

Dated: March 30, 2011.

E.J. Holland, Jr.,

Assistant Secretary for Administration.

[FR Doc. 2011–8357 Filed 4–6–11; 8:45 am]

BILLING CODE 4150–04–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–11–11EC]

Proposed Data Collections Submitted for Public Comment and Recommendations

In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the Centers for Disease Control and Prevention (CDC) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the data collection plans and instruments, call 404–639–5960 and send comments to Daniel Holcomb, CDC Acting Reports Clearance Officer, 1600 Clifton Road, MS–D74, Atlanta, GA 30333 or send an e-mail to *omb@cdc.gov*.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Written comments should be received within 60 days of this notice.

Proposed Project

Epidemiologic Study of Health Effects Associated With Low Pressure Events in Drinking Water Distribution Systems —New—National Center for Emerging and Zoonotic Infectious Diseases—Office of Infectious Diseases—CDC.

Background and Brief Description

In the United States, drinking water distribution systems are designed to deliver safe, pressurized drinking water to our homes, hospitals, schools and businesses. However, the water distribution infrastructure is 50–100 years old in much of the U.S. and an estimated 240,000 water main breaks occur each year. Failures in the distribution system such as water main breaks, cross-connections, back-flow, and pressure fluctuations can result in potential intrusion of microbes and other contaminants that can cause health effects, including acute gastrointestinal and respiratory illness.

Approximately 200 million cases of acute gastrointestinal illness occur in the U.S. each year, but we don't have reliable data to assess how many of these cases are associated with drinking water. Further, data are even more limited on the human health risks associated with exposure to drinking water during and after the occurrence of low pressure events (such as water main breaks) in drinking water distribution systems. A study conducted in Norway from 2003–2004 found that people exposed to low pressure events in the water distribution system had a higher risk for gastrointestinal illness. A similar study is needed in the United States.

The purpose of this data collection is to conduct an epidemiologic study in the U.S. to assess whether individuals exposed to low pressure events in the water distribution system are at an increased risk for acute gastrointestinal or respiratory illness. This study would be, to our knowledge, the first U.S. study to systematically examine the association between low pressure events and acute gastrointestinal and respiratory illnesses. Study findings will inform the Environmental Protection Agency (EPA), CDC, and other drinking water stakeholders of the potential health risks associated with low pressure events in drinking water distribution systems and whether additional measures (*e.g.,* new standards, additional research, or policy development) are needed to reduce the risk for health effects associated with low pressure events in the drinking water distribution system.

We will conduct a cohort study among households that receive water from five water utilities across the U.S. The water systems will be geographically diverse and will include both chlorinated and chloraminated systems. These water utilities will provide information about low pressure events that occur during the study period. Households in areas exposed to the low pressure event and an equal number of households in an unexposed area will be randomly selected and sent a survey questionnaire. After consenting to participate, households will be asked about symptoms and duration of any recent gastrointestinal or respiratory illness, tap water consumption, and other factors including international travel, daycare attendance or employment, and exposure to under-cooked or unpasteurized food, pets and other animal contact, and recreational water. Study participants will be able to choose their method of survey response from a variety of options including a paper survey, telephone-administered survey, or Web-based survey. A Spanish language version of the survey for all response options will also be available. Participation in this study will be voluntary. No financial compensation will be provided to study participants. The study duration is anticipated to last 12 months. An estimated 5,200 individuals will be contacted and we anticipate 2,080 adults (18 years of age or older) will consent to participate in this study. We will conduct a pilot study (duration 3 months) prior to launching the full epidemiologic study. An estimated 1,000 individuals will be contacted and we anticipate 400 adults (18 years of age or older) will consent to participate in the pilot study. The total estimated annualized hours associated with this study, including the pilot, is expected to be 601.

ESTIMATE OF ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (hours)	Total burden (hours)
Full Study:					
Households	Introductory letter and consent form	5,200	1	1/60	87
Households	Web-based questionnaire	1,248	1	12/60	250
Households	Paper-based questionnaire	624	1	12/60	125
Households	Telephone-based questionnaire	208	1	12/60	42
Total (full study):					504
Pilot Study:					
Households	Introductory letter and consent form	1000	1	1/60	17
Households	Web-based questionnaire	240	1	12/60	48
Households	Paper-based questionnaire	120	1	12/60	24
Households	Telephone-based questionnaire	40	1	12/60	8
Total (pilot study)					97
Total (Full & Pilot)					601

Daniel Holcomb,

Reports Clearance Officer, Centers for Disease Control and Prevention.

[FR Doc. 2011–8271 Filed 4–6–11; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day–11–0672]

Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for Disease Control and Prevention (CDC) publishes a list of information collection requests under review by the Office of Management and Budget (OMB) in compliance with the Paperwork Reduction Act (44 U.S.C. chapter 35). To request a copy of these requests, call the CDC Reports Clearance Officer at (404) 639–5960 or send an e-mail to *omb@cdc.gov.* Send written comments to CDC Desk Officer, Office of Management and Budget, Washington, DC or by fax to (202) 395–5806. Written comments should be received within 30 days of this notice.

Proposed Project

Indicators of the Performance of Local, State, Territorial, and Tribal Education Agencies in HIV Prevention, Coordinated School Health Program, and Asthma Management Activities for Adolescent and School Health Programs (OMB No. 0920–0672, exp. 6/30/2011)—Revision—National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

CDC is requesting OMB approval for three years to continue annual information collection for the Indicators for School Health programs. The Indicators assess programmatic activities among local education agencies (LEA) and State, territorial, and Tribal government education agencies (SEAs, TEAs, and TGs) funded by the Division of Adolescent and School Health (DASH), Centers for Disease Control and Prevention. Currently, the Indicators for School Health Programs are the only standardized annual reporting process for HIV prevention activities or coordinated school health program (CSHP) activities among LEAs and SEAs/TEAs/TGs funded by DASH. The questionnaires correspond to the specific funding source from the Division of Adolescent and School Health: two questionnaires pertain to HIV-prevention program activities among LEAs and SEAs/TEAs/TGs; one pertains to CSHP/PANT activities among SEAs/TGs; and one pertains to asthma management activities among LEAs. All information is collected electronically on a Web site managed by DASH.

Two HIV prevention questionnaires include questions on project planning, materials distribution, professional development activities, provision of technical assistance, collaboration with external partners, and reducing health disparities among populations at disproportionate risk. The CSHP/PANT questionnaire focuses on the activities above as well as on physical activity, healthy eating, and tobacco-use prevention activities. The asthma management questionnaire includes questions on project planning, materials distribution, professional development activities, provision of technical assistance, collaboration with external partners, reducing health disparities among populations at disproportionate risk, and health services.

The information collected by CDC is used to: (1) Provide standardized information about how LEAs and SEAs/TEAs/TGs use funds for programs in HIV prevention, asthma management, and coordinated school health/physical activity, nutrition, and tobacco-use prevention (CSHP/PANT); (2) assess the extent to which programmatic adjustments are indicated; (3) provide descriptive and process information about program activities; and (4) provide greater accountability for use of public funds.

The questionnaires previously approved for collecting FY2009 data will be used to collect FY2010 data. Minor changes to the questionnaires will be implemented for the FY2011 and FY2012 data collections, however, the proposed changes will not alter the estimated burden per response. An increase in the average number of funded programs over the three years of this clearance will result in a net increase in burden hours. A minor change to the title of the clearance is being requested to more accurately reflect the participation of Territorial and Tribal Education Agencies.

There are no costs to respondents other than their time. The total estimated annualized burden hours are 811.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	No. of respondents	No. of responses per respondent	Avg. burden per response (in hrs)
Local Education Agency Officials	Indicators for School Health Programs: HIV Prevention (LEA).	16	1	7
	Indicators for School Health Programs: Asthma Management (LEA).	10	1	7
State and Territorial Education Agency and Tribal Government Officials.	Indicators for School Health Programs: HIV Prevention (SEA).	57	1	7
	Indicators for School Health Programs: Coordinated School Health Programs.	23	1	10

Daniel Holcomb,

Acting Reports Clearance Officer, Centers for Disease Control and Prevention.

[FR Doc. 2011–8273 Filed 4–6–11; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day–11–0026]

Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for Disease Control and Prevention (CDC) publishes a list of information collection requests under review by the Office of Management and Budget (OMB) in compliance with the Paperwork Reduction Act (44 U.S.C. chapter 35). To request a copy of these requests, call the CDC Reports Clearance Officer at (404) 639–5960 or send an e-mail to *omb@cdc.gov.* Send written comments to CDC Desk Officer, Office of Management and Budget, Washington, DC 20503 or by fax to (202) 395–5806. Written comments should be received within 30 days of this notice.

Proposed Project

Report of Verified Case of Tuberculosis (RVCT), (OMB No. 0920–0026) exp. 05/31/2011—Extension—National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

In the United States, an estimated 10 to 15 million people are infected with *Mycobacterium tuberculosis* and about 10% of these persons will develop tuberculosis (TB) disease at some point in their lives. The purpose of this project is to continue ongoing national tuberculosis surveillance using the standardized Report of Verified Case of Tuberculosis (RVCT). Data collected using the RVCT help State and Federal infectious disease officials to assess changes in the diagnosis and treatment of TB, monitor trends in TB epidemiology and outbreaks, and develop strategies to meet the national goal of TB elimination.

CDC conducts and maintains the national surveillance system pursuant to the provisions of Section 301(a) of the Public Service Act [42 U.S.C. 241] and Section 306 of the Public Service Act [42 U.S.C. 241(a)]. National TB surveillance has been maintained by the U.S. Public Health Service and CDC through the cooperation of the States since 1953. Data are collected by 60 reporting areas (the 50 States, the District of Columbia, New York City, Puerto Rico, and 7 jurisdictions in the Pacific and Caribbean).

CDC publishes an annual report using RVCT data to summarize national TB statistics and also periodically conducts special analyses for publication to further describe and interpret national TB data. These data assist in public health planning, evaluation, and resource allocation. Reporting areas also review and analyze their RVCT data to monitor local TB trends, evaluate program success, and focus resources to eliminate TB. No other Federal agency collects this type of national TB data.

The total estimated burden hours are approximately 6720 burden hours, an estimated decrease of 1330 hours. This decrease is due to having fewer TB cases in the United States as we continue progress towards TB elimination. There is no cost to respondents except for their time.

ESTIMATE OF ANNUALIZED BURDEN HOURS

Types of respondents	No. of respondents	No. of responses per respondent	Average burden per response (in hours)
Local, State, and territorial health departments	60	192	35/60

Daniel Holcomb,

Reports Clearance Officer, Centers for Disease Control and Prevention.

[FR Doc. 2011–8272 Filed 4–6–11; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–1357–N]

RIN 0938–AQ97

Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and Fiscal Year 2011 Final Wage Indices Implementing the Medicare and Medicaid Extenders Act

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

ACTION: Notice.

SUMMARY: This notice contains the final fiscal year (FY) 2011 wage indices and hospital reclassifications and other related tables which reflect changes required by or resulting from the implementation of section 102 of the Medicare and Medicaid Extenders Act of 2010. MMEA requires the extension of the expiration date for certain geographic reclassifications and special exception wage indices through September 30, 2011.

DATES: *Applicability Date:* The revised wage indices for section 508 and special exception providers published in this notice are applicable for discharges on or after October 1, 2010 and on or before September 30, 2011. Certain hospitals that are not section 508/special exception providers, but that are located in areas affected by section 102 of the MMEA, are also identified in this notice, and will be paid based on the revised wage index published in this notice for discharges on or after April 1, 2011 and on or before September 30, 2011.

FOR FURTHER INFORMATION CONTACT: Brian Slater, (410) 786–5229.

SUPPLEMENTARY INFORMATION:

I. Background

The final rule setting forth the Medicare fiscal year (FY) 2011 hospital inpatient prospective payment systems (IPPS) for acute care hospitals and the long-term care hospital prospective payment system (LTCH PPS) (hereinafter referred to as the FY 2011 IPPS/LTCHPPS final rule) appeared in the August 16, 2010 **Federal Register** (75 FR 50042) and we subsequently corrected this final rule in an October 1, 2010 **Federal Register** notice (75 FR 60640).

On December 15, 2010, the Medicare and Medicaid Extenders Act (MMEA) of 2010 (Pub. L. 111–309) was enacted. Section 102 of the MMEA extends section 508 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173) reclassifications and certain additional special exceptions through September 30, 2011. This notice addresses the provisions of the MMEA that impact the FY 2011 IPPS final wage index tables.

II. Provisions of this Notice

A. Section 508 Extension

Section 102 of the MMEA of 2010, extends through the end of FY 2011 wage index reclassifications under section 508 of the MMA and certain special exceptions (for example, those special exceptions contained in the final rule that appeared in the **Federal Register** (69 FR 49105 and 49107) extended under section 117 of the Medicare, Medicaid and SCHIP Extension Act (MMSEA) of 2007 (Pub. L. 110–173) and further extended under section 124 of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA)(Pub. L. 110–275) and section 3137(a) of the Patient Protection and Affordable Care Act (PPACA) (Pub. L. 111–148) as amended by section 10317 of the Health Care and Education Reconciliation Act of 2010 (HCERA), (Pub. L. 111–152 enacted on March 30, 2010). (These public laws are collectively known as the Affordable Care Act (ACA).)

Under section 508 of MMA, a qualifying hospital could appeal the wage index classification otherwise applicable to the hospital and apply for reclassification to another area of the State in which the hospital is located or, at the discretion of the Secretary, to an area within a contiguous State. We implemented this process through notices published in the **Federal Register** on January 6, 2004 (69 FR 661), and February 13, 2004 (69 FR 7340). Such reclassifications were applicable to discharges occurring during the 3-year period beginning April 1, 2004, and ending March 31, 2007. Section 106(a) of the Medicare Improvements and Extension Act, Division B of the Tax Relief and Health Care Act of 2006 (MIEA–TRHCA) extended the geographic reclassifications of hospitals that were made under section 508 of the MMA. In the March 23, 2007 **Federal Register** (72 FR 3799), we published a notice that indicated how we were implementing section 106(a) of the MIEA–TRHCA through September 30, 2007. Section 117 of the MMSEA further extended section 508 reclassifications and certain special exceptions through September 30, 2008. On February 22, 2008 in the **Federal Register** (73 FR 9807), we published a notice regarding our implementation of section 117 of the MMSEA. In the October 3, 2008 **Federal Register** (73 FR 57888), we published a notice regarding our implementation of section 124 of MIPPA, which extended section 508 reclassifications and certain special exceptions through September 30, 2009. In the June 2, 2010 **Federal Register** (75 FR 31118), we explained our implementation of section 3137(a) of the ACA, as amended by section 10317 of ACA, which further extended section 508 reclassifications and certain special exceptions through the end of FY 2010.

Section 102 of the MMEA has extended the hospital reclassifications originally received under section 508 and certain special exceptions through September 30, 2011 (FY 2011). Furthermore, effective April 1, 2011, section 102 of the MMEA also requires that in determining the wage index applicable to hospitals that qualify for wage index reclassification, the Secretary shall remove the section 508 and special exception hospitals' wage data from the calculation of the reclassified wage index if doing so increases the reclassified wage index. If the section 508 or special exception hospital's wage index applicable for the period beginning on October 1, 2010, and ending on March 30, 2011, is lower than for the period beginning on April 1, 2011, and ending on September 30, 2011, the Secretary shall pay the hospital an additional amount that reflects the difference between the wage indices for the two periods. As a result of these changes, we have recalculated certain wage index values to account for the new legislation.

Hospitals receiving an extension of their section 508 reclassifications or special exceptions wage indices are shown in Table 9B of the Addendum to this notice. Please note we are not making reclassification decisions on behalf of hospitals in this extension as we did with the MIPPA provision. (Because MIPPA was enacted prior to the finalization of the FY 2009 rates, we were able to modify reclassifications that had not yet taken effect. In contrast, MMEA was enacted in the middle of the fiscal year, and reclassifications are already in effect). Also, as explained in this notice, in cases where we have removed section 508/special exception hospital data from the reclassification wage index (effective April 1), we have

done so only where the labor market area includes hospitals that have 508 reclassifications/special exceptions extended, or where an extended hospital was reclassified to such area for FY 2011.

When originally implementing section 508 of the MMA, we required each hospital to submit a request in writing by February 15, 2004, to the Medicare Geographic Classification Review Board (MGCRB), with a copy to CMS. We will neither require nor accept written requests for the extension required by MMEA, since that law simply provides a 1 year continuation through the end of FY 2011 for any section 508 reclassifications and special exceptions wage indices that expired September 30, 2010.

B. FY 2011 Final Wage Indices

The FY 2011 final wage index values and geographic adjustment factors (GAF) for hospitals affected by section 102 of the MMEA are included in Tables 2, 4C, and 9B of the Addendum to this notice, as well as in a Table showing the hospitals that have been removed from Table 9A. These tables also are posted on our Web site at *http://www.cms.hhs.gov/AcuteInpatientPPS/.* Table 2 of the Addendum to this notice includes the final wage index values for: (1) Section 508 and special exception hospitals; and (2) other hospitals affected by the extension. Table 4C of the Addendum to this notice lists the revised final wage index and GAF values for certain hospitals that are reclassified, for hospitals that have not had their section 508 reclassifications or special exceptions extended, will be effective April 1, 2011. The revised Table 9A of the Addendum lists hospitals removed from the table due to the enactment of section 102 of MMEA. In addition, Table 9B of the Addendum to this notice lists hospitals that are section 508 and special exception providers that have been extended until September 30, 2011. Please note that some hospitals that might otherwise qualify for an extension of their section 508 reclassification or special exception have not been so extended for FY 2011, because they are receiving a higher wage index as a result of maintaining their MGCRB reclassification or due to section 10324 of the ACA which provides for a floor (of 1.0) on the area wage index for hospitals in Frontier States. Therefore, in keeping with our historic practice, these providers continue to receive the wage index published in the FY 2011 IPPS/LTCH PPS final rule, or subsequent correction notice (published on October 1, 2010), and are neither removed from Table 9A nor listed in Table 9B.

III. Collection of Information Requirements

This document does not impose information collection and recordkeeping requirements. Consequently, it need not be reviewed by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 35).

IV. Waiver of Proposed Rulemaking and Delay of Effective Date

We ordinarily publish a notice of proposed rulemaking in the **Federal Register** and invite public comment prior to a rule taking effect in accordance with section 553(b) of the Administrative Procedure Act (APA) and section 1871 of the Act. In addition, in accordance with section 553(d) of the APA and section 1871(e)(1)(B)(i) of the Act, we ordinarily provide a 30-day delay to a substantive rule's effective date. For substantive rules that constitute major rules, in accordance with 5 U.S.C. 801, we ordinarily provide a 60-day delay in the effective date.

None of the above processes or effective date requirements apply, however, when the rule in question is interpretive, a general statement of policy, or a rule of agency organization, procedure or practice. They also do not apply when the Congress itself has created the rules that are to be applied, leaving no discretion or gaps for an agency to fill in through rulemaking.

In addition, an agency may waive notice and comment rulemaking, as well as any delay in effective date, when the agency for good cause finds that notice and public comment on the rule as well the effective date delay are impracticable, unnecessary, or contrary to the public interest. In cases where an agency finds good cause, the agency must incorporate a statement of this finding and its reasons in the rule issued.

The policies being publicized in this notice do not constitute agency rulemaking. Rather, the Congress, in the MMEA, has already required that the agency make these changes, and we are simply notifying the public of certain required revisions to wage index values that are effective either October 1, 2010 (or for certain affected non-508 hospitals April 1, 2011). As this notice merely informs the public of these required modifications to the wage index values under the IPPS, it is not a rule and does not require any notice and comment rulemaking. To the extent any of the policies articulated in this notice constitute interpretations of the Congress's requirements or procedures that will be used to implement the Congress's directive; they are interpretive rules, general statements of policy, and/or rules of agency procedure or practice, which are not subject to notice-and-comment rulemaking or a delayed effective date.

However, to the extent that notice and comment rulemaking or a delay in effective date or both would otherwise apply, we find good cause to waive such requirements. Specifically, we find it unnecessary to undertake notice and comment rulemaking in this instance as this notice does not propose to make any substantive changes to IPPS policies or methodologies already in effect as a matter of law, but simply applies rate adjustments required by MMEA to these existing policies and methodologies. Therefore, we would be unable to change any of the policies governing the IPPS for FY 2011 in response to public comment on this notice. Finally, even if any of the policies could be subject to change, as many of the changes outlined in this notice have already taken effect or must take effect within a very short period of time after enactment of the MMEA (that is, by April 1, 2011—approximately 3 months after enactment), it would also be impracticable to undertake notice and comment rulemaking. For these reasons, we also find that a waiver of any delay in effective date, if it were otherwise applicable, is necessary to comply with the requirements of the MMEA. Therefore, we find good cause to waive notice and comment procedures as well as any delay in effective date, if such procedures or delays are required at all.

V. Regulatory Impact Analysis

A. Introduction

We have examined the impacts of this notice 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 (Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999), and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits

(including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. A regulatory impact analysis (RIA) must be prepared for regulatory actions with economically significant effects ($100 million or more in any 1 year). This notice has been designated an "economically" significant regulatory action, under section 3(f)(1) of Executive Order 12866. Therefore, although we do not consider this notice to constitute a substantive rule, we have prepared a RIA, that to the best of our ability, presents the costs and benefits of this notice. In accordance with Executive Order 12866, the notice has been reviewed by the Office of Management and Budget.

The RFA requires agencies to analyze options for regulatory relief of small businesses, 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. We estimate that most hospitals and most other providers and suppliers are small entities as that term is used in the RFA. The great majority of hospitals and most other health care providers and suppliers are small entities, either by being nonprofit organizations or by meeting the SBA definition of a small business (having revenues of less than $7.5 to $34.5 million in any 1 year). (For details on the latest standard for health care providers, we refer readers to page 33 of the Table of Small Business Size Standards at the Small Business Administration's Web site at *http://www.sba.gov/services/contractingopportunities/sizestandardstopics/tableofsize/index.html*.) For purposes of the RFA, all hospitals and other providers and suppliers are considered to be small entities. Individuals and States are not included in the definition of a small entity. We believe that this notice will have a significant impact on small entities. Because we acknowledge that many of the affected entities are small entities, the analysis discussed in this section would fulfill any requirement for a final regulatory flexibility analysis.

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. With the exception of hospitals located in certain New England counties, for purposes of section 1102(b) of the Act, we now define a small rural hospital as a hospital that is located outside of an urban area and has fewer than 100 beds. Section 601(g) of the Social Security Amendments of 1983 (Pub. L. 98–21) designated hospitals in certain New England counties as belonging to the adjacent urban area. Thus, for purposes of the IPPS, we continue to classify these hospitals as urban hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) (Pub. L. 104–4) 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 notice will not mandate any requirements for State, local, or Tribal governments, nor will it affect private sector costs. 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. This notice will not have a substantial effect on State and local governments.

Although this notice merely reflects the implementation of provisions of the MMEA and does not constitute a substantive rule, we are nevertheless preparing this impact analysis in the interest of ensuring that the impacts of these changes are fully understood. The following analysis, in conjunction with the remainder of this document, demonstrates that this notice is consistent with the regulatory philosophy and principles identified in Executive Order 12866 and 13563, the RFA, and section 1102(b) of the Act. The notice will positively affect payments to a substantial number of small rural hospitals, as well as other classes of hospitals, and the effects on some hospitals may be significant. The impact analysis, which shows the effect on all payments to hospitals, is shown in Table I of this notice.

B. Statement of Need

This notice is necessary to update the final fiscal year (FY) 2011 wage indices and hospital reclassifications and other related tables to reflect changes required by or resulting from the implementation of section 102 of the MMEA. MMEA requires the extension of the expiration date for certain geographic reclassifications and special exception wage indices through September 30, 2011. We note that the changes in this notice are already in effect with changes made to PRICER and announced through a Joint Signature Memorandum.

C. Overall Impact

The FY 2011 IPPS final rule included an impact analysis for the changes to the IPPS included in that rule. This notice updates those impacts to the IPPS operating payment system as to reflect certain changes required by the MMEA. Because provisions in the MMEA were not budget neutral, the overall estimates for hospitals have changed from our estimate that was published in the FY 2011 IPPS final rule (75 FR 50042). We estimate that the changes in the FY 2011 IPPS final rule, in conjunction with the final IPPS rates and wage index included in this notice, will result in an approximate $279 million decrease in total operating payments relative to FY 2010. In the FY 2011 IPPS final rule (75 FR 50042), we had projected that total operating payments would decrease by $440 million relative to FY 2010. However, the changes in this notice will increase operating payments by $162 million relative to what was projected in the FY 2011 IPPS final rule, resulting in a net decrease of $279 million in total operating payments. Capital payments are estimated to increase by an additional $13.6 million in FY 2011 as a result of the changes in this notice.

D. Anticipated Effects

In Table I, we provide an impact analysis for changes to the IPPS operating payments in FY 2011 as a result of the changes required by the MMEA. The table categorizes hospitals by various geographic and special payment consideration groups to illustrate the varying impacts on different types of hospitals. The first row of Table I shows the overall impact on the 3,472 acute care hospitals included in the analysis. The impact analysis reflects the change in estimated operating payments in FY 2011 due to the provisions in the MMEA relative to estimated FY 2011 operating payments published in the FY 2011 IPPS final rule (75 FR 50042). Overall, all hospitals will experience an estimated 0.2 percent increase in operating payments in FY 2011 due to the provisions in MMEA compared to the previous estimates of operating payments in FY 2011 published in the FY 2011 IPPS final rule. Because the provisions in the MMEA were not budget neutral, all hospitals, depending on whether they were affected by the provisions in the MMEA, will either experience no

change or an increase in IPPS operating payments in FY 2011 in this notice relative to the previously published estimates. As such, hospitals located in urban areas will experience a 0.2 percent increase in payments while hospitals located in rural areas will not experience any change in payments in FY 2011 due to the provisions in this notice as compared to the estimated payments provided in the FY 2011 IPPS final rule. Among the hospitals that are subject to the changes in this notice, hospitals will experience a net effect increase in payments ranging from 0.1 percent to 0.4 percent where urban Middle Atlantic hospitals, urban East North Central hospitals and urban reclassified hospitals are expected to experience the largest net increase in operating payments of 0.4 percent in FY 2011.

TABLE I—IMPACT ANALYSIS OF CHANGES FOR FY 2011 ACUTE CARE HOSPITAL OPERATING PROSPECTIVE PAYMENT SYSTEM

	Number of hospitals	Percent net effect of all changes for FY 2011
All Hospitals	3472	0.2
By Geographic Location:		
Urban hospitals	2494	0.2
Large urban areas	1362	0.2
Other urban areas	1132	0.2
Rural hospitals	978	0
Bed Size (Urban):		
0–99 beds	622	0.1
100–199 beds	785	0.2
200–299 beds	460	0.2
300–499 beds	430	0.2
500 or more beds	197	0.2
Bed Size (Rural):		
0–49 beds	348	0
50–99 beds	368	0
100–149 beds	156	0
150–199 beds	60	0
200 or more beds	46	0
Urban by Region:		
New England	121	0.3
Middle Atlantic	330	0.4
South Atlantic	382	0
East North Central	403	0.4
East South Central	155	0
West North Central	167	0
West South Central	336	0
Mountain	161	0
Pacific	389	0.1
Puerto Rico	50	0
Rural by Region:		
New England	24	0
Middle Atlantic	70	0.1
South Atlantic	165	0
East North Central	121	0
East South Central	176	0
West North Central	100	0.1
West South Central	219	0
Mountain	72	0
Pacific	31	0
By Payment Classification:		
Urban hospitals	2551	0.2
Large urban areas	1404	0.2
Other urban areas	1147	0.2
Rural areas	921	0
Teaching Status:		
Nonteaching	2429	0.1
Fewer than 100 residents	805	0.2
100 or more residents	238	0.3
Urban DSH:		
Non-DSH	779	0.2
100 or more beds	1531	0.2
Less than 100 beds	356	0.1
Rural DSH:		
SCH	423	0
RRC	212	0
100 or more beds	30	0.2
Less than 100 beds	141	0.2
Urban teaching and DSH:		

TABLE I—IMPACT ANALYSIS OF CHANGES FOR FY 2011 ACUTE CARE HOSPITAL OPERATING PROSPECTIVE PAYMENT SYSTEM—Continued

	Number of hospitals	Percent net effect of all changes for FY 2011
Both teaching and DSH	818	0.2
Teaching and no DSH	161	0.3
No teaching and DSH	1069	0
No teaching and no DSH	503	0.2
Special Hospital Types:		
RRC	180	0.1
SCH	332	0
MDH	194	0
SCH and RRC	117	0
MDH and RRC	13	0
Type of Ownership:		
Voluntary	1990	0.2
Proprietary	859	0.1
Government	586	0
Medicare Utilization as a Percent of Inpatient Days:		
0–25	353	0
25–50	1593	0.2
50–65	1203	0.2
Over 65	233	0.2
FY 2011 Reclassifications by the Medicare Geographic Classification Review Board:		
All Reclassified Hospitals	773	0.3
Non-Reclassified Hospitals	2699	0.1
Urban Hospitals Reclassified	442	0.4
Urban Nonreclassified Hospitals, FY 2011	2022	0.1
All Rural Hospitals Reclassified FY 2011	331	0
Rural Nonreclassified Hospitals FY 2011	585	0.1
All Section 401 Reclassified Hospitals:	37	0
Other Reclassified Hospitals (Section 1886(d)(8)(B))	63	0
Specialty Hospitals:		
Cardiac Specialty Hospitals	19	0

E. Alternatives Considered

This notice provides descriptions of the statutory provisions that are addressed and identifies policies for implementing these provisions. Due to the prescriptive nature of the statutory provisions, no alternatives were considered.

F. Accounting Statement and Table

1. Acute Care Hospitals

As required by OMB Circular A–4 (available at *http://www.whitehouse.gov/omb/circulars/a004/a-4.pdf*), in Table II, we have prepared an accounting statement showing the classification of expenditures associated with the provisions of this notice as they relate to acute care hospitals. This table provides our best estimate of the change in Medicare payments to providers as a result of the changes to the IPPS presented in this notice. All expenditures are classified as transfers from the Federal government to Medicare providers. As previously discussed, relative to what was projected in the FY 2011 IPPS final rule, the changes in this notice will increase FY 2011 operating payments by $162 million and capital payments by $14 million. Thus, the total increase in Federal expenditures for FY 2011 is approximately $176 million.

TABLE II—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED EXPENDITURES UNDER THE IPPS FROM PUBLISHED FY 2011 TO REVISED FY 2011

Category	Transfers
Annualized Monetized Transfers.	$176 million
From Whom to Whom.	Federal Government to IPPS Medicare Providers
Total	$176 million

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

Dated: March 3, 2011.

Donald M. Berwick,

Administrator, Centers for Medicare & Medicaid Services.

Approved: April 1, 2011.

Kathleen Sebelius,

Secretary, Department of Health and Human Services.

Addendum

This addendum includes tables referred to throughout the notice which contain data relating to the final FY 2010 wage indices and the hospital reclassifications and payment amounts for operating costs discussed in section II. of this notice.

TABLE 2A—REVISED FY 2011 WAGE INDEX VALUES FOR SECTION 508/SPECIAL EXCEPTION HOSPITALS

(Effective October 1, 2010 through September 30, 2011).

CMS certification No.	Revised FY 2011 wage index
010150	0.8567
020008	1.2776
050549	1.5477
060075	1.1429

TABLE 2A—REVISED FY 2011 WAGE INDEX VALUES FOR SECTION 508/ SPECIAL EXCEPTION HOSPITALS—Continued

(Effective October 1, 2010 through September 30, 2011).

CMS certification No.	Revised FY 2011 wage index
070005	1.2529
070006*	1.2867
070010	1.2867
070016	1.2529
070017	1.2529
070018*	1.2867
070019	1.2529
070022	1.2529
070028	1.2867
070031	1.2529
070034*	1.2867
070036	1.3329
070039	1.2529
150034	1.0386
160040	0.8759
160064	0.9501
160067	0.8759
160110	0.8759
220046	1.1629
230003	0.9930
230004	0.9930
230013	1.0781
230019	1.0781
230020	1.0057
230024	1.0057
230029	1.0781
230036	1.0781
230038	0.9930
230053	1.0057
230059	0.9930
230066	0.9930
230071	1.0781
230072	0.9930
230089	1.0057
230097	0.9930
230104	1.0057
230106	0.9930
230130	1.0781
230135	1.0057
230146	1.0057
230151	1.0781
230165	1.0057
230174	0.9930
230176	1.0057
230207	1.0781
230236	0.9930
230254	1.0781
230269	1.0781
230270	1.0057
230273	1.0057
230277	1.0781
250002	0.8443
250078*	0.8443

TABLE 2A—REVISED FY 2011 WAGE INDEX VALUES FOR SECTION 508/ SPECIAL EXCEPTION HOSPITALS—Continued

(Effective October 1, 2010 through September 30, 2011).

CMS certification No.	Revised FY 2011 wage index
250122	0.8443
310021	1.2867
310028	1.2867
310050	1.2867
310051	1.2867
310060	1.2867
310115	1.2867
310120	1.2867
330023*	1.2867
330049	1.2867
330067*	1.2867
330106	1.4341
330126	1.2867
330135	1.2867
330205	1.2867
330264	1.2529
340002	0.9087
390001	0.9370
390003	0.9370
390045**	0.9370
390072	0.9370
390095	0.9370
390119	0.9370
390137	0.9370
390169	0.9370
390185	0.9852
390192	0.9370
390237	0.9370
390270	0.9852
430005	1.0934
470003	1.1629
490001	0.8514
530015	1.0577

*These hospitals are assigned a wage index value under a special exceptions policy (see the FY 2005 IPPS final rule, 69 FR 49105).

**This hospital has been assigned a wage index under a special exceptions policy (see the FY 2007 IPPS final rule, 71 FR 48070).

TABLE 2B—REVISED FY 2011 WAGE INDEX VALUES FOR OTHER AFFECTED HOSPITALS

(Effective April 1, 2011 through September 30, 2011)

CMS certification No.	Revised FY 2011 wage index
070015	1.2867

TABLE 2B—REVISED FY 2011 WAGE INDEX VALUES FOR OTHER AFFECTED HOSPITALS—Continued

(Effective April 1, 2011 through September 30, 2011)

CMS certification No.	Revised FY 2011 wage index
070033	1.2867
070038	1.2529
140012	1.0386
140110	1.0386
140161	1.0386
150002	1.0386
150004	1.0386
150008	1.0386
150090	1.0386
150125	1.0386
150126	1.0386
150165	1.0386
150166	1.0386
150170	1.0386
230002	1.0057
230037	1.0057
230069	1.0781
230077	1.0781
230099	1.0057
230142	1.0057
230244	1.0057
230279	1.0781
230297	1.0057
230301	1.0781
230302	1.0781
250023	0.8443
250040	0.8443
250094	0.8443
250117	0.8443
310002	1.2867
310009	1.2867
310015	1.2867
310017	1.2867
310038	1.2867
310039	1.2867
310054	1.2867
310070	1.2867
310076	1.2867
310083	1.2867
310096	1.2867
310108	1.2867
310119	1.2867
330027	1.2867
330167	1.2867
330181	1.2867
330182	1.2867
330198	1.2867
330225	1.2867
330259	1.2867
330331	1.2867
330332	1.2867
330372	1.2867

TABLE 4C.—REVISED WAGE INDEX AND CAPITAL GEOGRAPHIC ADJUSTMENT FACTORS (GAF) FOR ACUTE CARE HOSPITALS THAT ARE RECLASSIFIED BY CBSA AND BY STATE—FY 2011

[Wage index includes rural floor budget neutrality adjustment]

CBSA code	Area	State	Revised wage index	Revised GAF
11460	Ann Arbor, MI	MI	1.0057	1.0039
16974	Chicago-Joliet-Naperville, IL	IL	1.0386	1.0263
22420	Flint, MI	MI	1.0781	1.0528
25060	Gulfport-Biloxi, MS	MS	0.8443	0.8906

TABLE 4C.—REVISED WAGE INDEX AND CAPITAL GEOGRAPHIC ADJUSTMENT FACTORS (GAF) FOR ACUTE CARE HOSPITALS THAT ARE RECLASSIFIED BY CBSA AND BY STATE—FY 2011—Continued

[Wage index includes rural floor budget neutrality adjustment]

CBSA code	Area	State	Revised wage index	Revised GAF
35004	Nassau-Suffolk, NY	NY	1.2529	1.1670
35644	New York-White Plains-Wayne, CT	CT	1.2867	1.1884
35644	New York-White Plains-Wayne, NJ	NJ	1.2867	1.1884
35644	New York-White Plains-Wayne, NY	NY	1.2867	1.1884

The following providers have been removed from Table 9A published in the FY 2011 IPPS/LTCH final rule (or in the October 1, 2010 correction notice to that final rule) due to the implementation of section 102 of the MMEA:

TABLE 9A—HOSPITAL RECLASSIFICATIONS AND REDESIGNATIONS WITHDRAWN/TERMINATED DUE TO SECTION 102 OF THE MMEA—FY 2011

CCN	Geographic CBSA	Reclassified CBSA	LUGAR
020008	02	11260	
060075	06	24300	
070005	35300	35004	
070006	14860	35644	
070010	14860	35644	
070016	35300	35004	
070017	35300	35004	
070018	14860	35644	
070019	35300	35004	
070022	35300	35004	
070028	14860	35644	
070031	35300	35004	
070034	14860	35644	
070036	25540	35300	
070039	35300	35004	
150034	23844	16974	
160064	16	24	
230003	26100	34740	
230013	47644	22420	
230019	47644	22420	
230020	19804	11460	
230024	19804	11460	
230029	47644	22420	
230036	23	13020	
230038	24340	34740	
230053	19804	11460	
230071	47644	22420	
230072	26100	34740	
230089	19804	11460	
230097	23	24340	
230104	19804	11460	
230106	24340	34740	
230130	47644	22420	
230135	19804	11460	
230146	19804	11460	
230151	47644	22420	
230165	19804	11460	
230174	26100	34740	
230176	19804	11460	
230207	47644	22420	
230236	24340	34740	
230254	47644	22420	
230269	47644	22420	
230270	19804	11460	
230273	19804	11460	
230277	47644	22420	
250002	25	22520	
250078	25620	25060	
310050	35084	35644	
330023	39100	35644	
330106	35004	35644	
330126	39100	35644	
390185	42540	10900	

TABLE 9B.—HOSPITAL RECLASSIFICATIONS AND REDESIGNATIONS BY INDIVIDUAL HOSPITAL UNDER SECTION 508 OF PUBLIC LAW 108–173—FY 2011

CCN	Note	Geographic CBSA	Wage index CBSA section 508 reclassification	Own wage index
010150		17980	0.8567	
020008		02		1.2776
050549		42220	1.5477	
060075		06		1.1429
070005		35004	1.2529	
070006	*	35644	1.2867	
070010		35644	1.2867	
070016		35004	1.2529	
070017		35004	1.2529	
070018	*	35644	1.2867	
070019		35004	1.2529	
070022		35004	1.2529	
070028		35644	1.2867	
070031		35004	1.2529	
070034	*	35644	1.2867	
070036		25540		1.3329
070039		35004	1.2529	
150034		16974	1.0386	
160040		16300	0.8759	
160064		16		0.9501
160067		16300	0.8759	
160110		16300	0.8759	
220046		14484	1.1629	
230003		28020	0.9930	
230004		28020	0.9930	
230013		22420	1.0781	
230019		22420	1.0781	
230020		11460	1.0057	
230024		11460	1.0057	
230029		22420	1.0781	
230036		22420	1.0781	
230038		28020	0.9930	
230053		11460	1.0057	
230059		28020	0.9930	
230066		28020	0.9930	
230071		22420	1.0781	
230072		28020	0.9930	
230089		11460	1.0057	
230097		28020	0.9930	
230104		11460	1.0057	
230106		28020	0.9930	
230130		22420	1.0781	
230135		11460	1.0057	
230146		11460	1.0057	
230151		22420	1.0781	
230165		11460	1.0057	
230174		28020	0.9930	
230176		11460	1.0057	
230207		22420	1.0781	
230236		28020	0.9930	
230254		22420	1.0781	
230269		22420	1.0781	
230270		11460	1.0057	
230273		11460	1.0057	
230277		22420	1.0781	
250002		25060	0.8443	
250078	*	25060	0.8443	
250122		25060	0.8443	
310021		35644	1.2867	
310028		35644	1.2867	
310050		35644	1.2867	
310051		35644	1.2867	
310060		35644	1.2867	
310115		35644	1.2867	
310120		35644	1.2867	
330023	*	35644	1.2867	
330049		35644	1.2867	
330067	*	35644	1.2867	

TABLE 9B.—HOSPITAL RECLASSIFICATIONS AND REDESIGNATIONS BY INDIVIDUAL HOSPITAL UNDER SECTION 508 OF PUBLIC LAW 108–173—FY 2011—Continued

CCN	Note	Geographic CBSA	Wage index CBSA section 508 reclassification	Own wage index
330106		35004		1.4341
330126		35644	1.2867	
330135		35644	1.2867	
330205		35644	1.2867	
330264		35004	1.2529	
340002		16740	0.9087	
390001		10900	0.9370	
390003		10900	0.9370	
390045	**	10900	0.9370	
390072		10900	0.9370	
390095		10900	0.9370	
390119		10900	0.9370	
390137		10900	0.9370	
390169		10900	0.9370	
390185		29540	0.9852	
390192		10900	0.9370	
390237		10900	0.9370	
390270		29540	0.9852	
430005		39660	1.0934	
470003		14484	1.1629	
490001		31340	0.8514	
530015		53		1.0577

* These hospitals are assigned a wage index value under a special exceptions policy (see FY 2005 IPPS final rule, 69 FR 49105).
** This hospital has been assigned a wage index under a special exceptions policy (see FY 2007 IPPS final rule, 71 FR 48070).

[FR Doc. 2011–8209 Filed 4–6–11; 8:45 am]
BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0002]

The 14th Annual Food and Drug Administration-Orange County Regulatory Affairs Educational Conference in Irvine, California: New Regulatory Challenges

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of conference.

The Food and Drug Administration (FDA) is announcing the following conference: 14th Annual Educational Conference co-sponsored with the Orange County Regulatory Affairs Discussion Group (OCRA). The conference is intended to provide the drug, device, biologics, and dietary supplement industries with an opportunity to interact with FDA reviewers and compliance officers from the centers and District Offices, as well as from other industry experts. The main focus of this interactive conference will be product approval, compliance, and risk management in the three medical product areas. Industry speakers, interactive Q & A, and workshop sessions will also be included to assure open exchange and dialogue on the relevant regulatory issues.

Date and Time: The conference will be held on June 8 and 9, 2011, from 7:30 a.m. to 5 p.m.

Location: The conference will be held at the Irvine Marriott Hotel, 18000 Von Karman Ave., Irvine, CA 92612.

Contact: Linda Hartley, Office of Regulatory Affairs, Food and Drug Administration, 19701 Fairchild, Irvine, CA 92612, *Voice:* 949–608–4413, *Fax:* 949–608–4417; or Orange County Regulatory Affairs Discussion Group, Attention to Detail, 5319 University Dr., suite 641, Irvine, CA 92612, *Voice:* 949–387–9046, *Fax:* 949–387–9047, *Web site: http://www.ocra-dg.org*. (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**.)

Registration and Meeting Information: See OCRA's Web site at *http://www.ocra-dg.org*. Contact Attention to Detail at 949–387–9046.

Before May 1, 2011, registrations fees are as follows: $675.00 for members, $725.00 for non-members and $475.00 for FDA/Government/Students.* After May 1, 2011, $725.00 for members, $775.00 for non-members, and $475.00 for FDA/Government/Students.*

* OCRA student rate applies to those individuals enrolled in a regulatory or quality-related academic program at an accredited institution. Proof of enrollment required.

The registration fee will cover actual expenses including refreshments, lunch, materials, parking, and speaker expenses.

If you need special accommodations due to a disability, please contact Linda Hartley (*see Contact*) at least 10 days in advance.

Transcripts: Transcripts will not be available for the conference.

Dated: April 1, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–8283 Filed 4–6–11; 8:45 am]
BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0443]

Cathryn Lyn Chatman (also known as Cathryn Lyn Garcia): Debarment Order

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is issuing an order under the Federal Food, Drug, and Cosmetic Act (the FD&C Act) debarring

Cathryn Lyn Chatman (also known as Cathryn Lyn Garcia) for 5 years from providing services in any capacity to a person that has an approved or pending drug product application. FDA bases this order on findings that Ms. Chatman was convicted of a misdemeanor under Federal law for conduct relating to the regulation of a drug product under the FD&C Act and that the type of conduct underlying the conviction undermines the process for the regulation of drugs. Ms. Chatman was given notice of the proposed debarment and an opportunity to request a hearing within the timeframe prescribed by regulation. Ms. Chatman failed to respond. Ms. Chatman's failure to respond constitutes a waiver of her right to a hearing concerning this action.

DATES: This order is effective April 7, 2011.

ADDRESSES: Submit applications for termination of debarment to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Kenny Shade, Office of Regulatory Affairs (HFC–230), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–796–4640.

SUPPLEMENTARY INFORMATION:

I. Background

Section 306(b)(2)(B)(i)(I) of the FD&C Act (21 U.S.C. 335a(b)(2)(B)(i)(I)) permits FDA to debar an individual if it finds that the individual has been convicted of a misdemeanor under Federal law for conduct relating to the regulation of drug products under the FD&C Act, and if FDA finds that the type of conduct that served as the basis for the conviction undermines the process for the regulation of drugs.

On March 14, 2006, Cathryn Lyn Chatman (also known as Cathryn Lyn Garcia) pleaded guilty to a misdemeanor offense of misbranding a drug. On August 14, 2006, the United States District Court for the District of Oregon entered judgment against Ms. Chatman for misdemeanor misbranding a drug, in violation of 21 U.S.C. 331(k) and 333(a)(1).

FDA's finding that debarment is appropriate is based on the misdemeanor conviction referenced herein. The factual basis for the conviction is as follows: Ms. Chatman was a registered nurse licensed by the Oregon Board of Nursing. Throughout 2004, she assisted a codefendant in operating two clinics that offered treatments they claimed could combat the effects of aging, including injection with BOTOX. From August 2004 through December 2004, Ms. Chatman offered a botulinum toxin called "Refinex" for sale for injection to patients under the name of another drug, BOTOX. Refinex is manufactured by the Shandong Bioresearch Institute in the People's Republic of China and has never been approved or licensed by FDA for any use. Ms. Chatman misbranded a drug, namely botulinum toxin type A manufactured by Shandong Bioresearch Institute and known as Refinex, while it was held for sale and after shipment in interstate commerce, in that she offered Refinex for sale by injection to patients under the name of another drug that is approved, namely BOTOX, all in violation of 21 U.S.C. 331(k) and 333(a)(1).

As a result of her conviction, on January 5, 2011, FDA sent Ms. Chatman a notice by certified mail proposing to debar her for 5 years from providing services in any capacity to a person that has an approved or pending drug product application. The proposal was based on a finding, under section 306(b)(2)(B)(i)(I) of the FD&C Act, that Ms. Chatman was convicted of a misdemeanor under Federal law for conduct relating to the regulation of drug products under the FD&C Act, and that the conduct that served as a basis for the conviction undermines the process for the regulation of drugs. The proposal also offered Ms. Chatman an opportunity to request a hearing, providing her 30 days from the date of receipt of the letter in which to file the request, and advised her that failure to request a hearing constituted a waiver of the opportunity for a hearing and of any contentions concerning this action. Ms. Chatman failed to respond within the timeframe prescribed by regulation and has, therefore, waived her opportunity for a hearing and waived any contentions concerning her debarment (21 CFR part 12).

II. Findings and Order

Therefore, the Director, Office of Enforcement, Office of Regulatory Affairs, under section 306(b)(2)(B)(i)(I) of the FD&C Act, under authority delegated to him (Staff Manual Guide 1410.35), finds that Cathryn Lyn Chatman has been convicted of a misdemeanor under Federal law for conduct relating to the regulation of a drug product under the FD&C Act, and that the type of conduct that served as a basis for the conviction undermines the process for the regulation of drugs.

As a result of the foregoing finding, Ms. Chatman is debarred for 5 years from providing services in any capacity to a person with an approved or pending drug product application under sections 505, 512, or 802 of the FD&C Act (21 U.S.C. 355, 360b, or 382), or under section 351 of the Public Health Service Act (42 U.S.C. 262), effective (see **DATES**), (see sections 306(c)(1)(B), (c)(2)(A)(iii), and 201(dd) of the FD&C Act (21 U.S.C. 321(dd)). Any person with an approved or pending drug product application who knowingly employs or retains as a consultant or contractor, or otherwise uses the services of Ms. Chatman, in any capacity during Ms. Chatman's debarment, will be subject to civil money penalties (section 307(a)(6) of the FD&C Act (21 U.S.C. 335b(a)(6))). If Ms. Chatman provides services in any capacity to a person with an approved or pending drug product application during her period of debarment she will be subject to civil money penalties (section 307(a)(7) of the FD&C Act). In addition, FDA will not accept or review any abbreviated new drug applications submitted by or with the assistance of Ms. Chatman during her period of debarment (section 306(c)(1)(B) of the FD&C Act (21 U.S.C. 335a(c)(1)(B)). Any application by Ms. Chatman for termination of debarment under section 306(d)(1) of the FD&C Act should be identified with Docket No. FDA–2010–N–0443 and sent to the Division of Dockets Management (see **ADDRESSES**). All such submissions are to be filed in four copies. The public availability of information in these submissions is governed by 21 CFR 10.20(j).

Publicly available submissions may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 22, 2011.

Howard Sklamberg,

Director, Office of Enforcement, Office of Regulatory Affairs.

[FR Doc. 2011–8218 Filed 4–6–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0002]

Joint Meeting of the Cardiovascular and Renal Drugs Advisory Committee and the Drug Safety and Risk Management Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee

of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committees: Cardiovascular and Renal Drugs Advisory Committee and the Drug Safety and Risk Management Advisory Committee.

General Function of the Committees: To provide advice and recommendations to the Agency on FDA's regulatory issues.

Date and Time: The meeting will be held on May 2, 2011, from 8 a.m. to 4 p.m.

Location: FDA White Oak Campus, Building 31, the Great Room, White Oak Conference Center, rm. 1503, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002. Information regarding special accommodations due to a disability, visitor parking and transportation may be accessed at: *http://www.fda.gov/AdvisoryCommittees/default.htm;* under the heading "Resources for You", click on "White Oak Conference Center Parking and Transportation Information for FDA Advisory Committee Meetings". Please note that visitors to the White Oak Campus must enter through Building 1.

Contact Person: Nicole Vesely, Pharm.D., Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Avenue, WO31–2417, Silver Spring, MD 20993–0002, 301–796–9001, *Fax:* 301–847–8533, *e-mail: nicole.vesely@fda.hhs.gov,* or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), and follow the prompts to the desired center or product area. Please call the Information Line for up-to-date information on this meeting. A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site and call the appropriate advisory committee hot line/phone line to learn about possible modifications before coming to the meeting.

Agenda: On May 2, 2011, the committees will discuss safety considerations of ultrasound contrast agents (materials intended to improve the clarity of ultrasound imaging), particularly related to new information and developments since the prior Advisory Committee meeting on the same topic on June 24, 2008. The discussion will include the results of required postmarketing safety studies and data from postmarketing surveillance. Specific drugs to be discussed include: (1) New drug application (NDA) 21–064, perflutren lipid microsphere injectable suspension, Lantheus Medical Imaging, Inc.; (2) NDA 20–899, perflutren protein-type A microspheres injectable suspension, GE Healthcare; and (3) the investigational new drug (IND) application for sulfur hexafluoride microbubble injection, Bracco Diagnostics, Inc. Perflutren lipid microsphere injectable suspension and perflutren protein-type A microspheres injectable suspension are indicated for use in patients with suboptimal echocardiograms to opacify the left ventricular chamber and to improve the delineation of the left ventricular endocardial border (improve the clarity of imaging of specific areas of the left lower side of the heart).

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at *http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm.* Scroll down to the appropriate advisory committee link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committees. Written submissions may be made to the contact person on or before April 18, 2011. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before April 8, 2011. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by April 11, 2011.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Nicole Vesely at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at *http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated March 22, 2011.

Leslie Kux,

Acting Associate Commissioner for Policy.

[FR Doc. 2011–8284 Filed 4–6–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0002]

Safety and Efficacy of Hypnotic Drugs; Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting.

The Food and Drug Administration (FDA) is announcing a public meeting to discuss the safety and efficacy of drugs for the treatment of insomnia. The Division of Neurology Products (DNP) in FDA's Center for Drug Evaluation and Research and the Pharmaceutical Education and Research Institute (PERI) are cosponsoring the 2-day meeting, with the first day centered on issues of efficacy and the second day on safety.

Date and Time: The public meeting will be held on Tuesday, May 10, and Wednesday, May 11, 2011, from 8 a.m. to 5 p.m.

Location: The public meeting will be held at the Bethesda Marriott, 5151 Pooks Hill Rd., Bethesda, MD 20814.

Contact: Margaret Bogie, 703–276–0178, ext. 115, *Fax:* 703–276–0069; or Cathleen Michaloski, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 4342, Silver Spring, MD 20993, 301–796–1123, e-mail: *Cathleen.michaloski@fda.hhs.gov.*

Accommodations: Attendees are responsible for their own accommodations. Reservations can be

made on a space available basis at the Bethesda Marriott Pooks Hill (see *Location*).

Registration: You are encouraged to register at your earliest convenience.

A registration fee will be charged to help defray the costs of rental of the meeting spaces, meals and snacks provided, and to cover travel costs incurred by invited speakers, and other costs. The cost of registration is as follows:

One-Day Rates:
Government: $475
Academic: $795
Industry: $895
Two-Day Rates:
Government: $875
Academic: $1,495
Industry: $1,695

Registration fees will be waived for invited speakers and members of the working group. If you need special accommodations due to a disability, please contact Margaret Bogie or Cathleen Michaloski (see *Contact*) at least 7 days in advance of the meeting.

Registration Instructions: For further details on how to register for the public meeting, contact Margaret Bogie or Cathleen Michaloski (see *Contact*).

SUPPLEMENTARY INFORMATION: Insomnia is a common disorder in the United States, yet it remains relatively poorly understood. Questions remain, for example, about the definition of insomnia and the classification of patients with the disorder. A better understanding of insomnia should help lead to safer and more effective treatment. A number of medications have been approved for insomnia, and many experimental medications are currently in development. New concerns have arisen about the most appropriate way to evaluate both the safety and the efficacy of medications for insomnia, particularly given that they may differ in important characteristics, including both pharmacodynamic and pharmacokinetic properties.

DNP and PERI plan for the first day of the meeting to center on issues of efficacy, including the evolving definition of insomnia, the classification of patients with this disorder, and the measurement of clinically relevant outcomes, including the choice of endpoints, subjective versus objective assessments, and duration of effect. The second day of the meeting will center on safety issues of hypnotic drugs, including the nature and prevalence of adverse events (AEs) related to the use of hypnotic drugs and evaluation of these AEs with a concentration on psychovigilance testing and driving-related tests.

Additional information on the conference, program, and registration procedures is available on the Internet at *http://peri.org/course_details.cfm?course=2072*. FDA has verified the PERI Web site address, but FDA is not responsible for any subsequent changes to the Web site after this document publishes in the **Federal Register**.

Dated: April 4, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–8285 Filed 4–6–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0013]

Statement of Organizations, Functions, and Delegations of Authority

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has reorganized the Center for Drug Evaluation and Research (CDER), Office of Surveillance and Epidemiology (OSE). This reorganization includes the organizations and their substructure components as listed in this document. This reorganization includes the establishment of six Staffs: Executive Operations and Strategic Planning Staff, Regulatory Science Staff, Regulatory Affairs Staff, Program Management and Analysis Staff, Project Management Staff, and Technical Information Staff. It will also include Office of Medication Error Prevention and Risk Management (OMEPRM) and Office of Pharmacovigilance and Epidemiology (OPE) under OSE. OMEPRM will consist of the Division of Risk Management and the Division of Medication Error Prevention and Analysis. OPE will consist of the Division of Epidemiology I and Division of Epidemiology II and the Division of Pharmacovigilance I and Division of Pharmacovigilance II. Also included are the abolishment of Business Process Improvement Staff, Regulatory Policy Staff, and Review Management Staff within OSE Immediate Office.

FOR FURTHER INFORMATION CONTACT: Karen Koenick, Center for Drug Evaluation and Research (HFD–063), Food and Drug Administration, 11919 Rockville Pike, rm. 324, Rockville, MD 20852, 301–796–4422.

I. Summary

The Statement of Organization, Functions, and Delegations of Authority for the Department of Health and Human Services (35 FR 3685, February 25, 1970; 60 FR 56605, November 9, 1995; 64 FR 36361, July 6, 1999; and 72 FR 50112, August 30, 2007) is amended to reflect the restructuring of CDER, FDA as follows.

II. Organization

CDER is headed by the Director, and includes the following organizational unit:

Office of Surveillance and Epidemiology

1. Provides leadership, direction, planning, budgeting, management, and supervision of Divisions and Staffs; and premarketing and postmarketing risk assessment program operations.
2. Develops and maintains international and national contact with regulators.
3. Develops, coordinates, and implements postmarket risk assessment policy, guidance, and interpretations.
4. Initiates regulation development and enhancement.
5. Coordinates and implements policies and initiatives, including information management initiatives across the Agency.

Regulatory Science Staff

1. Provides leadership, direction, and coordination for OSE regulatory research activities.
2. Develops and manages relationships with outside scientific groups that interface with OSE scientists on a variety of projects that relate to OSE's drug safety mission. These outside groups include academic organizations, private organizations, and other Federal Agencies.
3. Coordinates the access to large databases for pharmacoepidemiologic and pharmacovigilance studies, as well as to the outside scientists with drug safety expertise to collaborate with CDER.
4. Develops regulatory research programs that will support OSE as a whole, including risk management, pharmacovigilance, and medication error detection and prevention; in addition to epidemiology.

Regulatory Affairs Staff

1. Responsible for the coordination and implementation of regulatory policies by staff within OSE by coordinating the development and upkeep of guidances, MAPPs, and standard operating procedures, answering regulatory questions, managing the process for waivers of

postmarketing safety reporting requirements and citizen petition responses, and being involved in the development of safety regulations.

2. Provides leadership on initiatives related to the Medical Dictionary for Regulatory Activities (MedDRA).

Executive Operations & Strategic Planning Staff

1. Creates and maintains professional and skills training programs for OSE personnel.

2. Plans and tracks goals and objectives of all OSE Offices and Divisions.

3. Evaluates OSE work products and communications using quality control technology.

4. Interacts with Executive Secretariat, Press Office, and etc.

Technical Information Staff

1. Provides coordination, development and assessment of policies, procedures, and best practices related to OSE data and information system management within OSE.

2. Provides representation for OSE on Center and Agency best practices boards associated with staff responsibilities.

3. Represents OSE in Center and Agency boards or workgroups that address business process improvements and information technology related to postmarket drug safety.

4. Ensures that OSE's informatics systems (*e.g.,* Adverse Event Reporting System, Phonetic Orthographic Computer Analysis, and Phonetic Orthographic Computer Analysis) serve OSE's needs.

Program Management and Analysis Staff

1. Provides leadership, direction, planning, budgeting, management, and supervision of programs related to the OSE office administration and contracts management.

2. Provides guidance and support services to the OSE on all aspects of administrative, budget, and facilities management and provides service and support on human resource, personnel operations services, and recruitment activities.

3. Provides management, tracking and facilitation of projects related to office administration and contracts management within OSE.

4. Provides coordination, development, and assessment of policies, procedures, and best practices related to OSE office administration and contract management within OSE.

5. Provides representation for OSE on center and Agency best practices boards associated with staff responsibilities.

Project Management Staff

1. Provides leadership, direction, planning, management, and supervision of programs related to drug safety reviews and staff.

2. Provides management, tracking, and facilitation of projects related to drug safety reviews within OSE.

3. Provides coordination, development, and assessment of policies and procedures related to drug safety reviews, review templates, and other best practices related to drug safety reviews within OSE.

4. Provides representation for OSE on Center best practices associated with staff responsibilities.

Office of Medication Error Prevention and Risk Management

1. Directs and supports the Divisions of Medication Error Prevention and Analysis and Risk Management.

2. Leads OSE review of proposed and implemented Risk Minimization Action Plans (RiskMAPs)/Risk Evaluation and Mitigation Strategies (REMS).

3. Coordinates risk communication components of drug safety risk management programs.

4. Coordinates reviews of proposed proprietary trade names for their potential to result in sound-alike or look-alike medication errors.

5. Performs root-cause analyses of postmarketing medication error reports.

Division of Medication Error Prevention and Analysis

1. Plans, directs, and provides information technology support to the OSE.

2. Develops and maintains necessary software, processes, procedures, training, and security or databases available to OSE.

3. Acts as focal point for all hardware, software, and other information systems issues.

4. In conjunction with the OSE programs, evaluates extant information resources for utility and value to the OSE missions. Arranges for necessary accesses, training, and other needs related to effective use of those resources.

5. Develops and maintains the OSE Center for Drug Evaluation and Research Network (CDERNET) Web pages and works with other Agency programs to develop and maintain Internet pages related to office programs.

6. Serves as the primary OSE contact for World Health Organization (WHO) searches, Freedom of Information (FOI) and National Technical Information Services (NTIS) issues, and for database searches.

7. Reviews proposed proprietary trade names for their potential to result in sound-alike or look-alike medication errors.

8. Analyzes and performs root-cause analyses of postmarketing medication error reports.

9. Develops and implements internal MAPPs and guidance on medication error and patient safety initiatives.

Division of Risk Management

1. Plans and directs all risk management activities in the OSE.

2. Provides risk management expertise to OSE and the center.

3. Reviews all proposed Risk Minimization Action Plans (RiskMAPs) or Risk Management Plans (RMPs) for conformance with FDA's standards.

4. Conducts postmarketing monitoring of all products with approved RiskMAPs.

5. Conducts evaluations of the performance of RiskMAPs.

6. In conjunction with Office of New Drugs (OND), conducts premarketing risk assessments for some products.

7. Helps develop and maintain the Agency's OSE CDERNET RiskMAP Web pages and works with other Agency programs to develop and maintain RiskMAP Internet pages.

8. Develops and implements internal MAPPs and guidance on risk management initiatives.

Office of Pharmacovigilance and Epidemiology

1. Directs and supports the Divisions of Pharmacovigilance and Epidemiology.

2. Evaluates the safety of marketed drugs.

3. Reviews adverse event reports with OND.

4. Collaborates with other offices to recommend appropriate actions.

5. Provides recommendations on risk management programs and REMS.

6. Coordinates the review and analysis of epidemiologic study protocols and results of epidemiologic studies submitted by industry, from the literature or other sources that are related to the postmarketing safety of drugs.

Division of Epidemiology I

1. Provides leadership, direction, planning, budgeting, management, and supervision of Division programs and staff.

2. Reviews and provides analyses of epidemiologic study protocols and results of epidemiologic studies submitted by industry, from the literature or other sources that are related to the postmarketing safety of drugs.

3. Provides development and assessment of methodologies and best practices for active and passive surveillance systems and for incorporating such data, when appropriate, into the review of the postmarketing safety of drugs.

4. Reviews and analyzes drug utilization information.

5. Performs epidemiologic research on drug safety issues.

6. Provides epidemiologic and drug utilization expertise to support medical review divisions in areas of responsibility, as well as, for Advisory Committee presentations and related documents.

7. Provides input on epidemiologic and drug utilization aspects of information for the public related to significant postmarketing safety information regarding drugs, biologics, devices, and foods.

8. Develops and implements internal MAPPs and guidance on epidemiologic and drug utilization initiatives.

Division of Epidemiology II

1. Provides leadership, direction, planning, budgeting, management, and supervision of Division programs and staff.

2. Reviews and analyzes epidemiologic study protocols and results of epidemiologic studies submitted by industry from the literature or other sources that are related to the postmarketing safety of drugs.

3. Provides for the development and assessment of methodologies and best practices for scientifically-sound observational studies related to postmarketing safety of drugs.

4. Reviews and analyzes drug utilization information.

5. Performs epidemiologic research on drug safety issues.

6. Provides epidemiologic and drug utilization expertise to support medical review divisions in areas of responsibility, as well as, for Advisory Committee presentations and related documents.

7. Provides input on epidemiologic and drug utilization aspects of information for the public related to significant postmarketing safety information regarding drugs, biologics, devices, and foods.

8. Develops and implements internal MAPPs and guidance on epidemiologic and drug utilization initiatives.

Division of Pharmacovigilance I

1. Provides leadership, direction, planning, budgeting, management, and supervision of Division programs and staff.

2. Reviews and provides analysis of adverse event reports from industry submissions and from reports submitted directly to FDA related to marketed drugs in order to detect safety signals and evaluate risk; and performs followup when such signals are detected.

3. Provides development and assessments of methodologies and best practices for scientifically-sound safety signal detection and drug risk evaluation related to the postmarketing safety of drugs.

4. Provides safety signal detection and drug risk evaluation support to medical review divisions in areas of responsibility, as well as, for Advisory Committee presentations.

5. Provides recommendations on safety signal detection and drug risk evaluation aspects of proposed and implemented RiskMAPs or RMPs.

6. Provides input on signal detection and drug risk evaluation included in information for the public related to significant safety information regarding drugs, biologics, devices, and foods.

7. Develops and implements internal MAPPs and guidance on safety signal detection and drug risk evaluation initiatives.

Division of Pharmacovigilance II

1. Provides leadership, direction, planning, budgeting, management, and supervision of Division programs and staff.

2. Reviews and provides analyses of adverse event reports from industry submissions and from reports submitted directly to FDA related to marketed drugs in order to detect safety signals and evaluate risk; performs followup when such signals are detected.

3. Provides development and assessment of methodologies and best practices for scientifically-sound safety signal detection and drug risk evaluation related to the postmarketing safety of drugs.

4. Provides safety signal detection and drug risk evaluation support to medical review divisions in areas of responsibility, as well as, for Advisory Committee presentations.

5. Provides recommendations on safety signal detection and drug risk evaluation aspects of proposed and implemented RiskMAPs or RMPs.

6. Provides input on signal detection and drug risk evaluation included in information for the public related to significant safety information regarding drugs, biologics, devices, and foods.

7. Develops and implements internal MAPPs and guidance on safety signal detection and drug risk evaluation initiatives.

III. Delegation of Authority

Pending further delegation, directives or orders by the Commissioner of the Food and Drugs or the Center Director, CDER, all delegations and redelegations of authority made to officials and employees of affected organizational components will continue in them or their successors pending further redelegations, provided they are consistent with this reorganization.

Dated: April 4, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–8313 Filed 4–6–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Environmental Health Sciences; 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: National Institute of Environmental Health Sciences Special Emphasis Panel, Baseline Study For Arsenic Exposure.

Date: April 27, 2011.

Time: 1:30 p.m. to 2:30 p.m.

Agenda: To review and evaluate grant applications.

Place: Nat. Inst. of Environmental Health Sciences, Building 101, Rodbell Auditorium, 111 T. W. Alexander Drive, Research Triangle Park, NC 27709, (Telephone Conference Call).

Contact Person: Sally Eckert-Tilotta, Ph.D., Scientific Review Administrator, Nat. Institute of Environmental Health Sciences, Office of Program Operations, Scientific Review Branch, P.O. Box 12233 MD EC–30, Research Triangle Park, NC 27709, (919) 541–1446, *eckertt1@niehs.nih.gov.*

Name of Committee: National Institute of Environmental Health Sciences Special Emphasis Panel, Loan Repayment Program.

Date: May 2, 2011.

Time: 1 p.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: NIEHS/National Institutes of Health, Building 4401, East Campus, 79 T.W. Alexander Drive, Research Triangle Park, NC 27709, (Virtual Meeting).

Contact Person: RoseAnne M. McGee, Associate Scientific Review Administrator, Scientific Review Branch, Division of Extramural Research and Training, Nat. Institute of Environmental Health Sciences, P.O. Box 12233, MD EC–30, Research Triangle Park, NC 27709, (919) 541–0752, *mcgee1@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: March 31, 2011.

Jennifer S. Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2011–8316 Filed 4–6–11; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of 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 Center for Scientific Review Advisory Council.

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: Center for Scientific Review Advisory Council.

Date: May 2, 2011.

Time: 8:15 a.m. to 4 p.m.

Agenda: Provide advice to the Director, Center for Scientific Review (CSR), on matters related to planning, execution, conduct, support, review, evaluation, and receipt and referral of grant applications at CSR.

Place: National Institutes of Health, Natcher Building, 45 Center Drive, Room E1/E2, Bethesda, MD 20892.

Contact Person: Cheryl A. Kitt, Ph.D., Executive Secretary, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3030, MSC 7776, Bethesda, MD 20892, 301–435–1112, *kittc@csr.nih.gov.*

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

In the interest of security, NIH has instituted stringent procedures for entrance onto the NIH campus. All visitor vehicles, including taxicabs, hotel, and airport shuttles will be inspected before being allowed on campus. Visitors will be asked to show one form of identification (for example, a government-issued photo ID, driver's license, or passport) and to state the purpose of their visit.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, 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: March 31, 2011.

Jennifer S. Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2011–8315 Filed 4–6–11; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Center for Complementary & Alternative Medicine; 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 the National Advisory Council for Complementary and Alternative Medicine (NACCAM) meeting.

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/or contract Proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable materials, and personal information concerning individuals associated with the grant applications and/or contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Advisory Council for Complementary and Alternative Medicine.

Date: June 3, 2011.

Closed: June 3, 2011, 8:30 a.m. to 10:30 a.m.

Agenda: To review and evaluate grant applications and/or proposals.

Place: National Institutes of Health, Building 31, 31 Center Drive, Conference Room 10, Bethesda, MD 20892.

Open: June 3, 2011, 11 a.m. to 4 p.m.

Agenda: Opening remarks by the Director of the National Center for Complementary and Alternative Medicine, presentation of a new research initiative, and other business of the Council.

Place: National Institutes of Health, Building 31, 31 Center Drive, Conference Room 10, Bethesda, MD 20892.

Contact Person: Martin H. Goldrosen, Ph.D., Executive Secretary, Director, Division of Extramural Activities, National Center for Complementary and Alternative Medicine, National Institutes of Health, 6707 Democracy Blvd., Suite 401, Bethesda, MD 20892, (301) 594–2014.

The public comments session is scheduled from 3:30 to 4 p.m. on June 3, 2011, but could change depending on the actual time spent on each agenda item. Each speaker will be permitted 5 minutes for their presentation. Interested individuals and representatives of organizations are requested to notify Dr. Martin H. Goldrosen, National Center for Complementary and Alternative Medicine, NIH, 6707 Democracy Boulevard, Suite 401, Bethesda, Maryland, 20892, 301–594–2014, *Fax:* 301–480–9970. Letters of intent to present comments, along with a brief description of the organization represented, should be received no later than 5 p.m. on May 26, 2011. Only one representative of an organization may present oral comments. Any person attending the meeting who does not request an opportunity to speak in advance of the meeting may be considered for oral presentation, if time permits, and at the discretion of the Chairperson. In addition, written comments may be submitted to Dr. Martin H. Goldrosen at the address listed above up to ten calendar days (June 13, 2011) following the meeting.

Copies of the meeting agenda and the roster of members will be furnished upon request by contacting Dr. Martin H. Goldrosen, Executive Secretary, NACCAM, National Center for Complementary and Alternative Medicine, National Institutes of Health, 6707 Democracy Boulevard, Suite 401, Bethesda, Maryland 20892, 301–594–2014, Fax 301–480–9970, or via e-mail at *naccames@mail.nih.gov.*

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: *nccam.nih.gov/about/naccam,* where an

agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.701, ARRA Related Biomedical Research and Research Support Awards; 93.213, Research and Training in Complementary and Alternative Medicine, National Institutes of Health, HHS)

Dated: April 1, 2011.

Jennifer S. Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2011–8314 Filed 4–6–11; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Proposed Collection; Comment Request

In compliance with Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 concerning opportunity for public comment on proposed collections of information, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the information collection plans, call the SAMHSA Reports Clearance Officer on (240) 276–1243.

Comments are invited on: (a) Whether the proposed collections of information are necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Proposed Project: 2012 National Survey on Drug Use and Health—(OMB No. 0930–0110)—Revision

The National Survey on Drug Use and Health (NSDUH) is a survey of the civilian, non-institutionalized population of the United States 12 years old and older. The data are used to determine the prevalence of use of tobacco products, alcohol, illicit substances, and illicit use of prescription drugs. The results are used by SAMHSA, ONDCP, Federal government agencies, and other organizations and researchers to establish policy, direct program activities, and better allocate resources.

The 2012 and 2013 NSDUHs will continue conducting a follow-up clinical interview with a subsample of approximately 1,500 respondents. The design of this Mental Health Surveillance Study (MHSS) is based on the recommendations from a panel of expert consultants convened by the Center for Mental Health Services (CMHS), SAMHSA, to discuss mental health surveillance data collection strategies. The goal is to create a statistically sound measure that may be used to estimate the prevalence of Serious Mental Illness (SMI) among adults (age 18+).

For the 2012 and 2013 NSDUHs, no questionnaire changes are proposed.

As with all NSDUH/NHSDA surveys conducted since 1999, the sample size of the survey for 2012 and 2013 will be sufficient to permit prevalence estimates for each of the fifty states and the District of Columbia. The total annual burden estimate is shown below:

ESTIMATED ANNUAL BURDEN FOR 2012/2013 NSDUH

Instrument	No. of respondents	Responses per respondent	Hours per response	Total burden hours	Hourly wage rate	Annualized hourly costs
Household Screening	191,100	1	0.083	15,861	$14.71	$233,315
Interview	67,500	1	1.000	67,500	14.71	992,925
Clinical Follow-up Certification	90	1	1.000	90	14.71	1,324
Clinical Follow-up Interview	1,500	1	1.000	1,500	14.71	22,065
Screening Verification	5,400	1	0.067	362	14.71	5,325
Interview Verification	10,125	1	0.067	678	14.71	9,973
Total	191,190	.....	.....	85,991	.....	1,264,927

Send comments to Summer King, SAMHSA Reports Clearance Officer, Room 8–1099, One Choke Cherry Road, Rockville, MD 20857 *And* e-mail a copy to *summer.king@samhsa.hhs.gov*. Written comments should be received within 60 days of this notice.

Dated: March 30, 2011.

Elaine Parry,

Director, Office of Management, Technology and Operations.

[FR Doc. 2011–8293 Filed 4–6–11; 8:45 am]

BILLING CODE 4162–20–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[Docket No. USCG–2011–0187]

Notice of Entry Into Effect of MARPOL Annex V Wider Caribbean Region Special Area

AGENCY: Coast Guard, DHS.

ACTION: Notice.

SUMMARY: The Coast Guard announces the date for the entry into effect of discharge requirements from ships in the Wider Caribbean Region (WCR) special area (SA) as specified in the International Convention for the Prevention of Pollution from Ships (MARPOL) Annex V, Regulation 5 and Coast Guard regulations. MARPOL Annex V and the U.S. regulations apply to vessel and reception facility activities in the WCR region.

DATES: IMO Resolution MEPC.191(60) established the date of entry for discharge requirements in the WCR SA as May 1, 2011.

ADDRESSES: The docket for this notice is 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. You may also find this docket on the Internet by going

to *http://www.regulations.gov*, inserting USCG–2011–0187 in the "Keyword" box, and then clicking "Search."

FOR FURTHER INFORMATION CONTACT: If you have questions about this notice, call or e-mail Mr. David Condino, MARPOL Certificate of Adequacy Project Manager, telephone: 202–372–1145, e-mail: david.a.condino@uscg.mil; or LCDR Kevin P. Lynn, Chief, Facility Safety Branch, Commandant, CG–5442, telephone: 202–372–1130, e-mail: kevin.p.lynn@uscg.mil. If you have questions on viewing material in the docket, call Renee V. Wright, Program Manager, Docket Operations, telephone: 202–366–9826.

SUPPLEMENTARY INFORMATION:

Background and Purpose

Under Coast Guard regulation 33 CFR 151.53(b), the Coast Guard announces the May 1, 2011 date for entry into effect of discharge requirements from ships in the WCR SA. The WCR is defined in 33 CFR 151.06(a)(12). As of May 1, 2011, the discharge restrictions for SAs set forth in 33 CFR 151.71 will be applicable to the WCR SA.

In accordance with the provisions of regulation 5(4)(b) found in MARPOL Annex V, the United States, along with a sufficient number of WCR States that are parties to MARPOL, submitted notices on the availability of adequate reception facilities in the region to the International Maritime Organization's (IMO) Marine Environment Protection Committee (MEPC) at a meeting of the MEPC in March, 2010. During the meeting the WCR States requested that the MEPC establish a date for the entry into effect of the WCR SA. The MEPC noted the information provided by Member States in the WCR SA, to include the United States, and decided that the requirements for sufficient notification of adequate reception facilities for the WCR SA had been met. The MEPC adopted resolution MEPC.191(60) and the IMO Secretariat transmitted the text of the resolution to all interested parties via Circular Letter No.3053 dated April 14, 2010. These documents are available on the IMO's Web site at *http://www.imo.org.*

As a party to MARPOL Annex V, the United States proposed to the IMO's MEPC to establish the Gulf of Mexico as an SA under MARPOL Annex V in September 1990. The country of Venezuela submitted an amendment to the proposal to include the WCR along with the Gulf of Mexico as an SA under MARPOL Annex V in November 1990. The MEPC adopted the proposal to establish the WCR SA, including the Gulf of Mexico and the Caribbean Sea, in July 1991. The SA entered into force in April 1993, and MARPOL Annex V discharge requirements for the SA will enter into effect May 1, 2011. When the discharge requirements in regulation 5 of MARPOL Annex V enter into effect for the WCR SA, the discharge restrictions in 33 CFR 151.71 will also enter into effect. These regulations state that no person may discharge garbage from a ship except food wastes. The disposal of food wastes into the sea shall be made as far as practicable from land, but in any case not less than 12 nautical miles from the nearest land. Food wastes comminuted or ground and capable of passing through a screen with openings no greater than 25 mm may be discharged not less than 3 nautical miles from the nearest land.

The Coast Guard intends to update the list of SAs, in accordance with 33 CFR 151.53(b), to include where discharge restrictions are effective in a separate rule change.

Dated: March 18, 2011.

Kevin S. Cook,

Rear Admiral, U.S. Coast Guard, Director of Prevention Policy.

[FR Doc. 2011–8244 Filed 4–6–11; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–5374–N–26]

Buy American Exceptions Under the American Recovery and Reinvestment Act of 2009

AGENCY: Office of the Assistant Secretary for Public and Indian Housing, HUD.

ACTION: Notice.

SUMMARY: In accordance with the American Recovery and Reinvestment Act of 2009 (Pub. L. 111–05, approved February 17, 2009) (Recovery Act), and implementing guidance of the Office of Management and Budget (OMB), this notice advises that certain exceptions to the Buy American requirement of the Recovery Act have been determined applicable for work using Capital Fund Recovery Formula and Competition (CFRFC) grant funds. Specifically, exceptions were granted to the Cambridge Housing Authority of Cambridge, MA for the purchase and installation of energy efficient hot water baseboards at the Cambridge Affordable Presidential Apartments, the Housing Authority of the City of Bowling Green in Bowling Green Missouri for the purchase and installation of dual flush toilets at the Bowling Green High Rise Apartments. An exception was also granted to the Housing Authority of the City of Runge in Runge, Texas, for the purchase and installation of ceiling fans in eleven scattered sites.

FOR FURTHER INFORMATION CONTACT: Donald J. LaVoy, Deputy Assistant Secretary for Office of Field Operations, Office of Public and Indian Housing, Department of Housing and Urban Development, 451 7th Street, SW., Room 4112, Washington, DC 20410–4000, telephone number 202–402–8500 (this is not a toll-free number); or Dominique G. Blom, Deputy Assistant Secretary for Public Housing Investments, Office of Public Housing Investments, Office of Public and Indian Housing, Department of Housing and Urban Development, 451 7th Street, SW., Room 4130, Washington, DC 20410–4000, telephone number 202–402–8500 (this is not a toll-free number). Persons with hearing- or speech-impairments may access this number through TTY by calling the toll-free Federal Information Relay Service at 800–877–8339.

SUPPLEMENTARY INFORMATION: Section 1605(a) of the Recovery Act provides that none of the funds appropriated or made available by the Recovery Act may be used for a project for the construction, alteration, maintenance, or repair of a public building or public work unless all of the iron, steel, and manufactured goods used in the project are produced in the United States. Section 1605(b) provides that the Buy American requirement shall not apply in any case or category in which the head of a Federal department or agency finds that: (1) Applying the Buy American requirement would be inconsistent with the public interest; (2) iron, steel, and the relevant manufactured goods are not produced in the U.S. in sufficient and reasonably available quantities or of satisfactory quality, or (3) inclusion of iron, steel, and manufactured goods will increase the cost of the overall project by more than 25 percent. Section 1605(c) provides that if the head of a Federal department or agency makes a determination pursuant to section 1605(b), the head of the department or agency shall publish a detailed written justification in the **Federal Register**.

In accordance with section 1605(c) of the Recovery Act and OMB's implementing guidance published on April 23, 2009 (74 FR 18449), this notice advises the public that, on March 17, 2011, the following exceptions were granted:

1. Cambridge Housing Authority. Upon request of Cambridge Housing

Authority, HUD granted an exception to applicability of the Buy American requirements with respect to work, using CFRFC grant funds, in connection with the Cambridge Affordable Presidential Apartments. The exception was granted by HUD on the basis that the relevant manufactured goods (energy efficient hot water baseboards) are not produced in the U.S. in sufficient and reasonably available quantities or of satisfactory quality.

2. Housing Authority of the City of Bowling Green. Upon request of the Housing Authority of the City of Bowling Green, HUD granted an exception to applicability of the Buy American requirements with respect to work, using CFRFC grant funds, in connection with the Bowling Green High Rise Apartments. The exception was granted by HUD on the basis that the relevant manufactured goods (dual flush toilets) are not produced in the U.S. in sufficient and reasonably available quantities or of satisfactory quality.

3. Housing Authority of the City of Runge. Upon request of the Housing Authority of the City of Runge, HUD granted an exception to applicability of the Buy American requirements with respect to work, using CFRFC funds, in connection with eleven scattered sites. The exception was granted by HUD on the basis that the relevant manufactured goods (ceiling fans) are not produced in the U.S. in sufficient and reasonably available quantities or of satisfactory quality.

Dated: March 30, 2011.

Deborah Hernandez,

General Deputy Assistant Secretary for Public and Indian Housing.

[FR Doc. 2011–8234 Filed 4–6–11; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

Notice of Proposed Information Collection

AGENCY: Office of Surface Mining Reclamation and Enforcement, Interior

ACTION: Notice and request for comments for 1029–0091.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, the Office of Surface Mining Reclamation and Enforcement (OSM) is announcing its intention to request continued approval for the collection of information under 30 CFR Part 750 which relates to surface coal mining and reclamation operations on Indian Lands.

DATES: Comments on the proposed information collection must be received by June 6, 2011.

ADDRESSES: Comments may be mailed to John Trelease, Office of Surface Mining Reclamation and Enforcement, 1951 Constitution Ave., NW., Room 202—SIB, Washington, DC 20240. Comments may also be submitted electronically to *jtrelease@osmre.gov.*

FOR FURTHER INFORMATION CONTACT: To receive a copy of the information collection request contact John Trelease at (202) 208–2783 or by e-mail at *jtrelease@osmre.gov.*

SUPPLEMENTARY INFORMATION: The Office of Management and Budget (OMB) regulations at 5 CFR 1320, which implement provisions of the Paperwork Reduction Act of 1995 (Pub. L. 104–13), require that interested members of the public and affected agencies have an opportunity to comment on information collection and recordkeeping activities [*see* 5 CFR 1320.8 (d)]. This notice identifies information collection that OSM will be submitting to OMB for approval. The collection is contained in 30 CFR part 750, Requirements for surface coal mining and reclamation operations on Indian Lands. OSM will request a 3-year term of approval for each information collection activity.

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 number for part 750 is 1029–0091. Responses are required to obtain a benefit.

Comments are invited on: (1) The need for the collection of information for the performance of the functions of the agency; (2) the accuracy of the agency's burden estimates; (3) ways to enhance the quality, utility and clarity of the information collection; and (4) ways to minimize the information collection burden on respondents, such as use of automated means of collection of the information. A summary of the public comments will accompany OSM's submission of the information collection request to OMB.

Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment, including your personal identifying information, may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

The following information is provided for the information collection: (1) Title of the information collection; (2) OMB control number; (3) summary of the information collection activity; and (4) frequency of collection, description of the respondents, estimated total annual responses, and the total annual reporting and recordkeeping burden for the collection of information.

Title: 30 CFR part 750—Requirements for surface coal mining and reclamation operations on Indian Lands.

OMB Control Number: 1029–0091.

SUMMARY: Operators who conduct or propose to conduct surface coal mining and reclamation operations on Indian lands must comply with the requirements of 30 CFR 750 pursuant to Section 710 of SMCRA.

Bureau Form Number: None.

Frequency of Collection: Once.

Description of Respondents: Applicants for coal mining permits on Indian lands.

Total Annual Responses: 1.

Total Annual Burden Hours: 1,300.

Total Annual Non-Wage Burden: $15,000.

April 1, 2011.

Stephen M. Sheffield,

Acting Chief, Division of Regulatory Support.

[FR Doc. 2011–8312 Filed 4–6–11; 8:45 am]

BILLING CODE 4310–05–M

INTERNATIONAL TRADE COMMISSION

[Investigation Nos. 701–TA–479 and 731–TA–1183–1184 (Preliminary)]

Galvanized Steel Wire From China and Mexico

AGENCY: United States International Trade Commission.

ACTION: Institution of antidumping and countervailing duty investigations and scheduling of preliminary phase investigations.

SUMMARY: The Commission hereby gives notice of the institution of investigations and commencement of preliminary phase antidumping and countervailing Investigation Nos. 701–TA–479 and 731–TA–1183–1184 (Preliminary) under sections 703(a) and 733(a) of the Tariff Act of 1930 (19 U.S.C. 1671b(a) and 1673b(a)) (the Act) to determine whether there is a reasonable indication that an industry in the United States is materially injured or threatened with material injury, or the establishment of an industry in the United States is materially retarded, by reason of

imports from China and Mexico of galvanized steel wire, provided for in subheading 7217.20.30 and 7217.20.45 of the Harmonized Tariff Schedule of the United States, that are alleged to be sold in the United States at less than fair value and alleged to be subsidized by the Government of China. Unless the Department of Commerce extends the time for initiation pursuant to sections 702(c)(1)(B) or 732(c)(1)(B) of the Act (19 U.S.C. 1671a(c)(1)(B) or 1673a(c)(1)(B)), the Commission must reach a preliminary determination in antidumping and countervailing duty investigations in 45 days, or in this case by May 16, 2011. The Commission's views are due at Commerce within five business days thereafter, or by May 23, 2011.

For further information concerning the conduct of these investigations and rules of general application, consult the Commission's Rules of Practice and Procedure, part 201, subparts A through E (19 CFR part 201), and part 207, subparts A and B (19 CFR part 207).

DATES: *Effective Date:* March 31, 2011.

FOR FURTHER INFORMATION CONTACT: Angela Newell (202–708–5409), Office of Investigations, U.S. International Trade Commission, 500 E Street, SW., Washington, DC 20436. Hearing-impaired persons can obtain information on this matter by contacting the Commission's TDD terminal on 202–205–1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at 202–205–2000. General information concerning the Commission may also be obtained by accessing its Internet server (*http://www.usitc.gov*). The public record for these investigations may be viewed on the Commission's electronic docket (EDIS) at *http://edis.usitc.gov*.

SUPPLEMENTARY INFORMATION:

Background.—These investigations are being instituted in response to a petition filed on March 31, 2011, by Davis Wire Corp., Irwindale, CA; Johnstown Wire Technologies, Inc.; Johnstown, PA; Mid-South Wire Co., Inc., Nashville, TN; National Standard, LLC, Niles, MI; and Oklahoma Steel and Wire Co., Inc., Madill, OK.

Participation in the investigations and public service list.—Persons (other than petitioners) wishing to participate in the investigations as parties must file an entry of appearance with the Secretary to the Commission, as provided in sections 201.11 and 207.10 of the Commission's rules, not later than seven days after publication of this notice in the **Federal Register**. Industrial users and (if the merchandise under investigation is sold at the retail level) representative consumer organizations have the right to appear as parties in Commission antidumping and countervailing duty investigations. The Secretary will prepare a public service list containing the names and addresses of all persons, or their representatives, who are parties to these investigations upon the expiration of the period for filing entries of appearance.

Limited disclosure of business proprietary information (BPI) under an administrative protective order (APO) and BPI service list.—Pursuant to section 207.7(a) of the Commission's rules, the Secretary will make BPI gathered in these investigations available to authorized applicants representing interested parties (as defined in 19 U.S.C. 1677(9)) who are parties to the investigations under the APO issued in the investigations, provided that the application is made not later than seven days after the publication of this notice in the **Federal Register**. A separate service list will be maintained by the Secretary for those parties authorized to receive BPI under the APO.

Conference.—The Commission's Director of Investigations has scheduled a conference in connection with these investigations for 8:45 a.m. on April 22, 2011, at the U.S. International Trade Commission Building, 500 E Street, SW., Washington, DC. Requests to appear at the conference should be filed in writing with the Secretary to the Commission on or before April 19, 2011. Parties in support of the imposition of antidumping duties in these investigations and parties in opposition to the imposition of such duties will each be collectively allocated one hour within which to make an oral presentation at the conference. A nonparty who has testimony that may aid the Commission's deliberations may request permission to present a short statement at the conference.

Written submissions.—As provided in sections 201.8 and 207.15 of the Commission's rules, any person may submit to the Commission on or before April 27, 2011, a written brief containing information and arguments pertinent to the subject matter of the investigations. Parties may file written testimony in connection with their presentation at the conference no later than three days before the conference. If briefs or written testimony contain BPI, they must conform with the requirements of sections 201.6, 207.3, and 207.7 of the Commission's rules. The Commission's rules do not authorize filing of submissions with the Secretary by facsimile or electronic means, except to the extent permitted by section 201.8 of the Commission's rules, as amended, 67 FR 68036 (November 8, 2002). Even where electronic filing of a document is permitted, certain documents must also be filed in paper form, as specified in II(C) of the Commission's Handbook on Electronic Filing Procedures, 67 FR 68168, 68173 (November 8, 2002).

In accordance with sections 201.16(c) and 207.3 of the rules, each document filed by a party to the investigations must be served on all other parties to the investigations (as identified by either the public or BPI service list), and a certificate of service must be timely filed. The Secretary will not accept a document for filing without a certificate of service.

Authority: These investigations are being conducted under authority of title VII of the Tariff Act of 1930; this notice is published pursuant to section 207.12 of the Commission's rules.

By order of the Commission.

Issued: April 1, 2011.

James R. Holbein,

Acting Secretary to the Commission.

[FR Doc. 2011–8223 Filed 4–6–11; 8:45 am]

BILLING CODE —P

INTERNATIONAL TRADE COMMISSION

[Investigation Nos. 731–TA–1186–1187 (Preliminary)]

Certain Stilbenic Optical Brightening Agents From China and Taiwan

AGENCY: United States International Trade Commission.

ACTION: Institution of antidumping investigations and scheduling of preliminary phase investigations.

SUMMARY: The Commission hereby gives notice of the institution of investigations and commencement of preliminary phase antidumping investigation Nos. 731–TA–1186–1187 (Preliminary) under section 733(a) of the Tariff Act of 1930 (19 U.S.C. 1673b(a)) (the Act) to determine whether there is a reasonable indication that an industry in the United States is materially injured or threatened with material injury, or the establishment of an industry in the United States is materially retarded, by reason of imports from China and Taiwan of certain stilbenic optical brightening agents, provided for in subheading 3204.20.80 of the Harmonized Tariff Schedule of the United States, that are alleged to be sold in the United States at less than fair

value. Unless the Department of Commerce extends the time for initiation pursuant to section 732(c)(1)(B) of the Act (19 U.S.C. 1673a(c)(1)(B)), the Commission must reach a preliminary determination in antidumping investigations in 45 days, or in this case by May 16, 2011. The Commission's views are due at Commerce within five business days thereafter, or by May 23, 2011.

For further information concerning the conduct of these investigations and rules of general application, consult the Commission's Rules of Practice and Procedure, part 201, subparts A through E (19 CFR part 201), and part 207, subparts A and B (19 CFR part 207).

DATES: *Effective Date:* March 31, 2011.

FOR FURTHER INFORMATION CONTACT: Cynthia Trainor (202–205–3354), Office of Investigations, U.S. International Trade Commission, 500 E Street, SW., Washington, DC 20436. Hearing-impaired persons can obtain information on this matter by contacting the Commission's TDD terminal on 202–205–1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at 202–205–2000. General information concerning the Commission may also be obtained by accessing its Internet server (*http://www.usitc.gov*). The public record for these investigations may be viewed on the Commission's electronic docket (EDIS) at *http://edis.usitc.gov.*

SUPPLEMENTARY INFORMATION:

Background.—These investigations are being instituted in response to a petition filed on March 31, 2011, by Clariant Corporation, Charlotte, NC.

Participation in the investigations and public service list.—Persons (other than petitioners) wishing to participate in the investigations as parties must file an entry of appearance with the Secretary to the Commission, as provided in sections 201.11 and 207.10 of the Commission's rules, not later than seven days after publication of this notice in the **Federal Register**. Industrial users and (if the merchandise under investigation is sold at the retail level) representative consumer organizations have the right to appear as parties in Commission antidumping investigations. The Secretary will prepare a public service list containing the names and addresses of all persons, or their representatives, who are parties to these investigations upon the expiration of the period for filing entries of appearance.

Limited disclosure of business proprietary information (BPI) under an administrative protective order (APO) and BPI service list.—Pursuant to section 207.7(a) of the Commission's rules, the Secretary will make BPI gathered in these investigations available to authorized applicants representing interested parties (as defined in 19 U.S.C. 1677(9)) who are parties to the investigations under the APO issued in the investigations, provided that the application is made not later than seven days after the publication of this notice in the **Federal Register**. A separate service list will be maintained by the Secretary for those parties authorized to receive BPI under the APO.

Conference.—The Commission's Director of Investigations has scheduled a conference in connection with these investigations for 1 p.m. on April 21, 2011, at the U.S. International Trade Commission Building, 500 E Street, SW., Washington, DC. Requests to appear at the conference should be filed in writing with the Secretary to the Commission on or before March 18, 2011. Parties in support of the imposition of antidumping duties in these investigations and parties in opposition to the imposition of such duties will each be collectively allocated one hour within which to make an oral presentation at the conference. A nonparty who has testimony that may aid the Commission's deliberations may request permission to present a short statement at the conference.

Written submissions.—As provided in sections 201.8 and 207.15 of the Commission's rules, any person may submit to the Commission on or before April 26, 2011, a written brief containing information and arguments pertinent to the subject matter of the investigations. Parties may file written testimony in connection with their presentation at the conference no later than three days before the conference. If briefs or written testimony contain BPI, they must conform with the requirements of sections 201.6, 207.3, and 207.7 of the Commission's rules. The Commission's rules do not authorize filing of submissions with the Secretary by facsimile or electronic means, except to the extent permitted by section 201.8 of the Commission's rules, as amended, 67 FR 68036 (November 8, 2002). Even where electronic filing of a document is permitted, certain documents must also be filed in paper form, as specified in II(C) of the Commission's Handbook on Electronic Filing Procedures, 67 FR 68168, 68173 (November 8, 2002).

In accordance with sections 201.16(c) and 207.3 of the rules, each document filed by a party to the investigations must be served on all other parties to the investigations (as identified by either the public or BPI service list), and a certificate of service must be timely filed. The Secretary will not accept a document for filing without a certificate of service.

Authority: These investigations are being conducted under authority of title VII of the Tariff Act of 1930; this notice is published pursuant to section 207.12 of the Commission's rules.

By order of the Commission.

Issued: April 1, 2011.

James R. Holbein,

Acting Secretary to the Commission.

[FR Doc. 2011–8222 Filed 4–6–11; 8:45 am]

BILLING CODE P

INTERNATIONAL TRADE COMMISSION

Notice of Receipt of Complaint; Solicitation of Comments Relating to the Public Interest

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has received a complaint entitled *In Re Certain Motion-Sensitive Sound Effects Devices and Image Display Devices and Components and Products Containing Same,* DN 2799; the Commission is soliciting comments on any public interest issues raised by the complaint.

FOR FURTHER INFORMATION CONTACT: James R. Holbein, Acting Secretary to the Commission, U.S. International Trade Commission, 500 E Street, SW., Washington, DC 20436, telephone (202) 205–2000. The public version of the complaint can be accessed on the Commission's electronic docket (EDIS) at *http://edis.usitc.gov, and will be available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E Street, SW., Washington, DC 20436, telephone (202) 205–2000.*

General information concerning the Commission may also be obtained by accessing its Internet server (*http://www.usitc.gov*). The public record for this investigation may be viewed on the Commission's electronic docket (EDIS) at *http://edis.usitc.gov.* Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205–1810.

SUPPLEMENTARY INFORMATION: The Commission has received a complaint filed on behalf of Ogma, LLC on April 1, 2011. The complaint alleges 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 motion-sensitive sound effects devices and image display devices and components and products containing same. The complaint names as respondents Activision Blizzard Inc. of CA; Apple Inc. of CA; Canon, Inc. of Japan; Canon USA, Inc. of NY; Seiko Epson Corporation of Japan; Epson America, Inc. of CA; HTC Corporation of Taiwan; HTC America, Inc. of WA; InFocus Corp. of OR; Jakks Pacific, Inc. of CA; Kyocera Communications, Inc. of CA; LEGO A/S (dba) LEGO Group of Denmark; LEGO Systems, Inc. of CT; Lenovo (United States), Inc. of NC; Lenovo Group Ltd. of China; Lenovo (Singapore) Pte. Ltd. of Singapore; Mad Catz, Inc. of CA; Motorola Mobility, Inc. of IL; Nintendo Co., Ltd. of Japan; Nintendo of America, Inc. of WA; Nyko Technologies, Inc. of CA; Sanyo North America Corp. of CA; Sanyo Electric Co., Ltd. of Japan; Sanyo Electronic Devices (U.S.A.) of CA; Sharp Corporation of Japan; Sharp Electronics Corporation of NJ; Sony Computer Entertainment America, LLC of CA; Sony Corporation of Japan; Sony Corporation of America of NY; Sony Electronics Inc. of CA; Sony Ericsson Mobile Communications (USA), Inc. of GA; Sony Ericsson Mobile Communications AB of Sweden; Vivitek Corporation of CA; VTech Electronic North America, LLC of IL; VTech Holdings, Ltd. of Hong Kong; ViewSonic Corp., Ltd. of CA; WowWee Group Ltd. of Hong Kong; and WowWee USA, Inc. of CA.

The complainant, proposed respondents, other interested parties, and members of the public are invited to file comments, not to exceed five pages in length, on any public interest issues raised by the complaint. Comments should address whether issuance of an exclusion order and/or a cease and desist order in this investigation would negatively affect the public health and welfare in the United States, competitive conditions in the United States economy, the production of like or directly competitive articles in the United States, or United States consumers.

In particular, the Commission is interested in comments that:

(i) Explain how the articles potentially subject to the orders are used in the United States;

(ii) Identify any public health, safety, or welfare concerns in the United States relating to the potential orders;

(iii) Indicate the extent to which like or directly competitive articles are produced in the United States or are otherwise available in the United States, with respect to the articles potentially subject to the orders; and

(iv) Indicate whether Complainant, Complainant's licensees, and/or third party suppliers have the capacity to replace the volume of articles potentially subject to an exclusion order and a cease and desist order within a commercially reasonable time.

Written submissions must be filed no later than by close of business, five business days after the date of publication of this notice in the **Federal Register**. There will be further opportunities for comment on the public interest after the issuance of any final initial determination in this investigation.

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. Submissions should refer to the docket number ("Docket No. 2799") in a prominent place on the cover page and/or the first page. The Commission's rules authorize filing submissions with the Secretary by facsimile or electronic means only to the extent permitted by section 201.8 of the rules (*see* Handbook for Electronic Filing Procedures, *http://www.usitc.gov/secretary/fed_reg_notices/rules/documents/handbook_on_electronic_filing.pdf*). Persons with questions regarding electronic filing should contact the Secretary (202–205–2000).

Any person desiring to submit a document to the Commission in confidence must request confidential treatment. All such requests should be directed to the Secretary to the Commission and must include a full statement of the reasons why the Commission should grant such treatment. *See* 19 CFR 201.6. Documents for which confidential treatment by the Commission is properly sought will be treated accordingly. All nonconfidential written submissions will be available for public inspection at the Office of the Secretary.

This action is taken under the authority of section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and of sections 201.10 and 210.50(a)(4) of the Commission's Rules of Practice and Procedure (19 CFR 201.10, 210.50(a)(4)).

By order of the Commission.

Issued: April 4, 2011.

James R. Holbein,

Acting Secretary to the Commission.

[FR Doc. 2011–8299 Filed 4–6–11; 8:45 am]

BILLING CODE 7020–02–P

DEPARTMENT OF JUSTICE

[OMB Number 1103–0105]

Agency Information Collection Activities: Revision to a Currently Approved Collection; Comments Requested

AGENCY: Office of Community Oriented Policing Services, Department of Justice.

ACTION: 30-Day Notice of Information Collection Under Review.

The Department of Justice (DOJ) Office of Community Oriented Policing Services (COPS) will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995. The information collection is published to obtain comments from the public and affected agencies. This proposed information collection was previously published in the **Federal Register** on January 28, 2011 (76 FR 5207), allowing for a 60 day comment period.

The purpose of this notice is to allow for 30 days for public comment until May 9, 2011. This process is conducted in accordance with 5 CFR 1320.10.

If you have comments especially on the estimated public burden or associated response time, suggestions, or need a copy of the proposed information collection instrument with instructions or additional information, please contact Ashley Hoornstra, Department of Justice Office of Community Oriented Policing Services, 145 N Street, NE., Washington, DC 20530.

Written comments concerning this information collection should be sent to the Office of Information and Regulatory Affairs, Office of Management and Budget, *Attn:* DOJ Desk Officer. The best way to ensure your comments are received is to e-mail them to *oira_submission@omb.eop.gov* or fax them to 202–395–7285. All comments should reference the 8 digit OMB number for the collection or the title of the collection. If you have questions concerning the collection, please call Ashley Hoornstra at 202–616–1314 or the DOJ Desk Officer at 202–395–3176.

Written comments and suggestions from the public and affected agencies concerning the proposed collection of

information are encouraged. Your comments should address one or more of the following four points:

—Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

—Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

—Enhance the quality, utility, and clarity of the information to be collected; and

—Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Overview of This Information Collection

(1) *Type of Information Collection:* Revision to a currently approved collection; comments requested.

(2) *Title of the Form/Collection:* Community Policing Self-Assessment (CP–SAT)

(3) *Agency form number, if any, and the applicable component of the Department sponsoring the collection:* None. U.S. Department of Justice Office of Community Oriented Policing Services.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract: Primary:* Law Enforcement Agencies and community partners. The purpose of this project is to improve the practice of community policing throughout the United States by supporting the development of a series of tools that will allow law enforcement agencies to gain better insight into the depth and breadth of their community policing activities.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond/reply:* It is estimated that approximately 29,235 respondents will respond with an average of 17 minutes per response.

(6) *An estimate of the total public burden (in hours) associated with the collection:* The total estimated burden is 10,847 hours across 1,213 agencies.

If additional information is required contact: Lynn Murray, Department Clearance Officer, United States Department of Justice, Justice Management Division, Policy and Planning Staff, Two Constitution Square, 145 N Street, NE., Room 2E–808, Washington, DC 20530.

Dated: March 28, 2011.

Lynn Murray,

Department Clearance Officer, PRA, U.S. Department of Justice.

[FR Doc. 2011–7922 Filed 4–6–11; 8:45 am]

BILLING CODE 4410–AT–P

DEPARTMENT OF JUSTICE

Notice of Lodging of Consent Decree Under Comprehensive Environmental Response, Compensation and Liability Act

Under 28 CFR 50.7, notice is hereby given that on April 1, 2011, a proposed Consent Decree in *United States* v. *Anacomp, Inc., et al,* No. 3:10–cv–1158, was lodged with the United States District Court for the District of Connecticut.

The proposed Consent Decree resolves claims of the United States, on behalf of the Environmental Protection Agency ("EPA"), under the Comprehensive Environmental Response, Compensation, and Liability Act ("CERCLA"), 42 U.S.C. 9601 *et seq.,* in connection with the Solvents Recovery Service of New England, Inc. Superfund Site ("SRS Site") in Southington, Connecticut, against the defendant, Compagnone Holdings, Inc., f/k/a Mace Adhesives, Inc. The proposed Consent Decree requires the defendant to pay $30,463.

The Department of Justice will receive for a period of 30 days from the date of this publication comments relating to the proposed Consent Decree. Comments should be addressed to the Assistant Attorney General of the Environment and Natural Resources Division, Department of Justice, Washington, DC 20530, and either e-mailed to *pubcomment-ees.enrd@usdoj.gov* or mailed to P.O. Box 7611, U.S. Department of Justice, Washington, DC 20044–7611, and should refer to *United States* v. *Anacomp, Inc., et al,* No. 3:10–cv–1158, D.J. No. 90–7–1–23/10. Commenters may request an opportunity for a public meeting in the affected area, in accordance with Section 7003(d) of RCRA, 42 U.S.C. 6973(d).

The proposed Consent Decree may be examined on the following Department of Justice Web site, *http://www.usdoj.gov/enrd/Consent_Decrees.html.* A copy of the proposed Consent Decree may be obtained by mail from the Consent Decree Library, P.O. Box 7611, U.S. Department of Justice, Washington, DC 20044–7611 or by faxing or e-mailing a request to Tonia Fleetwood (*tonia.fleetwood@usdoj.gov*), fax no. (202) 514–0097, phone confirmation number (202) 514–1547. In requesting a copy of the proposed Consent Decree, please enclose a check in the amount of $4.75 (25 cent per page reproduction cost), payable to the U.S. Treasury.

Ronald Gluck,

Assistant Section Chief, Environmental Enforcement Section, Environment and Natural Resources Division.

[FR Doc. 2011–8219 Filed 4–6–11; 8:45 am]

BILLING CODE 4410–15–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 10–36]

Jacobo Dreszer, M.D., Decision and Order

On August 10, 2010, Administrative Law Judge (ALJ) John J. Mulrooney, II, issued the attached recommended decision.[1] Thereafter, Respondent filed exceptions to the decision.

Having reviewed the entire record including the ALJ's recommended decision and Respondent's exceptions, I have decided to adopt the ALJ's rulings, findings of fact,[2] conclusions of law,[3] and recommended Order.

[1] All citations to the ALJ's Decision (ALJ) are to the slip opinion as issued on August 10, 2010, and not to the attached decision which has been reformatted.

[2] The ALJ found that there is "no evidence that the Respondent 'prescribe[d] and dispense[d] *inordinate* amounts of controlled substances." ALJ at 21. While there is no evidence as to the amounts Respondent may have dispensed directly, there is such evidence, which is unrefuted, with respect to his prescriptions. As explained in my discussion of Respondent's Exceptions, an Expert witness testified as to the usual starting doses of oxycodone and Xanax and that the prescriptions Respondent issued for both drugs, even at the initial visit, greatly exceeded the usual starting doses and lacked a legitimate medical purpose. 21 CFR 1306.04(a). Moreover, there is also unrefuted evidence that Respondent's prescribing of drug cocktails of oxycodone and Xanax lacked a legitimate medical purpose. I thus reject the ALJ's finding to the extent that it states that there was no evidence that Respondent prescribed inordinate amounts.

[3] I do not, however, adopt the ALJ's discussion of the standards applied by the Agency in assessing a practitioner's experience in dispensing controlled substances, which cites cases involving list chemical I distributors, a different category of registrant. *See* ALJ Dec. at 20–21. As the Agency has previously made clear, DEA can revoke based on a single act of intentional diversion and "evidence that a practitioner has treated thousands of patients" in circumstances that do not constitute diversion "does not negate a *prima facie* showing that the practitioner has committed acts inconsistent with the public interest." *Jayam Krishna-Iyer,* 74 FR 459, 463 (2009). *See also Dewey C. MacKay,* 75 FR49956, 49977 (2010); *Medicine Shoppe-Jonesborough,* 73

Respondent first takes exception to the ALJ's acceptance of L. Douglas Kennedy, M.D., as an expert on the proper prescribing of controlled substances. Respondent contends that Dr. Kennedy should not have been permitted to opine on his prescribing practices because he does not hold a DEA registration in Florida, has not prescribed a controlled substance since 2004, does not currently have either a medical office or hospital privileges in Florida, and "has never practiced medicine regularly in Florida and has not practiced medicine in Florida at all in over 10 years." Resp. Exc. at 1.

Respondent's contention is unavailing as Dr. Kennedy was clearly qualified to render an expert opinion on the proper practice for prescribing controlled substances to treat pain and whether Respondent's controlled substance prescriptions were issued in the usual course of professional practice and for a legitimate medical purpose. *See* 21 CFR 1306.04(a). Dr. Kennedy currently holds a Florida medical license, is a diplomate of both the American Board of Pain Medicine and the American Board of Anesthesiology, and is currently on the faculty of the University of Miami's Miller School of Medicine. GX 117, at 1, 10. Previously, Dr. Kennedy was a Fellow with the Pain Therapy Unit of the Cleveland Clinic, served as the Director of Chronic Pain Management at the University of Kentucky Medical Center, and, for fourteen years, was the Medical Director of a multidisciplinary pain medicine and rehabilitation practice. *Id.* at 1–2.

Dr. Kennedy has published several articles and book chapters on pain management issues and has made several dozen presentations on pain management issues at professional meetings.[4] *Id.* at 3–7. In addition, he is a member of several professional organizations including the American Academy of Pain Medicine, the American Board of Pain Medicine, the American Pain Society, the International Association for the Study of Pain, the American Society of Addiction Medicine, the American Board of Anesthesiology, and the American Society of Anesthesiology. *Id.* at 10; Tr. 22. Finally, Dr. Kennedy explained that he was familiar with the Florida Board of Medicine's standards for prescribing controlled substances to treat pain and that he had reviewed them prior to preparing his report. Tr. 24–26; GX 76, at 5–6.

Thus, Dr. Kennedy was clearly qualified to provide expert testimony. I therefore agree with the ALJ that Dr. Kennedy's testimony was sufficiently reliable to constitute substantial evidence on the issue of whether Respondent acted within the usual course of professional practice and had a legitimate medical purpose in prescribing controlled substances to the patients whose files he reviewed and reject this exception.

Next, Respondent contends that Dr. Kennedy's opinion testimony is entitled to no weight because it was based on only seventeen patient charts, which Respondent maintains were not randomly selected and is too small a sample to draw sufficient conclusions about the validity of his prescribing practices. Resp. Exc. at 2. Based on Dr. Kennedy's testimony that "'[i]t might not be fair'" to "'cherry-pick[]'" a small and non-random sample of charts out of a physician's patients because this might not provide "'a reasonable representation of what the practice was actually like,'" Respondent argues that "[e]ven improper prescribing practices reflected in a small and non-random sample of 17 charts * * * may be 'an administrative issue for education with the Board of Medical License'" and not necessarily justify the revocation of Respondent's medical license (or DEA registration). *Id.* (quoting Tr. 645).

However, even acknowledging that two of the seventeen files reviewed by Dr. Kennedy with respect to Respondent were not randomly selected (one being that of an undercover officer), the ALJ found credible the Diversion Investigator's testimony that the files were not specially selected to enhance the strength of the Government's case. ALJ at 5 (citing Tr. 768). More importantly, the requirement of Federal law that a prescription "must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice," 21 CFR 1306.04(a), applies to each and every prescription issued by a practitioner. Thus, contrary to the Expert's understanding, in determining whether a practitioner has committed acts which render his registration "inconsistent with the public interest," 21 U.S.C. 824(a)(4), the Government is not required to randomly select the files which it will base its case on.

For example, where the Government has developed information that particular patients are drug dealers or engaged in self-abuse, it is not required to ignore the files pertaining to these patients and base its case on a random sample of files. Rather, it can select the files pertaining to those patients and base its case entirely on them. Moreover, where the Government has seized files, it can review them and choose to present at the hearing only those files which evidence a practitioner's most egregious acts. Of course, where, as here, the Government's case relies so heavily on a chart review, the practitioner can put on his own evidence and argue that the Government's evidence does not establish that he violated the prescription requirement; the practitioner can also argue that even

FR 364, 386 & n.56 (noting that pharmacy "had 17,000 patients," but that "[n]o amount of legitimate dispensings can render * * * flagrant violations [acts which are] 'consistent with the public interest'"), *aff'd, Medicine Shoppe-Jonesborough* v. *DEA,* 300 Fed. Appx. 409 (6th Cir. 2008). As I further explained, "[w]hile such evidence may be [entitled to] some weight in assessing whether a practitioner has credibly shown that [he] has reformed his practices," it is entitled to no weight where a practitioner fails to acknowledge his wrongdoing. *Krishna-Iyer,* 74 FR at 463.

In any event, Respondent offered no evidence on the issue of his experience in dispensing controlled substances and the ALJ's ultimate conclusion that Respondent violated the CSA's prescription requirement because he dispensed controlled substance prescriptions that were not "within 'the usual course of [his] professional practice," ALJ at 33 (quoting 21 CFR 1306.04(a)), and that "the evidence under the [experience] * * * factor[] support[s]" the revocation of his registration, is consistent with Agency precedent. *Id.*

With respect to factor five, "[s]uch other conduct which may threaten public health and safety," 21 U.S.C. 823(f)(5), the ALJ opined that "an adverse finding under this factor requires some showing that the relevant conduct *actually constituted* a threat to public safety." ALJ at 34 (emphasis added). Contrary to the ALJ's reasoning, Congress, by inserting the word "may" in factor five, clearly manifested its intent to grant the Agency authority to consider conduct which creates a probable or possible threat (and not only an actual) threat to public health and safety. *See Webster's Third New Int'l Dictionary* 1396 (1976) (defining "may" in relevant part as to "be in some degree likely to"); *see also The Random House Dictionary of the English Language* 1189 (1987) (defining "may" in relevant part as "used to express possibility"). While the ALJ misstated the applicable standard, his conclusion that Respondent repeatedly ignored "red flags" indicative of likely diversion and thus "created a significant potential conduit for the unchecked diversion of controlled substances" is clearly supported by substantial evidence and warrants an adverse finding under factor five. ALJ at 34.

The ALJ also opined that "[i]t is clear that in assessing whether the controlled substance prescribing practices of a Florida practitioner fall within the acceptable range of what constitutes being within the bounds of being 'issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice,' resort must be had to an expert." ALJ at 29 (quoting 21 CFR 1306.04(a)). While the ALJ properly noted the importance of expert testimony in this case, in which the Government primarily relied on a review of the medical charts, whether expert testimony is needed is necessarily dependent on the nature of the allegations and the other evidence in the case. Where, for example, the Government produces evidence of undercover visits showing that a physician knowingly engaged in outright drug deals, expert testimony adds little to the proof necessary to establish a violation of Federal law.

[4] He also co-edited and contributed to the State of Kentucky's Guidelines for Prescribing Controlled Substances, 2nd Edition. GX 117, at 9.

though the Government has made out a *prima facie* case, his conduct was not so egregious as to warrant revocation. *See Paul Caragine,* 63 FR 51592 (1998) (granting restricted registration where practitioner did not engage in intentional misconduct, patients had legitimate medical conditions requiring treatment, and practitioner accepted responsibility and testified as to remedial measures he had undertaken). *See also Dewey C. MacKay,* 75 FR at 49977 (revoking registration based on intentional acts of diversion to two patients); *Krishna-Iyer,* 74 FR at 463 (holding that DEA can revoke based on a single act of diversion); *Medicine Shoppe-Jonesborough,* 73 FR at 386 & n.56; *Alan H. Olefsky,* 57 FR 928, 929 (1992) (revoking registration based on physician's single act of presenting two fraudulent prescriptions to pharmacist where physician failed to acknowledge wrongdoing).[5] Accordingly, there is no merit to Respondent's exception.

Finally, Respondent takes exception to the ALJ's findings that he violated Florida's standards for prescribing controlled substances. Resp. Exceptions at 4–5. More specifically, Respondent contends that he complied with the standards set forth under Florida regulations and that he "took a complete medical history and conducted a physical evaluation that was documented," that he maintained "medical records documenting the patient's intensity of pain, current and past treatments for pain, and the effect of pain on physical and psychological function." *Id.* at 4–5. He further argues that "[h]e set out a written treatment plan, discussed the risks and benefits of controlled substances and conducted periodic reviews" as also required by Florida's regulations. *Id.* at 5.

While it is true that Dr. Kennedy acknowledged that he was not familiar with the specific standard imposed by the State of Florida for excessive prescribing and that he had not reviewed any Florida Medical Board decisions addressing the issue of what is an adequate medical history, *see* ALJ at 15, in his report Dr. Kennedy discussed at length the Florida Board of Medicine's *Standards for the Use of Controlled Substances for the Treatment of Pain,* Fla. Admin. Code 64B8–9.013.[6] *See* GX 76, at 5–6.

In any event, Respondent produced no evidence that his recordkeeping and prescribing complied with the standards of the Florida Medical Board. Moreover, there is substantial evidence to support the conclusion that Respondent was not engaged in legitimate medical practice and was diverting drugs.

As Dr. Kennedy explained, the patients whose files he reviewed were relatively young (with an average age of 36), and most were from out-of-state, with some travelling up to 1200 miles,[7] even though Respondent had no specialized training in pain management. *Id.* at 15–16. Yet, Respondent did not obtain reports from the prescription monitoring programs run by the States where his patients lived. *Id.* at 1–2; 14. Moreover, Respondent did not obtain adequate medical histories and perform adequate physical examinations; he also never obtained medical records from other treating physicians (or even contacted them) for any of the patients whose files are in evidence. *Id.* at 4, 8–9.

As Dr. Kennedy explained, while "[t]he chart was set up to give the appearance of a legitimate medical practice in an attempt to justify the initial and continued prescription and dispensing of high dose multiple controlled substances ('drug cocktails')," and that while "on the surface [the charts] were adequate for evaluating and treating a patient," on closer review, "the actual contents in the charts, clearly evidence just the opposite" as the charts were "very difficult * * * to read [with] many sections * * * left blank or incompletely filled in." *Id.* at 15. Continuing, Dr. Kennedy explained that "[t]he notes were not within the standard of care; all were outside the boundaries of professional practice, lacking significant information and ignoring significant history that was present." *Id.* Moreover, Respondent's failure to obtain his patients' medical records "was well outside the boundaries of medical practice and below the standard of medical care," especially because the patients were receiving "very high dose[s]" of controlled substances. *Id.*

The evidence further shows that this case is not simply a matter of inadequate record keeping. While Respondent apparently required his patients to obtain an MRI, in multiple instances the MRI was obtained before the patient was even evaluated by Respondent, and generally, no other imaging studies such as x-rays or CT scans were done.[8] *Id.* at 14–15.

Moreover, notwithstanding the doses the patients were seeking, Respondent rarely referred a patient to another physician or health care professional for a consultation.[9] As Dr. Kennedy explained, "[a]lternative opinions should have been sought in order to better diagnose and treat; not to do so was outside the boundaries of professional practice and not within the standard of care." *Id.* at 14. Dr. Kennedy thus concluded that Respondent's "diagnoses were usually very vague and/or without medical merit" and were done in an "attempt[] to justify what controlled substances he prescribed." *Id.* at 15.

Dr. Kennedy also observed that while Respondent performed urine drug screens, he ignored the results even when they were inconsistent with other information provided by the patients such as when a patient tested positive for controlled substances which he had previously indicated that he was not currently taking. *See id.* at 11, 14. Moreover, the drug screens were rarely performed other than at the patient's initial visit and lacked quality controls.[10] *Id.* at 14.

Although the charts indicate that Respondent discussed doing yoga and stretching, using an anti-inflammatory diet, and taking several over-the-counter supplements (fish oil and glucosamine chondroitin), Respondent's treatment plan primarily involved prescribing high doses of controlled substances with the same regimen of drugs (oxycodone and Xanax) prescribed in nearly every case. *Id.* at 4, 6–7, 13. And while Respondent referred two patients to

[5] Consistent with DEA's longstanding precedent, *see* ALJ at 17, a respondent is also entitled to put on evidence as to his acceptance of responsibility and any remedial measures he has undertaken to prevent the re-occurrence of similar acts.

[6] Even after *Gonzales* v. *Oregon,* 546 U.S. 243 (2006), several courts of appeals, including the Eleventh Circuit, "have applied a general-practice standard when determining whether the practitioner acted in the 'usual course of professional practice.'" *United States* v. *Smith,* 573 F. 3d 639, 647–48 (8th Cir. 2009); *see also id.* at 648 (discussing *United States v. Moore,* 423 U.S. 122 (1975); "Thus informed by the Supreme Court and other controlling and persuasive precedent, we believe that it was not improper to measure the 'usual course of professional practice' under § 841(a)(1) and [21 CFR] 1306.04 with reference *to generally recognized and accepted medical practices* * * *."). To similar effect, the Eleventh Circuit has held that "[t]he appropriate focus * * * rests upon whether the physician prescribes medicine 'in accordance with *a standard of medical practice generally recognized and accepted in the United States.*'") (*United States* v. *Merrill,* 513 F.3d 1293, 1306 (11th Cir. 2008) (quoting *Moore,* 423 U.S. at 139)).

[7] Of the seventeen patients, only four were from Florida. Of the remaining patients, five were from Kentucky, three were from Ohio, two were from Tennessee and West Virginia, and one was from Georgia. GX 76, at 1.

[8] Dr. Kennedy explained that referring a patient to obtain an MRI prior to having some contact is unusual and medically inappropriate. Tr. 71–73.

[9] In only two of the seventeen files is there an indication that Respondent referred the patient to another physician.

[10] Dr. Kennedy explained that the urine drug screens did not indicate the temperature and specific gravity of the specimen, whether the giving of the sample had been observed, or the type of drug screen used. GX 76, at 14; Tr. 100–01.

their primary care physicians because they had high blood pressure, *see* GXs 78, 79; he never referred any patients for consultations with specialists, or for physical, occupational, or mental health therapy. GX 76, at 11.

Dr. Kennedy noted that Respondent frequently prescribed "drug cocktails" of two strengths of oxycodone immediate release and a high dose of Xanax, a benzodiazepine. *Id.* at 4, 9, 13. While Dr. Kennedy acknowledged that prescribing an additional strength of oxycodone could be legitimate if it was done to treat breakthrough or episodic pain on an as-needed basis, with respect to M.B., who received prescriptions for oxycodone 30 mg. and 15 mg., "there was no specific reason stated in the medical record" for prescribing both drugs. *Id.* at 9.

Dr. Kennedy further noted that while the typical starting dose of Xanax is 0.25 to 0.5 mg., once to twice per day, Respondent prescribed Xanax 2 mg., twice per day, to fifteen of the seventeen patients (including M.B.); another patient B.R. (GX 87) received Xanax 2 mg. once per day.[11] *Id.* at 9–10; GXs 78–86, 88–93. Moreover, Respondent prescribed this dose even for patients who had not been on the drug either before or recently and "no matter the [patient's] age or clinical situation." GX 76, at 10. While Xanax is used as an anti-anxiety agent, Respondent's medical records did not support the prescribing because "[h]e did not list * * * many important factors that could cause anxiety * * * such as depression, life stressors, psychosocial situation, caffeine intake, sleep disturbance [and] previous medical evaluation;" he also did not refer these patients for evaluation by a mental health professional. *Id.* With respect to M.B., Dr. Kennedy observed not only that "there was no specific reason stated in the medical record" for prescribing Xanax, but also that Respondent's prescribing of a very high dose of the drug "was clearly not within the boundaries of professional practice." *Id.* at 9–10.

Dr. Kennedy further noted that beginning with M.B.'s first visit, Respondent "prescribed very high initial and subsequent high doses of oxycodone and Xanax" and that these drugs "were prescribed excessively and inappropriately without medical justification." *Id.* at 9. Sections of the history and physical examination form "were grossly incomplete or missing entirely," and Respondent did not identify "past treating and prescribing physicians" and communicate them regarding M.B.'s previous treatment (and obtain medical records) even though M.B. had indicated that he had previously seen a doctor and had physical therapy for his condition. *Id.* at 9; GX 78, at 16.

While M.B. apparently told Respondent that he was taking 210 to 240 oxycodone 30 mg. per month, which he had obtained "off the street," and he also tested positive for the drug in a urine drug screen (UDS) done at his initial visit, Respondent prescribed 180 Roxicodone 30 mg., 60 Roxicodone 15 mg., and 60 Xanax 2 mg. to M.B. at each of the seven visits he made between August 20, 2009 and February 4, 2010. GX 78, at 7, 9, 13, 18–24.

M.B.'s statement that he was getting "large quantities of oxycodone 30 mg. pills 'off the street'" was a clear "warning sign" that he was "at high risk for drug abuse, addiction and/or diversion." GX 76, at 12; *see also id.* at 8. Yet, as Dr. Kennedy observed, Respondent "did not appropriately act on the initial UDS" and M.B.'s admission that he had obtained drugs off the street by requiring him to undergo "[f]urther testing." *Id.* at 11. Indeed, "[t]here were no other UDS tests obtained [after the initial visit] nor other toxicology testing." *Id.* Dr. Kennedy further noted that Respondent "did not obtain any pharmacy drug profiles [from] where [M.B.] had his prescriptions filled," his chart did not indicate where he was filling his prescriptions, and he did not obtain prescription monitoring reports from States where M.B. may have filled prescriptions. *Id.* He also did not obtain prescription monitoring reports for any of the other sixteen patients. *Id.*

Finally, Dr. Kennedy explained that the "drug cocktails" Respondent prescribed of "very potent, high doses" of oxycodone and Xanax (or Valium), *id.* at 11, are "attractive to 'patients' who abuse, are addicted and/or divert (sell or trade) their prescribed controlled substances. They might take them all together to achieve a 'high,' sell some for cash, or trade some for other drugs they prefer." *Id.* at 9. Dr. Kennedy also noted that "[w]hen opioids and benzodiazepines are used in combination, the potential for [a] drug overdose and death is increased," and "[t]he risk of abuse, addiction and/or diversion is also significantly increased." *Id.* at 7. As Dr. Kennedy observed, "[t]hese 'drug cocktails' were clearly not for any legitimate medical purpose." *Id.* at 13.

As Dr. Kennedy concluded, Respondent "was not engaged in the practice of medicine," and "[t]he vast majority of his prescriptions for controlled substances w[as] not for a legitimate medical purpose and w[as] beyond the boundaries of professional practice." *Id.* at 18. His "routine and excessive prescription of multiple controlled substances * * * and lack of arriving at a valid medical diagnosis and treatment most likely caused harm to the patients he saw as well as to other people in their communities." *Id.* I therefore reject this exception as well.

I therefore also reject Respondent's Exception to the ALJ's ultimate finding that Respondent has committed acts which render his registration inconsistent with the public interest. Resp. Exc. at 5. Because the record establishes that Respondent has repeatedly violated Federal law by issuing controlled substance prescriptions which lacked a legitimate medical purpose and were issued outside of the usual course of professional practice, 21 CFR 1306.04, and Respondent has offered no evidence establishing that he has accepted responsibility for his misconduct and that he has reformed his practice, *see Steven M. Abbadessa,* 74 FR 10077, 10081 (2009), I adopt the ALJ's recommendation that Respondent's registration be revoked.

Order

Pursuant to the authority vested in me by 21 U.S.C. 823(f) and 824(a), as well as 21 CFR 0.100(b) and 0.104, I order that DEA Certificate of Registration, AD7585865, issued to Jacobo Dreszer, M.D., be, and it hereby is, revoked. I further order that any pending application of Jacobo Dreszer, M.D., to renew or modify his registration, be, and it hereby is, denied. This Order is effective immediately.

Dated: March 31, 2011.

Michele M. Leonhart,

Administrator.

Larry P. Cote., Esq., for the Government
Sean M. Ellsworth, Esq., for the Respondent

Recommended Rulings, Findings of Fact, Conclusions of Law, and Decision of the Administrative Law Judge

John J. Mulrooney, II, Administrative Law Judge. On February 25, 2010, the Deputy Administrator, Drug Enforcement Administration (DEA or Government), issued an Order to Show Cause and Immediate Suspension of Registration (OSC/ISO), immediately suspending the DEA Certificate of Registration (COR), Number AD7585865, of Jacobo Dreszer, M.D. (Respondent), as a practitioner, pursuant to 21 U.S.C. 824(d), alleging

[11] The remaining patient, L.A., received Valium 10 mg. GX 77.

that such registration constitutes an imminent danger to the public health and safety. The OSC/ISO also sought revocation of the Respondent's registration, pursuant to 21 U.S.C. 824(a)(4), and denial of any pending applications for renewal [12] or modification of such registration, pursuant to 21 U.S.C. 823(f), alleging that the Respondent's continued registration is inconsistent with the public interest, as that term is used in 21 U.S.C. 823(f). On March 22, 2010, the Respondent timely requested a hearing, which, pursuant to a change of venue granted at his request, was conducted in Miami, Florida, on July 7, 2010 through July 9, 2010.[13] The immediate suspension of the Respondent's COR has remained in effect throughout these proceedings.

The issue ultimately to be adjudicated by the Deputy Administrator, with the assistance of this recommended decision, is whether the record as a whole establishes by substantial evidence that Respondent's registration with the DEA should be revoked as inconsistent with the public interest as that term is used in 21 U.S.C. 823(f) and 824(a)(4).

After carefully considering the testimony elicited at the hearing, the admitted exhibits, the arguments of counsel, and the record as a whole, I have set forth my recommended findings of fact and conclusions below.

The Evidence

The OSC/ISO issued by the Government alleges that the Respondent, through the medical practice he participated in at American Pain, LLC (American Pain), prescribed and dispensed inordinate amounts of controlled substances, primarily oxycodone,[14] under circumstances where he knew, or should have known, that the prescriptions were not dispensed for a legitimate medical purpose. ALJ Ex. 1. The OSC/ISO further charges that these prescriptions were issued outside the usual course of professional practice based on a variety of circumstances [15] surrounding the manner in which American Pain is operated, and the manner in which its physicians, including Respondent, engaged in the practice of medicine. *Id.* The Government also alleges that Respondent's former patients have apprised law enforcement personnel that "they were able to obtain prescriptions for controlled substances from [the Respondent] for other than a legitimate medical purpose and with the intention of selling the controlled substances and/or personally abusing the drugs." *Id.* Lastly, in its Prehearing Statement, the Government further alleges that one of the Respondent's patients died from an overdose of oxycodone and alprazolam [16] one day after obtaining prescriptions for those same controlled substances from a visit to the Respondent at American Pain. *Id.*

At the hearing, the Government presented the testimony of three witnesses, DEA Miami Field Division (MFD) Group Supervisor (GS) Susan Langston, DEA Special Agent (SA) Michael Burt, and L. Douglas Kennedy, M.D., D.A.B.P.M., Affiliate Clinical Assistant Professor at the University of Miami, Miller School of Medicine.

GS Langston testified that the investigation of the American Pain Clinic had its origins on November 30, 2009, during a routine inspection that she and a subordinate diversion investigator conducted at Appurtenance Biotechnology, LLC, a pharmacy doing business under the name Boca Drugs (Boca Drugs), and located a few blocks away from one of the former locations of American Pain. Tr. at 713, 717–20. According to Langston, an examination of the prescriptions seized from Boca Drugs revealed that the majority of those prescriptions were for oxycodone and alprazolam authorized over the signature of physicians associated with American Pain.[17] *Id.* at 721. Under Langston's supervision, DEA diversion investigators catalogued the prescriptions seized at Boca Drugs (Boca Drugs Prescription Log). Govt. Ex. 118. However, inasmuch as the Boca Drugs Prescription Log fails to distinguish between the Respondent, and one of the other co-Respondents (his son), the document is of no utility in reaching a disposition of the present case.

GS Langston also testified that, on March 3, 2010, a criminal search warrant was executed on the American Pain Clinic simultaneously with the OSC/ISO that initiated the present case. Tr. at 735. According to Langston, the items seized from American Pain included a sign that had been posted in what she believes to have served as the urinalysis waiting room. *Id.* at 735–37. The seized sign set forth the following guidance:

ATTENTION PATIENTS

Due to increased fraudulent prescriptions, [i]t's best if you fill your medication in Florida or your regular pharmacy. Don't go to a pharmacy in Ohio when you live in Kentucky and had the scripts written in Florida. The police will confiscate your scripts and hold them while they investigate. This will take up to 6 months. So only fill your meds in Florida or a pharmacy that you have been using for at least 3 months or more.

Govt. Ex. 119 at 1. This sign is attached, apparently by some sort of tape, to the top portion of two other signs, posted at the same location, the first of which reads:

ATTENTION:

Patients

Please do *NOT* fill your prescriptions at any *WALGREENS PHARMACY* [18] or *OUTSIDE* the STATE OF FLORIDA.

Id. The final attachment to the composite sign bears the words "24 Hour Camera Surveillance." *Id.* A photograph of the composite sign was admitted into evidence.

Langston also testified that while she was present in the American Pain offices, she noticed that each physician's desk was equipped with a group of stamps, each of which depicted a controlled substance medication with a corresponding medication usage instruction (sig). Tr. at 738–39. A photograph of one set of prescription script stamps was admitted as an exhibit.[19] Govt. Ex. 119 at 2.

GS Langston also testified that a great number of medical charts were seized from the American Pain offices, and that she and her staff selected a number of these files to be analyzed by an medical expert procured by the Government. Tr. at 762. According to GS Langston, after the execution of the warrant, the charts from the entire office were placed into piles in alphabetical order, and not separated by physician. Langston testified that she and three of her diversion

[12] Although the Respondent's COR expired on July 31, 2010, the parties stipulated that a timely renewal application has been submitted by the Respondent. ALJ Ex. 31.

[13] Pursuant to an order issued on April 15, 2010, with the consent of the Respondent, ALJ Ex. 9, the hearing in this matter was consolidated with the cases of four other registrants who were working at the same clinic as the Respondent and who were also issued OSC/ISOs on February 25, 2010, alleging similar and related conduct.

[14] A schedule II controlled substance.

[15] The majority of which are supported by no evidence introduced by the Government during the course of these proceedings.

[16] A schedule IV controlled substance.

[17] Although GS Langston testified that DEA immediately suspended the COR that had been issued to Boca Drugs, Tr. at 715, and that a voluntary surrender by that registrant followed a day later, *id.* at 776, no evidence has been presented that would lend that fact any particular significance related to any issue that must or should be found regarding the disposition of the present case.

[18] GS Langston testified that she was unaware of the location of the closest Walgreens to American Pain's offices. Tr. at 779. No evidence was presented that would tend to establish that any Walgreens or any other pharmacy has taken a position regarding its willingness to fill prescriptions authorized by American Pain.

[19] Although GS Langston testified that she did not actually take the photographs taken during the search warrant execution at American Pain, she did provide sufficient, competent evidence to support the admission of the photographs that were ultimately received into evidence. Tr. at 737, 739–41.

investigators reviewed the seized files with a view towards choosing approximately fifteen files for each doctor with the aspirational criteria that each would reflect at least three to four visits by that doctor with a patient. Each investigator was empowered to place a chart on the selected pile, and when the target number (or about that number) was reached for each physician, the selection effort relative to that physician was deemed accomplished. *Id.* at 765. Langston credibly testified that there was no effort to specially select files under some prosecution-enhancement or "cherry picking" purpose. *Id.* at 768.

Langston also explained DEA's Automated Record Consolidated Ordering System (ARCOS) and testified that she generated an ARCOS report relative to the Respondent's ordering of controlled substances from January 2009 through February 2010. Govt. Ex. 71.

In the same fashion, Langston explained the purposes of and circumstances behind the generation of state prescription monitoring reports (PMPs) relative to the Respondent maintained by West Virginia, Kentucky, and Ohio. Govt. Exs. 72–74. Review of the PMP report data reflects that during the time period of February 1, 2006 through February 11, 2010, pharmacies filled 229 controlled substance prescriptions issued over the Respondent's signature to seventy-three patients located in West Virginia, 135 similar prescriptions provided to fifty-three Kentucky-based patients were filled between January 1, 2009 and April 4, 2010, and 144 such prescriptions pertaining to sixty-three patients located in Ohio were filled between April 1, 2008 and April 19, 2010. *Id.*

No evidence was introduced at the hearing that would provide any reliable level of context regarding the raw data set forth in the databases received into evidence at the Government's request. Other than the observations noted above, no witness who testified at the hearing ever explained the significance of the data set forth in any of these databases to any issue that must or should be considered in deciding the present case. As discussed above, the fact that the Boca Drugs Prescription Log prepared by the agents does not distinguish between prescriptions authorized by the Respondent and another registrant of the same name deprives the document of virtually any relevance regarding the enforcement action against this Respondent.[20]

GS Langston provided evidence that was sufficiently detailed, consistent and plausible to be deemed credible in this recommended decision.

SA Michael Burt testified that he has been employed by DEA since March 2004 and has been stationed with the Miami Field Division (MFD) since September 2004. Tr. at 813–14. Burt testified that he is the lead case agent for DEA in the investigation of American Pain Clinic and has participated in the investigation since the latter part of 2008. According to Burt, American Pain, which was previously known by the name South Florida Pain, has conducted business at four different locations, and he surveilled the Boca Raton and Lake Worth locations both in person and by periodic live review of video captured via pole cameras[21] set up outside the clinic. *Id.* at 815–17. These pole cameras, which were in operation during a three week period from January to February 2010, were initially in operation on a 24-hour basis, but Burt testified that they were later activated only between the hours of 7 a.m. through 6:00 p.m. due to an observed lack of activity at the clinic outside of that time period. *Id.* at 820–21. The pole camera recordings were not offered into evidence at the hearing or made available to opposing counsel.

Based on these surveillance efforts, SA Burt testified concerning various activities he observed occurring outside the Boca and Lake Worth clinic locations, which were open to the public from 8 a.m. to 5 p.m. At the Boca location, Burt stated that on any given day, beginning at 7 a.m. in the morning, automobiles could be seen pulling into the parking lot and approximately twenty to thirty people were routinely lined up outside of the clinic waiting to gain admittance. Additionally, there was a steady stream of automobile and foot traffic in and out of the clinic throughout the day. *Id.* at 817, 821. Burt testified that in his estimation, approximately 80–90 percent of the automobiles had out-of-state tags, predominantly from Kentucky, Ohio, West Virginia and Tennessee. *Id.* at 817–18. Burt also observed security personnel with "staff" written on their shirts[22] riding around the exterior of the building in golf carts and who, in Burt's assessment, appeared to be directing patients into the American Pain facility. Burt indicated his surveillance of the Lake Worth location yielded similar observations. *Id.* at 818.

Based on his review of some (but not all)[23] of the audio and video tapes made by agents and informers sent into the clinic by the Government at various times, SA Burt also testified about his understanding of the process by which patients obtained controlled substance prescriptions at American Pain. According to Burt, after entering the clinic, a patient would meet with the receptionist, who would determine if the patient had an MRI. If not, the receptionist would issue that individual an MRI prescription in exchange for a $50 cash payment, and the patient "would be directed to a place to obtain an MRI." *Id.* at 822. Burt testified that one such MRI location was Faye Imaging, which was a mobile MRI trailer located behind a gentlemen's club several miles away from American Pain. *Id.* at 822–23. The cost for the MRI was $250, and the patient could pay an additional fee "to have the MRI expedited and faxed over to American Pain." *Id.* at 823–24. Once the MRI was procured and faxed to American Pain, the patient would return to the clinic and be seen by a doctor. According to Burt, the clinic accepted what he referred to as "*predominantly* cash only"[24] for these office visits, and the six doctors at the clinic saw "anywhere from 200 upward to 375 patients a day"[25] in this manner.[26] *Id.* at 882–83 (emphasis supplied).

SA Burt also testified regarding his review of some[27] of the video and audio recordings made by an undercover agent (UC) who assumed the name Luis Lopez, capturing activity inside of American Pain.[28] In those recordings, Burt observed who he believed to be an American Pain employee inside the facility standing up in a waiting room full of patients and directing them "not to have their prescriptions filled out of state, not to go out into the parking lot and snort their pills," and directing the patients to have their prescriptions filled "in house" (meaning at American Pain), at "a pharmacy they have in Orlando, Florida," or at "a pharmacy they have down the street," which, in Burt's view, was a reference to Boca Drugs. *Id.* at 825–26. Burt further testified that the purported employee on the recording told the patients to "obey all the traffic laws; do not give the police a reason to pull you over." *Id.* Although Burt testified as to the contents of these recordings, the physical recordings were not offered into evidence by the Government or made available to opposing counsel.

SA Burt also testified that he received information from Dr. Eddie Sollie, a former physician employed during the time period American Pain was doing business as South Florida Pain, who terminated his employment at the Oakland Park clinic location in November or December 2008 after working there for approximately two and a half to three months. *Id.* at 827, 898. During the course of an interview where Burt was present, Dr. Sollie related various "concerns about how the practice was being handled or

[20] Remarkably, although this unfortunate aspect of this document was brought to light during the course of the hearing, Tr. at 732, no effort on the part of the Government was made to provide additional details or explanation that might tend to differentiate between the respondents.

[21] SA Burt described the pole cameras as "covert cameras that are installed to observe the activity in the clinic." Tr. at 816. Burt testified that he was able to use a laptop to access the live video feed from the cameras after inputting a user name and password. The camera video was also recorded to DVR. *Id.* at 821.

[22] Tr. at 910.

[23] SA Burt conceded that although he is the designated lead case agent for DEA, he did not review all the audio and video tapes made in the case or even review the transcripts. Tr. at 1002–05.

[24] Later on cross-examination, SA Burt admitted that the clinic also accepted payment via credit card. Tr. at 916.

[25] Inasmuch as the Government provided no information from which any specific number of patients seen by any given clinic doctor on any day could be derived, or any expert testimony regarding a reasonable number of pain patients that could or should be seen per day, the value of providing the raw number of patients walking through the door at the clinic is negligible.

[26] Burt further testified that the doctors were paid $75.00 per patient visit, *id.* at 884, but because he indicated that he could not disclose his basis of knowledge for this information, this portion of his testimony can be afforded no weight. *See Richardson* v. *Perales,* 402 U.S. 389, 402 (1971); *J.A.M. Builders* v. *Herman,* 233 F.3d 1350, 1354 (11th Cir. 2000); *Keller* v. *Sullivan,* 928 F.2d 227, 230 (7th Cir. 1991); *Calhoun* v. *Bailar,* 626 F.2d 145, 149 (9th Cir. 1980).

[27] Tr. at 1002–05.

[28] The fact that these recordings were made during the course of seven different office visits by an undercover agent to both the Boca Raton and Lake Worth locations was established on cross-examination. Tr. at 900, 985.

managed." *Id.* at 827–28. These concerns included medical records being, in his opinion, annotated inadequately by the doctors, and what he perceived as a lack of supervision during patient urinalysis testing, where patients would "go[] to the bathrooms together, bringing items with them to the bathrooms that could possibly disguise the urinalysis." According to Burt, Sollie explained that he perceived that patients were substituting urine produced by other persons that contained the metabolites for controlled substances that the patients claimed to be legitimately taking, with a view towards falsely providing evidence to the American Pain doctors showing that they were actually taking prescribed medications and not diverting them. *Id.* at 828–29. During cross-examination, Burt explained that Dr. Sollie told him he had raised these concerns with Christopher George, the owner of American Pain, and that Burt had no evidence that the deficient practices that Sollie had objected to continued through 2010. *Id.* at 900, 906. Burt also acknowledged that he was aware Dr. Sollie had been involved in litigation with Mr. George and that their relationship was strained. *Id.* at 1009. Dr. Sollie was not called as a witness by either party.

SA Burt also testified regarding the drug overdose deaths of TY and SM after obtaining controlled substances from American Pain.[29] Burt's record testimony indicates that DEA Task Force Officer [30] (TFO) Barry Adams informed him that a Kentucky resident named TY overdosed in Kentucky from oxycodone intoxication induced by medication procured at American Pain. Burt testified that this information was furnished pursuant to a working law enforcement relationship between the Kentucky State Police, Kentucky FBI, Kentucky DEA and Miami DEA aimed at addressing "the brunt of the pill problem" centered within the state of Kentucky relative to illegal use and resale of prescription pain medications. *Id.* at 833–35. However, in his testimony, Burt was unable to recall the name of the doctor from whom TY obtained his pills, and, thus, no admissible evidence was presented by the Government with respect to TY's death.[31] Likewise, the record evidence concerning SM did not implicate prescribing activity by the Respondent.

Perhaps among the more striking aspects of SA Burt's performance on the witness stand is the anticipated testimony which he did not provide. When viewed in its entirety, SA Burt's record testimony was stunningly sparse when compared with his proposed testimony as noticed in the Government's prehearing statement.[32] That certain information may be unavailable for reasons related to other litigation forums or other equally valid reasons are of no moment with respect to the evaluation that must be made at this administrative forum. Equally important, such considerations do not alter the burdens imposed upon the respective parties. Simply put, the admitted evidence must succeed or fail on its own merits, irrespective of extraneous considerations.

Even apart from the marked contrast between the Burt testimony as proffered and as realized, his testimony was marred by periodic memory failures on significant issues and an inability to supply details to an extent that it could arguably have diminished the weight that could be fairly attached to those aspects of his own investigation that he did manage to recollect. During his testimony, SA Burt acknowledged his own marked lack of preparation and unfamiliarity with the investigation and confessed simply that "[t]here's no excuse * * *." *Id.* at 1003–05.

Even acknowledging its obvious suboptimal aspects, SA Burt's testimony had no apparent nefarious motivation or indicia of intentional deceit. Burt came across as an earnest and believable witness, who, regarding the aspects of the case that he did recall, was able to impart substantial information about the investigation and activities involving American Pain and its doctors. While frequently lacking in detail, his testimony was not internally inconsistent or facially implausible, and although the legal weight I have assigned to certain portions of Burt's testimony varies given the issues described, I find his testimony to be credible overall.

The Government presented the bulk of its case through the report and testimony of its expert, L. Douglas Kennedy, M.D., D.A.B.P.M., Affiliate Clinical Assistant Professor at the University of Miami, Miller School of Medicine.[33] Dr. Kennedy, who testified that he is board certified by the American Board of Pain Medicine and the American Board of Anesthesiology,[34] was offered and accepted as an expert in the field of pain medicine. *Id.* at 39.

Dr. Kennedy testified that after a review of a group of selected patient files from those seized at the Respondent's practice that were to him provided by the Government, he concluded that the Respondent's physical examinations, treatment plans, and patient histories were below the standard fixed by the Florida Medical Board and that that controlled substances was not for a legitimate medical purpose. *Id.* at 579–82.

Dr. Kennedy took professional issue with several aspects of the Respondent's patient care as reflected in the charts regarding the prescribing of controlled substances. It is apparent from his testimony that Dr. Kennedy's analysis is restricted to those matters which can be gleaned from an examination of the written word in that subset of the Respondent's patient charts provided by the Government for his review, and that limitation perforce circumscribes the breadth of his input. That being said, Dr. Kennedy highlighted numerous features in the Respondent's chart documentation that he found wanting, or at least remarkable.

Dr. Kennedy explained that there are basic elements to practicing pain medicine. The acquisition of a thorough history and physical examination is important. *Id.* at 41–42. He also stressed the vital importance of obtaining past medical records to evaluate what treatments, therapies, medications, and dosages have been utilized in the past so that correct current treatment decisions can be made. *Id.* at 45–46. Reliance upon the patient's memory of these elements without the prior medical records, in Dr. Kennedy's view is not reliable or acceptable. *Id.* at 46–47. Dr. Kennedy acknowledged that physicians customarily accept patients at their word, but on the subject of verifying a patient's subjective complaint and medication history, Dr. Kennedy explained that

> [s]ometimes you have to help people understand why they're suffering or what their problems are. A person with an addiction or drug abuse problem is no worse a human being than me. I'm not any better than them. But it's your job as a doctor to sit down and find out what the truth is as well as you reasonably can under the circumstances.

Id. at 357.

Dr. Kennedy also prepared a report in connection with the Government's case against the Respondent, which is dated April 30, 2010, and was admitted into evidence. Govt. Ex. 76; Tr. at 579. The report describes a general analysis of seventeen charts that the Respondent maintained on as many patients, that were (selected by and) provided to Dr. Kennedy by the Government from among patient files seized pursuant to a criminal search warrant executed at the Respondent's practice on March 3, 2010 (Patient Charts Analysis). Although this report purports to describe practices common to all seventeen files reviewed by Dr. Kennedy, much of the analysis is directed toward a chart prepared in connection with MB,[35] one of the Respondent's patients.

Dr. Kennedy's report makes it unambiguously clear that, in his opinion, all seventeen of the Respondent's charts that he reviewed suffered from the same shortcomings.[36]

[29] Although similar testimony concerning the overdose death of a third individual, OB, was noticed in the Government's prehearing statement, it was not offered by the Government at the hearing. ALJ Ex. 6 at 8.

[30] According to SA Burt, a "task force officer" is a local police officer or sheriff's deputy that is assigned to work on a DEA task force, rather than a sworn DEA criminal investigator. Tr. at 1031.

[31] *See* Tr. at 836–53 (addressing exclusion of Govt. Ex. 27 and associated testimony).

[32] ALJ Ex. 6.

[33] Dr. Kennedy's CV was admitted into evidence. Govt. Ex. 117.

[34] Tr. at 17.

[35] At the request of the Government, a protective order was issued that is designed to minimize the risk of the dissemination of identifying information related to patients and their relatives associated with this case. Accordingly, initials have been substituted for the names of individuals within the protection of the protective order throughout the body of this decision. ALJ Ex.15.

[36] The Government's tactical decision to essentially unload a pile of charts that are explained only by the representations and generalizations in a report, with no attempt whatsoever to have its expert witness explain the applicable aspects of most charts to this tribunal or any future reviewing body is clearly at odds with the directive provided by the Deputy Administrator in *Gregg & Son*

The Patient Charts Analysis states that the Respondent's patient charts that Dr. Kennedy reviewed "are essentially the same with regard to review issues; as stated in the report of [MB] referenced and discussed in this report in detail, [and that] there were no significant differences that affected [his] conclusions and summary." Govt. Ex. 76 at 2.

In Dr. Kennedy's opinion, the patient charts he reviewed that were prepared by the Respondent reflected care that fell below the applicable standard on multiple levels. In his report, Dr. Kennedy noted that the treatment notes in the charts: (1) Contained no typewritten clinical notes and were "very brief, difficult to read (often impossible) and not within the standard of care due to their brevity and quality"; [37] (2) reflected prescriptions, right from the initial patient visit, that "were almost entirely for controlled substances, most often one or two immediate release oxycodone pills with Xanax," and which were, in Dr. Kennedy's view, inappropriate and more powerful than justified by the objective signs documented in the written notes; [38] (3) showed that "the same or very similar 'drug cocktails' were prescribed [among all patients in the reviewed files] in the same or very similar doses, [directions] * * * with a 30-day supply," and were affixed to the prescription scripts with a few prepared stamps utilized by all American Pain physicians that reflected "drug, dose, sig (directions) and quantity dispensed"; [39] (4) contained medication contracts that were "not always signed" and "listed criteria that was not followed by the doctors at American Pain; [40] (5) failed to adequately document the efficacy of the prescribed medication; (6) did not set forth a "diagnostic plan except to obtain an occasional MRI, the results of which made no difference in the 'treatment' "; [41] (7) reflected "no therapeutic plan, except to use controlled substances to 'treat' the subjective complaint of 'pain' which was inadequately described"; [42] (8) reflected "no real therapeutic goals * * * for improvement of quality of life (activities of daily living, work, sleep, mood)"; [43] (9) did not reflect "consultations with other physicians or specialists outside the American Pain group [which] could have and in some cases should have included orthopedics, neurology, neurosurgery, psychiatry, addiction medicine and psychology"; [44] (10) reflected "a gross lack of past medical records in all charts reviewed and in some cases none at all"; [45] and, (11) demonstrated controlled substance patient monitoring practices that were "not within the standard of care and was outside the boundaries of professional practice." [46]

Dr. Kennedy found the Respondent's controlled substance patient monitoring to be deficient in numerous respects. From the reviewed patient charts, Dr. Kennedy gleaned that an initial, in-office urine drug screen was frequently executed during the patients' initial visit to the office but repeated only occasionally. Govt. Ex. 76 at 14. It was Dr. Kennedy's observation that even a drug screen anomaly did not alter the seemingly inexorable continuation of controlled substance prescribing from the Respondent. *Id.* For instance, Dr. Kennedy notes that MB's patient file contains a notation about the patient getting Roxicodone "off the street," along with an initial positive urinalysis screen for oxycodone, yet the Respondent continued to prescribe MB with additional Roxicodone during his initial and subsequent visits. *Id.* at 8–9, 11; *see also* Govt. Ex. 87 at 4, 9; 90 at 3, 9; 91 at 4, 8; 93 at 5, 10 (similar notations involving other patient's acquiring controlled substances "off the street"). Dr. Kennedy also noted that the Respondent did not utilize out-of-office toxicology tests, or obtain out-of-state prescription monitoring program or outside pharmacy drug profiles. Furthermore, the charts contained only rare evidence of contact with primary care physicians, treating physicians, pharmacists, or other health care providers. *Id.*

The identified shortcomings of controlled substance patient monitoring systems was of particular significance where Dr. Kennedy identified specific evidence that he identified as "red flags" of possible or likely diversion. Red flags noted by Dr. Kennedy in the reviewed charts included the relatively young age of the Respondent's chronic pain patients,[47] incomplete history information provided by the patients, periodically significant gaps between office visits,[48] referrals from friends, relatives, or advertising, but not other physicians,[49] and the fact that a relatively high number of patients were traveling significant distances to American Pain for pain treatment, although no physician employed at that facility had any specialized training in pain management.[50]

Dr. Kennedy also found it remarkable that each American Pain patient file provided notice to its patients that American Pain did not accept any form of health care insurance. Govt. Ex. 76 at 3, 16. Dr. Kennedy's report set forth his opinion that this practice was designed to "effectively keep [the physicians at American Pain] 'off the radar' from monitoring by any private health care insurance company as well as all state and federal agencies (Medicaid and Medicare respectively). *Id.* at 16. Significantly, however, when asked, Dr. Kennedy acknowledged that he conducts his own current medical practice on a cash-only basis. Tr. at 151.

A review of the seventeen patient files that informed the analysis, findings and conclusions offered in Dr. Kennedy's written report and testimony does reflect the presence of at least some of the red flag issues he identified therein, but there was not the unanimity among the files that he repeatedly urges. For instance, in terms of evidence related to therapeutic plans, it is notable that Respondent's patient files contain at least some indications of recommended treatment modalities in addition to the Respondent's exclusive use of

Distributors that "it is the Government's obligation as part of its burden of proof and not the ALJ's responsibility to sift through the records and highlight that information which is probative of the issues in the proceeding" 74 FR 17517 n.1.

[37] Govt. Ex. 76 at 4.

[38] Govt. Ex. 76 at 4. In Dr. Kennedy's opinion, the Respondent "prescribed, at the first visit, very high initial doses of controlled substance combinations despite not being within the standard of care for histories, physical examinations and/or absent past medical records." *Id.* at 7.

[39] Govt. Ex. 76 at 4.

[40] Govt. Ex. 76 at 3. As an example of the failure to adhere to the terms of the medication contract, Dr. Kennedy cites a contract term that provides notice that the physician may stop prescribing opioids or change treatment if pain or activity improvement is not demonstrated, and points out that pain and activity levels are routinely not documented in treatment notes. *Id.* at 3–4. Similarly, Dr. Kennedy references a medication contract warning that termination of services may result from failure to make regular follow-up appointments with primary care physicians, and notes that the American Pain charts contain no notes from primary care physicians or medical records generated by them. *Id.* at 4.

[41] Govt. Ex. 76 at 7. In Dr. Kennedy's opinion, Respondent in effect, acted as a 'barrier' for [MB] to receive appropriate medical evaluation and treatment. In other words, the very potent, high doses of opioids (oxycodone) and benzodiazepine (Xanax) could mask or cover up [MB's] underlying disease process(s), making them more difficult to diagnose, and allowing the disease(s) to unnecessarily worsen. Without an accurate diagnosis[] and no plan to obtain one, [the Respondent] was masking the symptoms. *Id.* at 10–11.

[42] Govt. Ex. 76 at 7.

[43] Govt. Ex. 76 at 7.

[44] Govt. Ex. 76 at 7.

[45] Govt. Ex. 76 at 15. MB's chart did not contain any past medical records, save for a Lumbar report from an MRI performed six weeks before MB's first clinic visit to see the Respondent. *Id.* at 8.

[46] Govt. Ex. 76 at 14.

[47] Govt. Ex. 76 at 16.

[48] Govt. Ex. 76 at 13.

[49] Govt. Ex. 76 at 8, 15.

[50] Govt. Ex. 76 at 16.

controlled substances for pain management. For example, Respondent included notations in the records of referring patients to see a "PCP," or primary care physician, for elevated blood pressure. Govt. Exs. 78 at 1–3, 6; 79 at 1. Furthermore, some of the patient history and physical exam forms contain some effort in documenting medication efficacy. Govt. Exs. 83 at 7; 92 at 2.

An examination of the reviewed patient charts does reveal the presence of other red flags that should have inspired additional diligence or inquiry on the part of the Respondent. LA's patient file, for example, contains a form indicating a positive UDS for oxycodone and benzodiazepine from 5/18[/09], yet on the same date, the medication contract signed by LA is blank in the section where a patient is supposed to list any medications they are currently taking; likewise, the similarly worded section on the "Patient Comfort Assessment Guide" form also has no medications listed. Govt. Ex. 77 at 12–13, 30; *see also* Govt. Exs. 78 at 13–14, 32; 86 at 14–15, 30; 89 at 8–9, 22 (similar issues). CR's patient file, on the other hand, indicates a positive UDS for "THC" in addition to benzodiazepine and hydrocodone, yet the patient does not disclose marijuana as a "medication" he is currently taking on any of the relevant forms, and, in fact, this positive test is not addressed by the Respondent in any discernible manner in the chart. Govt. Ex. 79 at 9. Patient KL's 7/17/09 UDS indicates a negative test for all listed substances, yet on two different forms dated 7/13/09 he indicates he is currently taking two strengths of oxycodone along with Xanax. Govt. Ex. 82 at 13–14, 31. The UDS form in patient GE's file reflects circled positive results for benzodiazepines, opiates, and oxycodone. This is noteworthy in that the currently-taking list of medications includes seven other drugs, but not these three. Govt. Ex. 80 at 9, 24–25. Patient BR's UDS form, on the other hand, lists a positive test result for oxycodone only on July 24, 2009, yet the patient states she is also currently taking Xanax elsewhere on the medical forms from the same date. Govt. Ex. 88 at 11–12, 25; *see also* Govt. Exs. 90 at 9–10, 22; 92 at 8–9; 93 at 5, 10–11, 26 (same issue). A prescribed controlled substance that is not reflected in a drug screen should have raised a sufficient suspicion of diversion to merit further inquiry by the registrant reflected in the patient file. At a minimum, these observations support the conclusion there was a general lack of vigilance on the part of the Respondent regarding his obligations as a registrant to minimize the risk of controlled substance diversion.

In addition to the lack of adequately completed forms in some patient files noted by Dr. Kennedy, other patient files appear to be missing key documentation altogether. *See* Govt. Ex. 92 (no pain management agreement, medication contract, or diversion policy present).

Dr. Kennedy concluded his report regarding the Respondent's prescribing practices with the following summary:

> [The Respondent] was not engaged in the practice of medicine, rather he was engaged in an efficient, "[a]ssembly [l]ine" business. His "patients" were revenue streams, not true patients. This business allowed him to collect cas[h] for office visits as well as being a "[d]ispensing [p]hysician" for controlled substances. He prescribed controlled substances so that "patients" would return to his office on a regular basis, allowing him to generate further revenue. [The Respondent's] routine and excessive prescription of multiple controlled substances (oxycodone and Xanax) and lack of arriving at a valid medical diagnosis and treatment most likely caused harm to the "patients" he saw. Drug diversion most likely caused a "mushroom" effect of increased drug abuse, drug addiction, drug overdoses, serious bodily injury and death in those communities spread over several different states. [The Respondent's] continued ability to prescribe controlled substances will only perpetuate the suffering and be a threat to the public.

Govt. Ex. 76 at 16.

On cross examination, Dr. Kennedy agreed that he assumed, for the purposes of his analysis, that where the Respondent's charts reflected an entry or a procedure, that the event actually occurred. Tr. at 654. Kennedy also acknowledged that every one of the patient files he reviewed contained at least a complaint of chronic pain symptoms by the patient and MRI results that could support such a diagnosis. *Id.* at 655–57.

The Government's presentation of Dr. Kennedy's testimony at the hearing was substantially consistent with the conclusions included in the Patient Charts Analysis, but Dr. Kennedy's presentation was clearly not without its blemishes. Although he testified that he was familiar with prescribing practices in Florida, and that he utilized the medical standards applicable to Florida practice,[51] he was unable to identify the documentation standard in the Florida Administrative code with any degree of particularity, and he also acknowledged that he was not aware of what the standard is in Florida Medical Board administrative decisions regarding the overprescribing of medication or what constitutes an adequate medical history. *Id.* at 149–51, 233, 304. While, overall, Kennedy presented testimony that appeared candid and knowledgeable, there were areas in his written report that rang of hyperbole and over-embellishment. The reasoning behind some of the seemingly critical observations in the written report, such as the "cash basis" of the Respondent's practice and the absence of doctor referrals among the reviewed patient files, did not well survive the crucible of cross examination at the hearing. However, overall, Dr. Kennedy's testimony was sufficiently detailed, plausible, and internally consistent to be considered credible, and, consistent with his qualifications, he spoke persuasively and with authority on some relevant issues within his expertise, and notwithstanding the Respondent's objections relative to his Florida-related experience, he is currently an assistant professor teaching at a Florida Medical School. It may well be that the greatest and most significant aspect of Dr. Kennedy's opinion is that on the current record, it stands unrefuted. Thus, his opinion is the only expert opinion available for reliance in this action.[52] Accordingly, Dr. Kennedy's expert opinion that the Respondent's controlled substance prescribing practices, at least as evidenced through his examination of the patient charts he reviewed, fell below the standards applicable in Florida, and that the controlled substance prescriptions contained in those files were not issued for a legitimate medical purpose is unrefuted on this record and (although by no means overwhelming) is sufficiently reliable to be accepted and relied upon in this recommended decision.

The Analysis

Pursuant to 21 U.S.C. § 824(a)(4), the Deputy Administrator[53] may revoke a registrant's DEA Certificate of Registration if persuaded that the registrant "has committed such acts that would render * * * registration under section 823 * * * inconsistent with the public interest * * *." The following factors have been provided by Congress in determining "the public interest":

(1) The recommendation of the appropriate State licensing board or professional disciplinary authority.

[51] Tr. at 628.

[52] The Respondent did not testify on her own behalf.

[53] This authority has been delegated pursuant to 28 CFR 0.100(b) and 0.104.

(2) The applicant's experience in dispensing, or conducting research with respect to controlled substances.

(3) The applicant's conviction record under Federal or State laws relating to the manufacture, distribution, or dispensing of controlled substances.

(4) Compliance with applicable State, Federal or local laws relating to controlled substances.

(5) Such other conduct which may threaten the public health and safety. 21 U.S.C. 823(f).

"[T]hese factors are considered in the disjunctive." *Robert A. Leslie, M.D.,* 68 FR 15227, 15230 (2003). Any one or a combination of factors may be relied upon, and when exercising authority as an impartial adjudicator, the Deputy Administrator may properly give each factor whatever weight she deems appropriate in determining whether an application for a registration should be denied. *JLB, Inc., d/b/a Boyd Drugs,* 53 FR 43945 (1988); *England Pharmacy,* 52 FR 1674 (1987); *see also David H. Gillis, M.D.,* 58 FR 37507, 37508 (1993); *Joy's Ideas,* 70 FR 33195, 33197 (2005); *Henry J. Schwarz, Jr., M.D.,* 54 FR 16422 (1989). Moreover, the Deputy Administrator is "not required to make findings as to all of the factors * * *." *Hoxie* v. *DEA,* 419 F.3d 477, 482 (6th Cir. 2005); *see also Morall* v. *DEA,* 412 F.3d 165, 173–74 (DC Cir. 2005). The Deputy Administrator is not required to discuss consideration of each factor in equal detail, or even every factor in any given level of detail. *Trawick* v. *DEA,* 861 F.2d 72, 76 (4th Cir. 1988) (the Administrator's obligation to explain the decision rationale may be satisfied even if only minimal consideration is given to the relevant factors and remand is required only when it is unclear whether the relevant factors were considered at all). The balancing of the public interest factors "is not a contest in which score is kept; the Agency is not required to mechanically count up the factors and determine how many favor the Government and how many favor the registrant. Rather, it is an inquiry which focuses on protecting the public interest * * *." *Jayam Krishna-Iyer, M.D.,* 74 FR 459, 462 (2009).

In an action to revoke a registrant's DEA COR, the DEA has the burden of proving that the requirements for revocation are satisfied. 21 CFR 1301.44(e). Once DEA has made its *prima facie* case for revocation of the registrant's DEA Certificate of Registration, the burden of production then shifts to the Respondent to show that, given the totality of the facts and circumstances in the record, revoking the registrant's registration would not be appropriate. *Morall,* 412 F.3d at 174; *Humphreys* v. *DEA,* 96 F.3d 658, 661 (3d Cir. 1996); *Shatz* v. *U.S. Dept. of Justice,* 873 F.2d 1089, 1091 (8th Cir. 1989); *Thomas E. Johnston,* 45 FR 72, 311 (1980). Further, "to rebut the Government's *prima facie* case, [the Respondent] is required not only to accept responsibility for [the established] misconduct, but also to demonstrate what corrective measures [have been] undertaken to prevent the reoccurrence of similar acts." *Jeri Hassman, M.D.,* 75 FR 8194, 8236 (2010).

Where the Government has sustained its burden and established that a registrant has committed acts inconsistent with the public interest, that registrant must present sufficient mitigating evidence to assure the Deputy Administrator that he or she can be entrusted with the responsibility commensurate with such a registration. *Steven M. Abbadessa, D.O.,* 74 FR 10077 (2009); *Medicine Shoppe-Jonesborough,* 73 FR 364, 387 (2008); *Samuel S. Jackson, D.D.S.,* 72 FR 23848, 23853 (2007). Normal hardships to the practitioner, and even the surrounding community, that are attendant upon the lack of registration are not a relevant consideration. *Abbadessa,* 74 FR at 10078; *see also Gregory D. Owens, D.D.S.,* 74 FR 36751, 36757 (2009).

The Agency's conclusion that past performance is the best predictor of future performance has been sustained on review in the courts, *Alra Labs.* v. *DEA,* 54 F.3d 450, 452 (7th Cir. 1995), as has the Agency's consistent policy of strongly weighing whether a registrant who has committed acts inconsistent with the public interest has accepted responsibility and demonstrated that he or she will not engage in future misconduct. *Hoxie,* 419 F.3d at 483; *George C. Aycock, M.D.,* 74 FR 17529, 17543 (2009); *Abbadessa,* 74 FR at 10078; *Krishna-Iyer,* 74 FR at 463; *Medicine Shoppe,* 73 FR at 387.

While the burden of proof at this administrative hearing is a preponderance-of-the-evidence standard, *see Steadman* v. *SEC,* 450 U.S. 91, 100–01 (1981), the Deputy Administrator's factual findings will be sustained on review to the extent they are supported by "substantial evidence." *Hoxie,* 419 F.3d at 481. While "the possibility of drawing two inconsistent conclusions from the evidence" does not limit the Deputy Administrator's ability to find facts on either side of the contested issues in the case, *Shatz,* 873 F.2d at 1092; *Trawick,* 861 F.2d at 77, all "important aspect[s] of the problem," such as a respondent's defense or explanation that runs counter to the Government's evidence, must be considered. *Wedgewood Vill. Pharmacy* v. *DEA,* 509 F.3d 541, 549 (DC Cir. 2007); *Humphreys,* 96 F.3d at 663. The ultimate disposition of the case must be in accordance with the weight of the evidence, not simply supported by enough evidence to justify, if the trial were to a jury, a refusal to direct a verdict when the conclusion sought to be drawn from it is one of fact for the jury. *Steadman,* 450 U.S. at 99 (internal quotation marks omitted).

Regarding the exercise of discretionary authority, the courts have recognized that gross deviations from past agency precedent must be adequately supported, *Morall,* 412 F.3d at 183, but mere unevenness in application does not, standing alone, render a particular discretionary action unwarranted. *Chein* v. *DEA,* 533 F.3d 828, 835 (DC Cir. 2008) (citing *Butz* v. *Glover Livestock Comm. Co., Inc.,* 411 U.S. 182, 188 (1973)), *cert. denied,* _ U.S. _, 129 S.Ct. 1033 (2009). It is well-settled that since the Administrative Law Judge has had the opportunity to observe the demeanor and conduct of hearing witnesses, the factual findings set forth in this recommended decision are entitled to significant deference, *Universal Camera Corp.* v. *NLRB,* 340 U.S. 474, 496 (1951), and that this recommended decision constitutes an important part of the record that must be considered in the Deputy Administrator's decision, *Morall,* 412 F.3d at 179. However, any recommendations set forth herein regarding the exercise of discretion are by no means binding on the Deputy Administrator and do not limit the exercise of that discretion. 5 U.S.C. 557(b); *River Forest Pharmacy, Inc.* v. *DEA,* 501 F.2d 1202, 1206 (7th Cir. 1974); *Attorney General's Manual on the Administrative Procedure Act* 8 (1947).

Factors 1 and 3: The Recommendation of the Appropriate State Licensing Board or Professional Disciplinary Authority and Conviction Record Under Federal or State Laws Relating to the Manufacture, Distribution, or Dispensing of Controlled Substances

In this case, it is undisputed that the Respondent holds a valid and current state license to practice medicine. The record contains no evidence of a recommendation regarding the Respondent's medical privileges by any cognizant state licensing board or professional disciplinary authority. However, that a state has not acted against a registrant's medical license is not dispositive in this administrative determination as to whether continuation of a registration is consistent with the public interest.

Patrick W. Stodola, M.D., 74 FR 20727, 20730 (2009); *Jayam Krishna-Iyer,* 74 FR at 461. It is well-established Agency precedent that a "state license is a necessary, but not a sufficient condition for registration." *Leslie,* 68 FR at 15230; *John H. Kennedy, M.D.,* 71 FR 35705, 35708 (2006). Even the reinstatement of a state medical license does not affect the DEA's independent responsibility to determine whether a registration is in the public interest. *Mortimer B. Levin, D.O.,* 55 FR 9209, 8210 (1990). The ultimate responsibility to determine whether a registration is consistent with the public interest has been delegated exclusively to the DEA, not to entities within state government. *Edmund Chein, M.D.,* 72 FR 6580, 6590 (2007), *aff'd, Chein* v. *DEA,* 533 F.3d 828 (DC Cir. 2008), *cert. denied,* __ U.S. __, 129 S.Ct. 1033 (2009). Congress vested authority to enforce the CSA in the Attorney General and not state officials. *Stodola,* 74 FR at 20375. Thus, on these facts, the fact that the record contains no evidence of a recommendation by a state licensing board does not weigh for or against a determination as to whether continuation of the Respondent's DEA certification is consistent with the public interest.

Similarly, regarding Factor 3, while testimony was received at the hearing that indicated that a criminal search warrant was executed regarding the Respondent and American Pain, the record contains no evidence that the Respondent has ever been convicted of any crime or even arrested in connection with any open criminal investigation. Thus, consideration of the record evidence under the first and third factors does not militate in favor of revocation.

Factors 2, 4 and 5: The Respondent's Experience in Dispensing Controlled Substances, Compliance With Applicable State, Federal or Local Laws Relating to Controlled Substances, and Such Other Conduct Which May Threaten the Public Health and Safety

In this case, the gravamen of the allegations in the OSC/ISO, as well as the factual concentration of much of the evidence presented, share as a principal focus the manner in which the Respondent has managed that part of his practice relative to prescribing and dispensing controlled substances and acts allegedly committed in connection with his practice at American Pain. Thus, it is analytically logical to consider public interest factors two, four and five together. That being said, factors two, four and five involve analysis of common and distinct considerations.

Regarding Factor 2, the qualitative manner and the quantitative volume in which a registrant has engaged in the dispensing of controlled substances, and how long he has been in the business of doing so are factors to be evaluated in reaching a determination as to whether he should be entrusted with a DEA certificate. In some cases, viewing a registrant's actions against a backdrop of how he has performed activity within the scope of the certificate can provide a contextual lens to assist in a fair adjudication of whether continued registration is in the public interest.

There are two principal considerations embedded within a consideration of this public interest factor. In considering a similar factor under the List I chemical context, the Agency has recognized that the level of experience held by those who will be charged with recognizing and taking steps to minimize diversion factors greatly in determining whether entrusting a COR will be in the public interest. *See Volusia Wholesale,* 69 FR 69409, 69410 (2004); *Xtreme Enters., Inc.,* 67 FR 76195, 76197–98 (2004); *Prachi Enters.,* 69 FR 69407, 69409 (2004); *J&S Distribs.,* 69 FR 62089, 62090 (2004); *K.V.M. Enters.,* 67 FR 70968, 70969 (2002). The Agency has also recognized that evidence that a registrant may have conducted a significant level of sustained activity within the scope of the registration for a sustained period is a relevant and correct consideration, which must be accorded due weight. However, this factor can be outweighed by acts held to be inconsistent with the public interest. Experience which occurred prior and subsequent to proven allegations of malfeasance may be relevant. Evidence that precedes proven misconduct may add support to the contention that, even acknowledging the gravity of a particular registrant's transgressions, they are sufficiently isolated and/or attenuated that adverse action against its registration is not compelled by public interest concerns. Likewise, evidence presented by the Government that the proven allegations are consistent with a consistent past pattern of poor behavior can enhance the Government's case.

In this case, the Respondent introduced no evidence regarding his level of knowledge and experience, or even the quality or length of his experience as a physician-registrant, but the Government has elected to do so.

Regarding the Government's presentation, Agency precedent has long held that in DEA administrative proceedings that "the parameters of the hearing are determined by the prehearing statements." *CBS Wholesale Distribs.,* 74 FR 36746, 36750 (2009) (citing *Darrel Risner, D.M.D.,* 61 FR 728, 730 (1996); *see also Roy E. Berkowitz, M.D.,* 74 FR 36758, 36759–60 (2009) ("pleadings in administrative proceedings are not judged by the standards applied to an indictment at common law" and "the rules governing DEA hearings do not require the formality of amending a show cause order to comply with the evidence"). That being said, however, the marked difference between the amount of evidence that the Government noticed in its OSC/ISO and the amount that it introduced at the hearing is striking. For example, contrary to its allegations, there was no evidence that the Respondent "prescribe[d] and dispense[d] *inordinate* amounts of controlled substances," that the "*majority*" of the Respondent's patients were "from states other than Florida," and there was no evidence that American Pain patients were issued "*pre-signed* prescriptions to obtain MRI[s]," nor was there evidence that individuals positioned outside the American Pain building were there to "monitor the activity of patients in the parking lot *to prevent patients from selling their recently obtained controlled substances.*" Likewise, no evidence was introduced at the hearing that could support the allegations that "employees of American Pain [] *frequently* ma[d]e announcements to patients in the clinic advising them on how to avoid being stopped by law enforcement upon departing the pain clinic" and "*frequently* ma[d]e announcements [] advising [patients], among other things, not to attempt to fill their prescriptions at out-of-state pharmacies and warning them against trying to fill their prescriptions at particular local retail pharmacies." ALJ Ex. 1 (emphasis supplied).

In like fashion, the Government's prehearing statement proffered that SA Burt would testify to several of the items described but not established in the OSC/ISO. Among the list of allegations that were *not supported by any evidence introduced at the hearing,* were representations that SA Burt would testify concerning the following:

> Law enforcement in Florida and [other states that correspond to license plates seen in the American Pain parking lot] frequently arrest people for illegal possession and/or illegal distribution of controlled substances who have obtained the controlled substances from American Pain;
>
> American Pain hired individuals to "roam" the parking lot of the clinic to dissuade people from selling their recently obtained controlled substances on the property;

[The reason American Pain placed] signs within American Pain warning individuals not to have their prescriptions filled at Walgreens pharmacies [is] because Walgreens refuses to dispense the prescriptions;

Walgreens has flagged all American Pain doctors and will not fill any of their prescriptions;

[Physical exams at American Pain are] usually no more than a blood pressure check and some bending and stretching;

Dismissed patients would be routed to other doctors within the clinic;

[There was] co-mingling of [American Pain] physician's drugs;

[American Pain maintained] no inventories of drugs dispensed;

[Details surrounding] the death of [American Pain] patient OB [where] [t]he cause of death was determined to be drug intoxication—opiate and benzodiazepine;

[Information] from a confidential source [who indicated] that she traveled to American Pain in order to obtain controlled substances that were later sold in Kentucky for $25 per pill[,] [that] [the American Pain physician she encountered] did not spend any significant time conducting a physical examination of [her] [,] [that she would simply ask questions regarding [her] well being and would then "stamp" a prescription for [controlled substances][,] * * * that on one visit [during a power failure a] security guard working for the clinic instructed everyone to be patient and that the doctors would be with them shortly to "get your fix."

ALJ Ex. 6 at 3–9.

To be clear, it is not that the evidence was introduced and discredited; no evidence to support these (and other) allegations was introduced at all. To the extent the Government had this evidence, it left it home. While the stunning disparity between the allegations proffered and those that were supported with any evidence does not raise due process concerns, it is worthy of noting, without deciding the issue, that Agency precedent has acknowledged the Supreme Court's recognition of the applicability of the *res judicata* doctrine in DEA administrative proceedings. *Christopher Henry Lister, P.A.,* 75 FR 28068, 28069 (2010) (citing *Univ. of Tenn.* v. *Elliot,* 478 U.S. 788, 797–98 (1986) ("When an administrative agency is acting in a judicial capacity and resolves disputed issues of fact properly before it which the parties have had an adequate opportunity to litigate, the courts have not hesitated to apply *res judicata*[.]")

The evidence the Government did present raises issues regarding not only Factor 2 (experience dispensing[54] controlled substances), but also Factors 4 (compliance with federal and state law relating to controlled substances) and 5 (other conduct which may threaten public health and safety). Succinctly put, the Government's evidence related to the manner in which the Respondent practiced, and whether his practice complied with the law and/or was a threat to the public.

While true that GS Langston convincingly testified about the course of her investigation and laid an adequate foundation for numerous database results, the Government provided no foundational context for any relevant uses for those database results. Even apart from the unfortunate reality that one of the databases contained data that could not be directly tied to this Respondent as opposed to another with the same last name, without some insight into what types of results from these databases should be expected when compared to similarly-situated registrants engaged in acceptable prescribing practices, the raw data is without use. In short, there was no evidence elicited wherein the percentage of the Respondent's in-state to out-of-state patients could be assessed, and no reasonable measuring stick based on sound principles upon which to evaluate such data. Likewise, there was no reliable yardstick upon which to measure the amount of controlled substances reflected in the databases compared to what a reasonable regulator would expect to see regarding a compliant registrant. To the extent Langston possessed this information (and she well may have) it was not elicited from her. The same could be said of the allegation set forth in the Government's Prehearing Statement that alleges that from a given period the Respondent "was the 8th largest practitioner purchaser of oxycodone in the United States."[55] No evidence to support that allegation (or its relevance) was ever brought forth at the hearing. To the extent that fact may have been true or relevant, it was never developed. What's more, the Florida Administrative Code specifically eschews pain medication prescribing analysis rooted only in evaluation of medication quantity. Fla. Admin. Code r. 64B8–9.013(g). Lastly, there was no indication that despite Langston's obvious qualifications to do so, that she or anyone else ever conducted an audit of the controlled-substance-inventory-related recordkeeping practices at American Pain.

SA Burt testified that, during a temporally limited period of time, he observed some of the images captured by a pole camera positioned outside American Pain, and that he observed what in his view was a high percentage of vehicles in the parking lot with out-of-state license tags. This testimony arguably provides some support for the Government's contention that out-of-state patients (or at least patients being dropped off by cars with out-of-state tags) were being seen at the clinic, but his testimony did not provide much else in terms of relevant information. In any event, recent Agency precedent holds that details such as "where [a registrant's] patients were coming from," without additional factual development, can support a "strong suspicion that [a] respondent was not engaged in a legitimate medical practice" but that "under the substantial evidence test, the evidence must 'do more than create a suspicion of the existence of the fact to be established.'" *Alvin Darby, M.D.,* 75 FR 26993, 26999, n.31 (2010) (citing *NLRB* v. *Columbian Enameling & Stamping Co.,* 306 U.S. 292, 300 (1939).

Likewise, without additional details or at least some context, Burt's testimony that individuals with "staff" written on their shirts appeared to be directing patients into the clinic reveals virtually nothing about the Respondent's prescribing practices. Tr. at 818, 910. Furthermore, that Burt observed an individual on a videotape, who he believed to be an American Pain employee, on a single occasion, instruct patients not to "snort [their] pills" in the parking lot,[56] or advising them to comply with vehicle and traffic laws,[57] does not shed illumination on the Respondent's prescribing practices. There was no evidence that the Respondent knew that these isolated incidents occurred, nor was there contextual evidence from which the relevance to these proceedings could be gleaned. Even if this tribunal was inclined to engage in the unsupported assignment of motives to the actions of these employees, under these circumstances, such an exercise could not constitute substantial evidence that could be sustained at any level of appeal.

Burt's testimony regarding his conversations with Dr. Sollie, who was formerly employed by American Pain, was also not received in a manner that could meaningfully assist in the decision process. According to Burt, Sollie told him that some (unnamed) physicians at American Pain were inadequately documenting their patient charts in some manner that was

[54] The statutory definition of the term "dispense" includes the prescribing and administering of controlled substances. 21 U.S.C. 802(10).

[55] ALJ Ex. 6 at 11–12.

[56] Tr. at 825.

[57] Tr. at 826.

apparently never explained to Burt,[58] and that some patients were intentionally evading the American Pain urinalysis process. Sollie did not specifically name the Respondent or any physician as being connected with his allegations of misconduct. Tr. at 853. Thus, this tribunal is at something of a loss as to how the information, as presented, would tend to establish a fact relevant to whether the continuation of the Respondent's authorization to handle controlled substances is in the public interest.

The Government's evidence targeted not only the Respondent's experience practicing under Factor 2, but also his compliance with applicable state and federal laws relating to controlled substances under Factor 4. To effectuate the dual goals of conquering drug abuse and controlling both legitimate and illegitimate traffic in controlled substances, "Congress devised a closed regulatory system making it unlawful to manufacture, distribute, dispense, or possess any controlled substance except in a manner authorized by the CSA." *Gonzales* v. *Raich,* 545 U.S. 1, 13 (2005). Consistent with the maintenance of that closed regulatory system, subject to limited exceptions not relevant here, a controlled substance may only be dispensed upon a prescription issued by a practitioner, and such a prescription is unlawful unless it is "issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice." 21 U.S.C. 829; 21 CFR 1306.04(a). Furthermore, "an order purporting to be a prescription issued not in the usual course of professional treatment * * * is not a prescription within the meaning and intent of [21 U.S.C.
829] and the person knowingly * * * issuing it, shall be subject to the penalties provided for violations of the provisions of law related to controlled substances." *Id.*

A registered practitioner is authorized to dispense,[59] which the CSA defines as "to deliver a controlled substance to an ultimate user[60] * * * by, or pursuant to the lawful order of a practitioner." 21 U.S.C. 802(10); *see also Rose Mary Jacinta Lewis,* 72 FR 4035, 4040 (2007). The prescription requirement is designed to ensure that controlled substances are used under the supervision of a doctor, as a bulwark against the risk of addiction and recreational abuse. *Aycock,* 74 FR at 17541 (citing *Gonzales* v. *Oregon,* 546 U.S. 243, 274 (2006); *United States* v. *Moore,* 423 U.S. 122, 135, 142–43 (1975) (noting that evidence established that a physician exceeded the bounds of professional practice when he gave inadequate examinations or none at all, ignored the results of the tests he did make, and took no precautions against misuse and diversion)). The prescription requirement likewise stands as a proscription against doctors "peddling to patients who crave the drugs for those prohibited uses." *Id.* The courts have sustained criminal convictions based on the issuing of illegitimate prescriptions where physicians conducted no physical examinations or sham physical examinations. *United States* v. *Alerre,* 430 F.3d 681, 690–91 (4th Cir. 2005), *cert. denied,* 574 U.S. 1113 (2006); *United States* v. *Norris,* 780 F.2d 1207, 1209 (5th Cir. 1986).

While true that the CSA authorizes the "regulat[ion] of medical practice so far as it bars doctors from using their prescription-writing powers as a means to engage in illicit drug dealing and trafficking as conventionally understood," *Gonzales,* 546 U.S. at 266–67, an evaluation of cognizant state standards is essential. *Joseph Gaudio, M.D.,* 74 FR 10083, 10090 (2009); *Kamir Garces-Mejias, M.D.,* 72 FR 54931, 54935 (2007); *United Prescription Servs., Inc.,* 72 FR 50397, 50407 (2007). In this adjudication, the evaluation of the Respondent's prescribing practices must be consistent with the CSA's recognition of state regulation of the medical profession and its bar on physicians from peddling to patients who crave drugs for prohibited uses. The analysis must be "tethered securely" to state law and federal regulations in application of the public interest factors, and may not be based on a mere disagreement between experts as to the most efficacious way to prescribe controlled substances to treat chronic pain sufferers. *Volkman* v. *DEA,* 567 F.3d 215, 223 (6th Cir. 2009) (citing *Gonzales,* 546 U.S. at 272, 274).

Under the CSA, it is fundamental that a practitioner must establish a bonafide doctor-patient relationship in order to act "in the usual course of * * * professional practice" and to issue a prescription for a legitimate medical purpose." *Stodola,* 74 FR at 20731; *Shyngle,* 74 FR at 6057–58 (citing *Moore,* 423 U.S. at 141–43). The CSA looks to state law to determine whether a bonafide doctor-patient relationship existed. *Stodola,* 74 FR at 20731; *Shyngle,* 74 FR at 6058; *Garces-Mejias,* 72 FR at 54935; *United Prescription Servs.,* 72 FR at 50407. It was Dr. Kennedy's uncontroverted opinion that his evaluation of chart entries convinced him that they were so defective that the Respondent did not establish a sufficient doctor-patient relationship to justify the prescribing of controlled substances, and that "this was not the practice of medicine in [his] opinion." Tr. at 160–61.

Under Florida law, grounds for disciplinary action or denial of state licensure include "prescribing * * * any controlled substance, other than in the course of the physician's professional practice," and prescribing such substances "inappropriately or in excessive or inappropriate quantities is not in the best interest of the patient and is not in the course of the physician's professional practice, without regard to his or her intent." Fla. Stat. § 458.331(q) (2009). Florida law further provides that grounds for such disciplinary action also include:

> Failing to keep legible, as defined by department rule in consultation with the board, medical records that identify the licensed physician * * * and that justify the course of treatment of the patient, including, but not limited to, patient histories; examination results; test results; records of drugs prescribed, dispensed, or administered; and reports of consultations and hospitalizations.

Id. § 458.331(m).

In exercising its rulemaking function,[61] the Florida Board of Medicine (Florida Board) promulgated a regulation addressing "Standards for Adequacy of Medical Records" applicable to all physicians. Fla. Admin. Code r. 64B8–9.003 (2009). That regulation provides, in pertinent part:

> (2) A licensed physician shall maintain patient medical records in English, in a legible manner and with sufficient detail to clearly demonstrate why the course of treatment was undertaken.
>
> (3) The medical record shall contain sufficient information to identify the patient, support the diagnosis, justify the treatment and document the course and results of treatment accurately, by including, at a minimum, patient histories; examination results; test results; records of drugs prescribed, dispensed or administered; reports of consultations and hospitalizations; and copies of records or reports or other documentation obtained from other health care practitioners at the request of the physician and relied upon by the physician in determining the appropriate treatment of the patient.

[58] Tr. at 898.

[59] 21 U.S.C. 823(f).

[60] "Ultimate user" is defined as "a person who has lawfully obtained, and who possesses, a controlled substance for his own use or for the use of a member of his household or for an animal owned by him or by a member of his household." 21 U.S.C. 802(27).

[61] Rulemaking authority regarding the practice of medicine within the State of Florida has been delegated to the Florida Board of Medicine (Florida Board). Fla. Stat. § 458.309(1) (2009).

(4) All entries made into the medical records shall be accurately dated and timed. Late entries are permitted, but must be clearly and accurately noted as late entries and dated and timed accurately when they are entered in to the record * * *.

Fla. Admin. Code r. 64B8–9.003 (2009).

With respect to defining the parameters of what constitutes "professional practice" in the context of pain management prescribing, Florida state law provides:

Notwithstanding any other provision of law, a physician may prescribe or administer any controlled substance under Schedules II–V * * * to a person for the treatment of intractable pain,[62] provided the physician does so in accordance with that level of care, skill, and treatment recognized by a reasonably prudent physician under similar conditions and circumstances.

Fla. Stat. § 458.326 (2009). Moreover, the Florida Board has adopted,[63] albeit in modified version, the *Model Policy for the Use of Controlled Substances for the Treatment of Pain* (*Model Policy*), a document drafted by the Federation of State Medical Boards (FSMB) to provide professional guidelines for the treatment of pain with controlled substances. The standards adopted by Florida share the key tenets of the *Model Policy's* standards for pain management prescribing, including the emphasis on diligent efforts by physicians to prevent drug diversion, prescribing based on clear documentation of unrelieved pain and thorough medical records, and compliance with applicable federal and state law.

Like the *Model Policy,* which was promulgated "to encourage the legitimate medical uses of controlled substances for the treatment of pain while stressing the need to safeguard against abuse and diversion," Florida's regulation providing "Standards for the Use of Controlled Substances for Treatment of Pain," Fla. Admin. Code r. 64B8–9.013 (2009) (Florida Standards), recognizes that "inappropriate prescribing of controlled substances * * * may lead to drug diversion and abuse by individuals who seek them for other than legitimate medical use." The language employed by the regulation under the preamble section titled "Pain Management Principles" makes clear that the standards "are not intended to define *complete or best practice,* but rather to communicate what the [Florida Board] considers to be *within the boundaries of professional practice*" (emphasis supplied), *id.* at 9.013(1)(g); thus, the plain text supports an inference that the standards provide the *minimum* requirements for establishing conduct that comports with the professional practice of controlled substance-based pain management within the state. Likewise, the level of integral range of acceptable practice that is built into the regulation underscores the importance of seeking an expert professional opinion in reaching a correct adjudication of whether a registrant has met the applicable Florida standard. It is clear that in assessing whether the controlled substance prescribing practices of a Florida practitioner fall within the acceptable range of what constitutes being within the bounds of being "issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice," [64] resort must be had to an expert.

The Florida Standards direct that "[p]hysicians should be diligent in preventing the diversion of drugs for illegitimate purposes," *id.* at 9.013(1)(d), and provide that the prescribing of controlled substances for pain will be considered to be for a legitimate medical purpose if based on accepted scientific knowledge of the treatment of pain or if based on sound clinical grounds. All such prescribing must be based on *clear documentation* of unrelieved pain and in compliance with applicable state or federal law.

Id. at 9.013(1)(e) (emphasis supplied).

The Florida Standards further provide that the validity of prescribing will be judged "based on the physician's treatment of the patient and *on available documentation,* rather than on the quantity and chronicity of prescribing" (emphasis supplied). *Id.* at 9.013(1)(g). Furthermore, the Standards advise that physicians should not fear disciplinary action for "prescribing controlled substances * * * for a legitimate medical purpose and that is supported by *appropriate documentation* establishing a valid medical need and treatment plan" (emphasis supplied), or "for failing to adhere strictly to the provisions of these standards, *if good cause is shown for such deviation*" (emphasis supplied). *Id.* at 9.013(1)(b), (f).

Although, as discussed above, the Florida Board instituted general guidance applicable to all physicians regarding medical records, it also promulgated a separate set of documentation requirements in the Florida Standards applicable specifically to those physicians who prescribe controlled substances in the pain-management context. The Florida Standards, under the subheading "Medical Records," state that "[t]he physician is required to keep *accurate and complete records*" (emphasis supplied) including, though not limited to:

1. The medical history and physical examination, including history of drug abuse or dependence, as appropriate;
2. Diagnostic, therapeutic, and laboratory results;
3. Evaluations and consultations;
4. Treatment objectives;
5. Discussion of risks and benefits;
6. Treatments;
7. Medications (including date, type, dosage, and quantity prescribed);
8. Instructions and agreements; and
9. Periodic reviews.

Id. at 9.013(3)(f). The same section directs that "[r]ecords must remain current and be maintained in an acceptable manner and readily available for review." *Id.*

The Florida Standards similarly emphasize the need for proper documentation in the patient evaluation context by specifying:

A complete [65] medical history and physical examination must be conducted and documented in the medical record. The medical record should document the nature and intensity of the pain, current and past treatments for pain, underlying or coexisting diseases or conditions, the effect of the pain on physical and psychological function, and history of substance abuse. The medical record also should document the presence of one or more recognized medical indications for the use of a controlled substance.

Id. at 9.013(3)(a).

Furthermore, the Florida Standards require a written treatment plan that "should state objectives that will be used to determine treatment success, such as pain relief and improved physical and psychosocial function, and should indicate if any further diagnostic evaluations or other treatments are planned." *Id.* at 9.013(3)(b). Subsequent to the initiation of treatment, "the physician should *adjust* drug therapy to the individual medical needs of each patient. Other treatment modalities or a rehabilitation program may be necessary

[62] Florida defines "intractable pain" to mean "pain for which, in the generally accepted course of medical practice, the cause cannot be removed and otherwise treated." Fla. Stat. § 458.326 (2009).

[63] Pursuant to authority vested in the Florida Board by the Florida legislature to promulgate rules regarding State standards for pain management clinical practice specifically. Fla. Stat. § 458.309(5) (2009).

[64] 21 CFR 1306.04(a).

[65] The original *Model Policy* version of the guidelines does not contain a reference to the need for a *complete* medical history, instead only requiring a medical history generally. Thus, the Florida Board has adopted a higher standard than the measure that has been set in the *Model Policy* by the FSMB.

depending on the etiology of the pain and the extent to which the pain is associated with physical and psychosocial impairment." (emphasis supplied). *Id.*

Another standard adopted by the Florida Board, under the subheading "Informed Consent and Agreement for Treatment," is the directive that

> [t]he physician should discuss the risks and benefits of the use of controlled substances with the patient, persons designated by the patient, or with the patient's surrogate or guardian if the patient is incompetent. The patient should receive prescriptions from one physician and one pharmacy where possible. If the patient is determined to be at high risk for medication abuse or have a history of substance abuse, the physician should employ the use of a written agreement between the physician and patient outlining patient responsibilities, including, but not limited to:
>
> 1. Urine/serum medication levels screening when requested;
>
> 2. Number and frequency of all prescription refills; and
>
> 3. Reasons for which drug therapy may be discontinued (i.e., violation of agreement).

Id. at 9.003(3)(c).

The Florida Standards contain a further requirement to periodically review "the course of pain treatment and any new information about the etiology of the pain or the patient's state of health." *Id.* at 9.013(3)(d). The Florida Standards explain the importance of periodic review in the following manner:

> Continuation or modification of therapy depends on the physician's evaluation of the patient's progress. If treatment goals are not being achieved, despite medication *adjustments,* the physician should reevaluate the appropriateness of continued treatment. The physician should monitor patient compliance in medication usage and related treatment plans.

Id.

Under the subheading "Consultation," the Florida Board promulgated the instruction that

> [t]he physician should be willing to refer the patient as necessary for additional evaluation and treatment in order to achieve treatment objectives. Special attention should be given to those pain patients who are at risk for misusing their medications and those whose living arrangements pose a risk for medication misuse or diversion. The management of pain in patients with a history of substance abuse or with a comorbid psychiatric disorder requires extra care, monitoring, and documentation, and may require consultation with or referral to an expert in the management of such patients.

Id. at 9.003(3)(e).

It is abundantly clear from the plain language of the Florida Standards that the Florida Board places critical emphasis on physician implementation of adequate safeguards in their practice to minimize diversion and the need to document the objective signs and rationale employed in the course of pain treatment utilizing the prescription of controlled substances. Conscientious documentation is repeatedly emphasized as not just a ministerial act, but a key treatment tool and a vital indicator to evaluate whether the physician's prescribing practices are "within the usual course of professional practice." Here, the uncontroverted expert opinion of Dr. Kennedy, the only expert opinion presented [66] in these proceedings, reflects that the documentation he reviewed in the Respondent's patient charts reflected care that was markedly below the standard of care set by the Florida Medical Board. Dr. Kennedy's expert assessment was consistent with the state statutory and regulatory guidance. In Kennedy's view, the Respondent's charts demonstrated minimalistic, incomplete, and otherwise medically inadequate documentation of his contacts with patients, and the prescribing rationale for his issuance of controlled substance prescriptions to those patients for alleged pain management purposes. The boilerplate-style, "one high-dosage controlled substances treatment plan fits all" nature of nearly all of the patient medical records at issue, at least in the view of the uncontroverted expert, evidences a failure on the part of the Respondent to conduct his practice of medicine in a manner to minimize the potential of controlled substance abuse and diversion, and supports a conclusion that he failed to even substantially comply with the minimum obligations for professional practice imposed under the Florida Standards—and without "good cause [] shown for such deviation." *Id.* at 9.013(1)(f).

In his Post-Hearing Brief (Respondent's Brief), the Respondent's counsel has prepared and submitted a thoughtful and detailed review of one of the patient charts that was analyzed by Dr. Kennedy in his report. Respt's Br. at 22–26. While counsel argues that the patient chart entries were, at least by his interpretation of his client's obligations, satisfactory, the expert's opinion at the hearing remained unchanged. Even acknowledging, as this recommended decision does, that Dr. Kennedy's presentation was not without its deficiencies, its shortcomings do not render it so fundamentally defective as to completely undermine his credibility and viability as within the scope of what a litigant may depend upon.[67] As recognized in the Respondent's Brief, "the [G]overnment, like any party in a contested hearing, is free to hire an expert to advocate its position." Respt's Br. at 12. Unfortunately, counsel's analysis is the product of a lay evaluation of standards applicable to the nuanced and sophisticated science that is the practice of medicine. Where his opinion and that of the only accepted medical expert to provide an expert opinion conflict, his opinion cannot and will not be afforded controlling deference. Argument supplied by counsel (albeit a diligent and persuasive counsel) that the relevant standards were satisfactorily applied as evidenced by the protocols and procedures documented in the patient charts cannot supplant the unrefuted view of an accepted expert witness.

The Respondent, who was in a unique position to conclusively refute Dr. Kennedy's views and explain the format and nuances of the reviewed documentation, elected not to testify in this matter. At a DEA administrative hearing, it is permissible to draw an adverse inference from the silence of the Respondent, even in the face of a Fifth Amendment invocation. *Hoxie* v. *DEA,* 419 F.3d 477, 483 (6th Cir. 2005) (citing *United States* v. *Hale,* 422 U.S. 171, 176 (1975) ("silence gains more probative weight where it persists in the face of accusation, since it is assumed in such circumstances that the accused would be more likely than not to dispute an untrue accusation.")); *Joseph Baumstarck, M.D.,* 74 FR 17525, 17528, n.3 (2009) (citing *Ohio Adult Parole Auth.* v. *Woodward,* 523 U.S. 272, 286 (1998)). On the facts of this case, where the allegations are of a nature that a registrant would be more likely than not to dispute them if untrue, an adverse inference based on the Respondent's silence is appropriate. Where, as here,

[66] Respondent, in his brief, correctly points out that (for reasons not readily apparent) the Government elicited no testimony from Dr. Kennedy regarding any patient treated by the Respondent. Respt's Br. at 10–11.

[67] Likewise, contrary to the position taken by the Respondent in his brief (Respt's Br. at 7), Dr. Kennedy's opinions are not invalidated by the size of the representative sample of files he reviewed or the manner in which they were selected. Firstly, SA Langston provided credible testimony regarding the selection process, which although admittedly not a paradigm of scientific sampling methodology, was likewise not designed to achieve a particular result. Secondly, contrary to the assertion in the Respondent's brief (Respt's Br. at 15), there is no baseline magic number of files or registrant actions that must be examined to support an expert opinion and ultimately an Agency determination as to whether a registrant has committed acts inconsistent with the public interest sufficient to merit adverse action relative to a DEA COR. *See Krishna-Iyer,* 74 FR at 464.

the Government, through its expert, has alleged that the Respondent's charts do not reflect genuine analysis, but rather (at least in its view and the opinion of its expert), a sort of sham-by-check-box form designed specifically to present a false impression of a compliant registrant, it is precisely the type of allegation that would naturally all but oblige a registrant to spring to offer a contradictory account. The Respondent's choice to remain silent in the face of such allegations, where he could have related his version of his practice as a registrant, adds at least some additional credence to the factual and analytical views of the Government's expert in this regard.

In the Social Security context, where an Administrative Law Judge has received expert medical opinions on the issue of the claimant's ability to work and they are not repudiated in any respect by substantial evidence, an adverse decision should be set aside as based on "suspicion and speculation." *Miracle* v. *Celebrezze,* 351 F.2d 361, 378 (6th Cir. 1965); *see also Hall* v. *Celebrezze,* 314 F.2d 686, 689–90 (6th Cir. 1963); *cf. Harris* v. *Heckler,* 756 F.2d 431, 436 (6th Cir. 1985) (improper to reject uncontroverted evidence supporting complaints of pain simply because of claimant's demeanor at hearing). When an administrative tribunal elects to disregard the uncontradicted opinion of an expert, it runs the risk of improperly declaring itself as an interpreter of medical knowledge. *Ross* v. *Gardner,* 365 F.2d 554 (6th Cir. 1966). While in this case it is ironically true, much like in the Social Security context, that the opinion of a treating physician should be afforded greater weight than the opinion of an expert whose opinion is limited to a review of the patient file, *see Magallenes* v. *Bowen,* 881 F.2d 747, 751 (9th Cir. 1989), the treating-source Respondent in this case offered no evidence, not even his own opinion, regarding the treatment rendered. Thus, in this adjudication, the record contains no dispute between experts to be resolved; instead, there is but one, unrefuted, uncontroverted, credible expert opinion. To ignore that expert opinion on this record and replace it with the opinion of this tribunal, Respondent's counsel, or any other lay source would be a dangerous course and more importantly, a plainly erroneous one.

Accordingly, after carefully balancing the admitted evidence, the evidence establishes, by a preponderance, that the prescriptions the Respondent issued in Florida were not issued within "the usual course of [the Respondent's] professional practice." 21 CFR 1306.04(a). Consideration of the evidence under the second and fourth factors support the COR revocation sought by the Government in this case.

To the extent that the Respondent's prescribing practices fell below the requisite standard in Florida, that conduct also impacts upon the Fifth statutory factor. Under Factor 5, the Deputy Administrator is authorized to consider "other conduct which may threaten the public health and safety." 21 U.S.C. 823(f)(5). Although this factor authorizes consideration of a somewhat broader range of conduct reaching beyond those activities typically associated with a registrant's practice, an adverse finding under this factor requires some showing that the relevant conduct actually constituted a threat to public safety. *See Holloway Distrib.,* 72 FR 42118, 42126 (2007).

The evidence establishes that the Respondent engaged in a course of practice wherein he prescribed controlled substances to patients irrespective of the patients' need for such medication and ignoring any and all red flags that could or did indicate likely paths of diversion. The testimony of Dr. Kennedy, the DEA regulations, and the Florida Standards make clear that physicians prescribing controlled substances do so under an obligation to monitor the process to minimize the risk of diversion. The patient charts reflect that the Respondent, contrary to his obligations as a DEA registrant, did not follow up in the face of multiple red flags. The Respondent's disregard of his obligations as a DEA registrant and Federal and state laws related to controlled substances militate in favor of revocation.

By ignoring his responsibilities to monitor the controlled substance prescriptions he was authorizing to minimize diversion, and by participating in an insufficiently documented and thoughtful process for the issuance of potentially dangerous controlled substances, the Respondent created a significant potential conduit for the unchecked diversion of controlled substances. *See Holloway Distrib.,* 72 FR at 42124 (a policy of "see no evil, hear no evil" is fundamentally inconsistent with the obligations of a DEA registrant). Agency precedent has long recognized that "[l]egally, there is absolutely no difference between the sale of an illicit drug on the street and the illicit dispensing of a licit drug by means of a physician's prescription." *EZRX, LLC,* 69 FR 63178, 63181 (1988); *Floyd A. Santner, M.D.,* 55 FR 37581 (1988).

Agency precedent has consistently held that where, as here, the Government has met its burden to establish a prima facie case that a registrant has committed acts demonstrating that continued registration is inconsistent with the public interest, acceptance of responsibility is a condition precedent to continued registration. *Jeri Hassman, M.D.,* 75 FR 8194, 8236 (2010); *Medicine Shoppe,* 73 FR at 387. The record contains no evidence that the Respondent has either acknowledged or accepted responsibility for the misconduct at issue in these proceedings.

Recommendation

Based on the foregoing, the evidence supports a finding that the Government has established that the Respondent has committed acts that are inconsistent with the public interest. A balancing of the statutory public interest factors supports the revocation of the Respondent's Certificate of Registration and a denial of his application to renew. The Respondent has not accepted responsibility for his actions, expressed remorse for his conduct at any level, or presented evidence that could reasonably support a finding that the Deputy Administrator should continue to entrust him with a Certificate of Registration.

Accordingly, the Respondent's Certificate of Registration should be *revoked* and any pending applications for renewal should be *denied.*

Dated: August 10, 2010.

John J. Mulrooney, II,

U.S. Administrative Law Judge.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 10–35]

Beau Boshers, M.D.; Decision and Order

On August 10, 2010, Administrative Law Judge (ALJ) John J. Mulrooney, II, issued the attached recommended decision.[1] Thereafter, Respondent filed exceptions to the decision.

Having reviewed the record in its entirety including Respondent's exceptions, I have decided to adopt, except as explained below, the ALJ's

[1] All citations to the ALJ's Decision (ALJ) are to the slip opinion as issued on August 10, 2010, and not to the attached decision which had been reformatted.

rulings, findings of fact, conclusions of law, and recommended Order.

Respondent raises two exceptions to the ALJ's recommended decision. First, he argues that "he was denied the ability to present his positive experience in dispensing controlled substances." Resp. Exc. at 1. More specifically, he argues that he was denied "access to files seized" by the Government which show that he discharged patients, and that "[w]ithout access to those files," he was left "with his hands tied behind his back and [was] unable to demonstrate his successful treatment of patients with controlled substances." *Id.* at 1–2. Respondent contends that this "effectively crippl[ed] his ability to present any evidence of his positive, or successful, experience in dispensing and treating patients with controlled substances." *Id.* at 1.

As support for his contention that he is entitled to present evidence of his "positive experience," Respondent cites the Agency's decision on remand in *Jayam Krishna-Iyer,* 74 FR 459 (2009). That decision addressed an unpublished decision of the United States Court of Appeals for the Eleventh Circuit, which vacated the Agency's Order revoking a practitioner's registration on the ground that it failed to consider the practitioner's "experience with twelve patients whose medical charts were seized by the DEA, or with thousands of other patients. In short, the DEA did not consider any of the Petitioner's positive experience in dispensing controlled substances." *Id.* (quoting *Krishna-Iyer* v. *DEA,* 249 Fed. Appx. 159, 160 (11th Cir. 2007)).

While this Agency complied with the Eleventh Circuit's order, unpublished decisions are "not precedential." *United States* v. *Shaw,* 560 F.3d 1230, 1241 (11th Cir. 2009). Moreover, as I noted in *Krishna-Iyer,* "[t]he Court of Appeals did not cite to any decision of either this Agency or another court defining the term 'positive experience.' Nor did the Court offer any guidance as to the meaning of this term, which is not to be found in the" Controlled Substances Act. 74 FR at 460.

I thus assumed—even though there was no evidence (except for twelve patient files) in the record regarding the legitimacy of the practitioner's prescribing of controlled substances to the "thousands of other patients" she had treated—that her prescribings to these patients constituted "positive experience." *Id.* at 460–61. However, the practitioner's "prescribings to thousands of other patients [did] not * * * render her prescribings to the undercover officers any less unlawful, or any less acts which 'are inconsistent with the public interest.'" *Id.* at 463 (quoting 21 U.S.C. 823(f)).[2]

As *Krishna-Iyer* explained, because the CSA limits registration as a practitioner "to those who have authority to dispense controlled substances in the course of professional practice, and patients with legitimate medical conditions routinely seek treatment from licensed medical professionals, every registrant can undoubtedly point to an extensive body of legitimate prescribing over the course of her professional career." *Id.; see also* 21 U.S.C. 823(f) (registration limited to a practitioner "authorized to dispense * * * controlled substances under the laws of the State in which he practices"). I further noted that "in past cases, [DEA] has given no more than nominal weight to a practitioner's evidence that he has dispensed controlled substances to thousands of patients in circumstances which did not involve diversion." *Id.* (quoting *Paul J. Caragine, Jr.,* 63 FR 51592, 51599 (1998) ("[T]he Government does not dispute that during Respondent's 20 years in practice he has seen over 15,000 patients. At issue in this proceeding is Respondent's controlled substance prescribing to 18 patients."); *id.* at 51600 ("[E]ven though the patients at issue are only a small portion of Respondent's patient population, his prescribing of controlled substances to these individuals raises serious concerns regarding [his] ability to responsibly handle controlled substances in the future."); *Medicine Shoppe-Jonesborough,* 73 FR 364, 386 & n.56 (2008) (noting that pharmacy "had 17,000 patients," but that "[n]o amount of legitimate dispensings can render * * * flagrant violations [acts which are] 'consistent with the public interest.'"), *aff'd, Medicine Shoppe-Jonesborough* v. *DEA,* 300 Fed. Appx. 409 (6th Cir. 2008)).

DEA has thus revoked a practitioner's registration based on a single act of presenting two fraudulent prescriptions to a pharmacy for filling; *see Alan H. Olefsky,* 57 FR 928, 928–29 (1992), and DEA can revoke based on a single act of diversion. *Dewey C. MacKay,* 75 FR 49956, 49977 (2010). *See also Sokoloff* v. *Saxbe,* 501 F.2d 571, 576 (2d Cir. 1974) (upholding revocation of practitioner's registration based on *nolo contendre* plea to three counts of unlawful distribution). Undoubtedly, each of these practitioners could have pointed to evidence of having treated a large number of patients in circumstances in which he did not divert controlled substances to drug abusers or drug dealers.

Consistent with these precedents, I held in *Krishna-Iyer* that "evidence that a practitioner has treated thousands of patients in circumstances which do not constitute diversion," and has even refused to prescribe to certain patients,[3] "does not negate a *prima facie* showing that the practitioner has committed acts inconsistent with the public interest."[4] 74 FR at 463. I further held

[2] As I also explained in *Krishna-Iyer*, while Congress directed the Agency to consider all of the section 823(f) factors, I am entitled to give each factor the weight I deem appropriate and the courts of appeals have recognized that findings under a single factor are sufficient to support the revocation of a registration. 74 FR at 462 (citing *Hoxie* v. *DEA,* 419 F.3d 477, 482 (6th Cir. 2005); *Morall* v. *DEA,* 412 F.3d 165, 173–174 (DC Cir. 2005). As I further explained, ''this is not a contest in which score is kept; the Agency is not required to mechanically count up the factors and determine how many favor the Government and how many favor the registrant. Rather, it is an inquiry which focuses on protecting the public interest; what matters is the seriousness of the registrant's misconduct." *Id.* at 462.

[3] In *Krishna-Iyer*, I noted that the practitioner had discharged several patients. 74 FR at 462. However, I held that this evidence was not probative of the practitioner's intent in prescribing to the other patients who were focus of the proceeding. *Id.* & n.6.

[4] I do not adopt the ALJ's discussion of the standards applied by the Agency in assessing a practitioner's experience in dispensing controlled substances, which cites primarily to cases involving list chemical I distributors, a different category of registrant. *See* ALJ Dec. at 25–26. As one example as to why, DEA routinely issues registrations to newly-licensed practitioners even though they cannot point to any experience in dispensing controlled substances (provided they have not previously violated controlled substance laws.). Conversely, DEA has never held that a practitioner's lengthy experience in dispensing controlled substances without diverting precludes a finding (where supported by substantial evidence showing that he did divert) that a practitioner has committed acts which render his registration "inconsistent with the public interest." 21 U.S.C. 824(a)(4).

In any event, as discussed above, Respondent offered no evidence on the issue of his experience in dispensing controlled substances and the ALJ's ultimate conclusion that Respondent violated the CSA's prescription requirement because he dispensed controlled substance prescriptions that were not "within" 'usual course of [his] professional practice,'' ALJ at 41 (quoting 21 CFR 1306.04(a)), and that "the evidence under the [experience] * * * factor[] support[s]" the revocation of his registration, is consistent with Agency precedent. *Id.*

With respect to factor five, "[s]uch other conduct which may threaten public health and safety," 21 U.S.C. 823(f)(5), the ALJ opined that "an adverse finding under this factor requires some showing that the relevant conduct *actuallys constituted* a threat to public safety." ALJ at 41 (emphasis added and citation omitted.) Contrary to the ALJ's reasoning, Congress, by inserting the word "may" in factor five, clearly manifested its intent to grant the Agency authority to consider conduct which creates a probable or possible threat (and not only an actual) threat to public health and safety. *See Webster's Third New Int'l Dictionary* 1396 (1976) (defining "may" in relevant part as to "be in some degree likely to"); *see also The Random House Dictionary of the English Language* 1189 (1987) (defining "may" in relevant part as "used to express possibility"). While the ALJ misstated the applicable standard, his conclusion that

that while such evidence may be entitled to some weight in assessing "whether a practitioner has credibly shown that she has reformed her practices, where a practitioner commits intentional acts of diversion and insists she did nothing wrong, such evidence is entitled to no weight." *Id.*

Respondent's exception is neither factually nor legally well taken. Contrary to his assertion that his hands were "tie[d] behind his back" and that he was "effectively cripple[ed]" from "present[ing] any evidence of" what he terms "his positive * * * experience,"[5] Respondent could have testified about his dispensing practices and addressed those instances in which he refused to prescribe controlled substances; his decision to not put on evidence on this issue was not a matter "of impossibility," but of "choice." Resp. Exc. at 1.

Most significantly, Respondent could have testified regarding his prescribing practices with respect to the patients whose files were reviewed by the Government's Expert and which formed the basis for the latter's (and the ALJ's) conclusion that Respondent acted outside of the usual course of professional practice and lacked a legitimate medical purpose in prescribing controlled substances to them. *See* ALJ Dec. at 41 (citing 21 CFR 1306.04(a)). Alternatively, he could have retained his own expert to review the files and called the expert to testify. Notably, Respondent makes no claim that the files, which were reviewed by the Government's Expert, were not timely provided to him.[6]

Respondent also takes exception to the ALJ's finding that he was not prejudiced by the Government's failure to turn over "the discharged patient files," as well as evidence pertaining to a second undercover officer to whom he refused to prescribe. Resp. Exc. at 2. Respondent asserts that his right to Due Process was violated because this evidence "could have exonerated" him, "or at the very least, given him an opportunity to meaningfully defend against the Government's allegations," and that prejudice "must [be] assume[d] * * * because neither he nor the Court were ever given access to it." *Id.*

As an initial matter, while there is evidence that Respondent refused to prescribe to a second undercover officer, there is no evidence establishing that there were, in fact, "discharged patient files." Respondent neither testified, nor offered any other evidence such as an affidavit establishing, that such files exist. Most significantly, in his Exceptions, Respondent does not cite any authority for the proposition that the Agency is required to provide broad discovery in a proceeding under sections 303 and 304 of the CSA. *See generally* Resp. Exc. Indeed, Respondent's contention far exceeds what the Supreme Court has held that an agency must do to comply with the Due Process Clause. *See, e.g., Goldberg* v. *Kelly,* 397 U.S. 254, 270 (1970).

In *Goldberg,* the Supreme Court held that "'where governmental action seriously injures an individual, and the reasonableness of the action depends on fact findings, *the evidence used to prove the Government's case* must be disclosed to the individual so that he has an opportunity to show that it is untrue.'" 397 U.S. at 270 (quoting *Greene* v. *McElroy,* 360 U.S. 474, 496 (1959) (emphasis added)). The Court has further explained that "[a] party is entitled * * * to know the issues on which [the] decision will turn and to be apprised of the factual material on which the agency relies for decision so that he may rebut it. Indeed, the Due Process Clause forbids an agency to use evidence in a way that forecloses an opportunity to offer a contrary presentation." *Bowman Transp., Inc.,* v. *Arkansas-Best Freight System, Inc.,* 419 U.S. 281, 288 n.4 (1974).

It is well settled, however, that neither the Due Process Clause, nor the Administrative Procedure Act (nor DEA's rules of procedure) require the Agency to provide a general right of discovery in administrative proceedings. *See Echostar Comm. Corp.* v. *FCC,* 292 F.3d 749, 756 (DC Cir. 2002); *Mister Discount Stockbrokers, Inc.,* v. *SEC,* 768 F.2d 875, 878 (7th Cir. 1985); *Nicholas A. Sychak, d/b/a/ Medicap Pharmacy,* 65 FR 75959, 75961 (2000). While "discovery must be granted if in the particular situation a refusal to do so would so prejudice a party as to deny him due process," *McClelland* v. *Andrus,* 606 F.2d 1278, 1285–86 (DC Cir. 1979), the party seeking discovery must rely on more than speculation and must show that the evidence is relevant, material, and that the denial of access to the documents is prejudicial. *See Echostar,* 292 F.3d at 756; *Silverman* v. *CFTC,* 549 F.2d 28, 34 (7th Cir. 1977).

In this case, the ALJ based his conclusion that Respondent issued numerous prescriptions outside of the usual course of professional practice in violation of both Federal and State laws and thus had committed acts which render his registration inconsistent with the public interest, *see* ALJ Dec. at 39–42, on the Expert's testimony and report regarding the various patients files the latter reviewed, each of which was provided to Respondent. Accordingly, the evidence which was the basis of the decision was disclosed to him, and contrary to his contention, *see* Resp. Exc. at 2, Respondent had a meaningful "opportunity to show that it is untrue."[7] *Goldberg,* 397 U.S. at 270. Respondent offers no explanation as to why other patient files would have "exonerated" him from the allegations that his prescriptions to the patients, whose files were reviewed by the Expert, were issued outside of the usual course of professional practice and lacked a legitimate medical purpose. Nor does Respondent offer any legal authority for his contention that prejudice—which he cannot show—

Respondent repeatedly ignored "red flags" indicative of likely diversion and thus "created a significant potential conduit for the unchecked diversion of controlled substances" is clearly support by substantial evidence and warrants an adverse finding under factor five. ALJ at 42.

The ALJ also opined that "[i]t is clear that in assessing whether the controlled substance prescribing practices of a Florida practitioner fall within the acceptable range of what constitutes being within the bounds of being 'issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice,' resort must be had to an expert." ALJ at 37 (quoting 21 CFR 1306.04(a)). While the ALJ properly noted the importance of expert testimony in this case, in which the Government primarily relied on a review of the medical charts, whether expert testimony is needed is necessarily dependent on the nature of the allegations and the other evidence in the case. Where, for example, the Government produces evidence of undercover visits showing that a physician knowingly engaged in outright drug deals, expert testimony adds little to the proof necessary to establish a violation of Federal law.

[5] Nor is it clear what Respondent means by "positive experience." Resp. Exc. at 1. While at various points Respondent refers to files which he asserts show that he discharged patients, he then maintains that his lack of access to the files prevent him from presenting "any evidence of his positive, or successful, experience in dispensing and *treating patients* with controlled substances." *Id.* (emphasis added). He likewise contends that he was "unable to demonstrate his *successful treatment* of patients with controlled substances." *Id.* at 2 (emphasis added). However, it is not DEA's role to assess whether a practitioner has successfully treated patients, but rather, to determine whether a practitioner is either diverting drugs or engaging in practices (whether intentional or not) that create a substantial risk of diversion. *See Caragine,* 63 FR at 51601 ("Careless or negligent handling of controlled substances creates the opportunity for diversion and [can] justify revocation [or a registration] or denial" of an application).

[6] Indeed, it appears that the patient files (which the expert reviewed) were provided to Respondent nearly two months before the hearing.

[7] The Government also attempted to introduce evidence that Respondent prescribed to a member of a Boston-based drug trafficking organization, who had been arrested with 3,000 oxycodone tablets in his possession, and who stated that he did not have a legitimate medical need for the drugs he obtained from Respondent. Tr. 829–32. For the reasons stated in his decision, the ALJ properly gave this testimony no weight. *See* ALJ Dec. at 10 n.23.

must be assumed. *See Mister Discount Stockbrokers,* 768 F.2d at 878 (rejecting challenge to discovery procedures in administrative proceeding noting that party failed "to demonstrate *any* prejudice * * * let alone prejudice to a significant degree so as to result in a denial of due process").

There is likewise no merit to Respondent's contention that he was prejudiced by the Government's failure to turn over the patient file of the undercover officer to whom he refused to prescribe. A Special Agent testified that Respondent had refused to prescribe to a second undercover officer and the Government failed to put forward any evidence regarding the circumstances of this visit (such as what the officer said to Respondent). For this reason alone, it was proper for the ALJ to draw an inference adverse to the Government and conclude that Respondent properly complied with the rules of the Florida Board of Medicine in evaluating the undercover officer. *See* ALJ at 32 (citing *UAW* v. *NLRB,* 459 F.2d 1329, 1335–39 (D.C. Cir. 1972)).[8] However, as the ALJ held, that Respondent refused to prescribe controlled substances in this single instance does not refute the Government's *prima facie* showing that Respondent repeatedly violated the prescription requirement of Federal law as established by the Expert's review of eighteen patient files. *See id.* at 41 (quoting 21 CFR 1306.04(a)) ("after carefully balancing the admitted evidence, [and] even applying an adverse inference that permits the assumption that the Respondent was approached by an undercover agent and acted appropriately, the evidence establishes, by a preponderance, that the prescriptions the Respondent issued * * * were not issued within 'the usual course of [the Respondent's] professional practice' ").

As noted above, Respondent did not testify. Nor did he offer the testimony of an expert. Thus, Respondent did not refute the opinion testimony of the Government's Expert that he repeatedly violated the prescription requirement of Federal law. Because Respondent failed "to testify in response to [the] probative evidence offered against" him, I conclude (as did the ALJ) that it is appropriate to draw an adverse inference against him and hold that he knowingly issued prescriptions in violation of 21 CFR 1306.04(a). *Baxter* v. *Palmigiano,* 425 U.S. 308, 316 (1976); *see also The Lawsons, Inc.,* 72 FR 74334, 74339 (2007). Because Respondent failed to testify, I also conclude that he has not accepted responsibility for his misconduct nor demonstrated that he will not engage in future misconduct, and therefore, he has not rebutted the Government's *prima facie* showing that his continued registration is inconsistent with the public interest.[9] *See Medicine Shoppe-Jonesborough,* 73 FR at 387; *Samuel S. Jackson,* 72 FR 23848, 23853 (2007). I thus reject Respondent's Exceptions and adopt the ALJ's recommended Order.

Order

Pursuant to the authority vested in me by 21 U.S.C. 823(f) and 824(a), as well as 21 CFR 0.100(b) and 0.104, I order that DEA Certificate of Registration, FB0254918, issued to Beau Boshers, M.D., be, and it hereby is revoked. I further order that any pending application of Beau Boshers, M.D., to renew or modify his registration, be, and it hereby is, denied.

This Order is effective immediately.

Dated: March 31, 2011.

Michele M. Leonhart,

Administrator.

Larry P. Cote, Esq., for the Government
Jose M. Quinon, Esq., for the Respondent

Recommended Rulings, Findings of Fact, Conclusions of Law, and Decision of the Administrative Law Judge

John J. Mulrooney, II, Administrative Law Judge. On February 25, 2010, the Deputy Administrator, Drug Enforcement Administration (DEA or Government), issued an Order to Show Cause and Immediate Suspension of Registration (OSC/ISO), immediately suspending the DEA Certificate of Registration (COR), Number FB02549187, of Beau Boshers, M.D. (Respondent), as a practitioner, pursuant to 21 U.S.C. 824(d), alleging that such registration constitutes an imminent danger to the public health and safety. The OSC/ISO also sought revocation of the Respondent's registration, pursuant to 21 U.S.C. 824(a)(4), and denial of any pending applications for renewal [10] or modification of such registration, pursuant to 21 U.S.C. 823(f), alleging that the Respondent's continued registration is inconsistent with the public interest, as that term is used in 21 U.S.C. 823(f). On March 22, 2010, the Respondent timely requested a hearing, which, pursuant to a change of venue granted at his request, was conducted in Miami, Florida, on July 7, 2010 through July 9, 2010.[11] The immediate suspension of the Respondent's COR has remained in effect throughout these proceedings.

The issue ultimately to be adjudicated by the Deputy Administrator, with the assistance of this recommended decision, is whether the record as a whole establishes by substantial evidence that Respondent's registration with the DEA should be revoked as inconsistent with the public interest as that term is used in 21 U.S.C. 823(f) and 824(a)(4).

After carefully considering the testimony elicited at the hearing, the admitted exhibits, the arguments of counsel, and the record as a whole, I have set forth my recommended findings of fact and conclusions below.

The Evidence

The OSC/ISO issued by the Government alleges that the Respondent, through the medical practice he participated in at American Pain, LLC (American Pain), prescribed and dispensed inordinate amounts of controlled substances, primarily oxycodone,[12] under circumstances where he knew, or should have known, that the prescriptions were not dispensed for a legitimate medical purpose. ALJ Ex. 1. The OSC/ISO further charges that these prescriptions were issued outside the usual course of professional practice based on a variety of circumstances [13] surrounding the manner in which American Pain is operated and the manner in which its physicians, including the Respondent, engaged in the practice of medicine. *Id.* The Respondent is also alleged, on several occasions, to have provided undercover law enforcement personnel with controlled substances, including, *inter alia,* oxycodone and

[8] The ALJ explained that drawing an adverse inference was "appropriate under the circumstances of this case where the evidence of the unsuccessful US was clearly within the Government's control and should, to maintain the integrity of the proceedings, have been disclosed if not produced." ALJ at 32. It is unclear whether the ALJ believed that disclosure of this evidence was required as a matter of Due Process as the ALJ did not cite any authority for his reasoning and numerous courts (as well as this Agency) have held that *Brady* v. *Maryland*, 373 U.S. 83 (1963), does not apply to administrative proceedings. *See Mister Discount Stockbrokers,* 768 F.2d at 878; *NLRB* v. *Nueva Engineering, Inc.,* 761 F.2d 961, 969 (4th Cir. 1985); *Nicholas A. Sychak*, 65 FR 75,959, 75960–61 (2000). Even if this evidence is of the type which a refusal to disclose "would so prejudice a party as to deny him due process," *McClelland* v. *Andrus*, 606 F.2d at 1286, the evidence was disclosed through the testimony of the Special Agent. Respondent thus cannot show prejudice.

[9] A registrant's obligation to accept responsibility and demonstrate that he will not engage in future misconduct applies even where the Government's evidence does not establish that a registrant has committed intentional acts. *See Krishna-Iyer*, 74 FR at 464 n.9; *Caragine*, 63 FR at 51601 (granting restricted registration where physician showed that he underwent remedial "training to become better educated in controlled substances and how to deal with drug-seeking patients"). Thus, even if I had concluded that the evidence did not establish that Respondent knowingly diverted controlled substances, I would still revoke his registration because he failed to rebut the Government's *prima facie* case.

[10] Although the Respondent's COR expired on July 31, 2010, the parties stipulated that a timely renewal application has been submitted by the Respondent. ALJ Ex. 40.

[11] Pursuant to an order issued on April 15, 2010, the hearing in this matter was consolidated with the cases of four other registrants who were working at the same clinic as the Respondent and who were also issued OSC/ISOs on February 25, 2010, alleging similar and related conduct.

[12] A schedule II controlled substance.

[13] The majority of which are supported by no evidence introduced by the Government during the course of these proceedings.

alprazolam,[14] after cursory or no medical examinations, and therefore without a legitimate medical purpose. *Id.* The Government's OSC/ISO also alleges that the Respondent's former patients apprised law enforcement personnel that "they were able to obtain prescriptions for controlled substances from [the Respondent] for other than a legitimate medical purpose and with little or no medical examination." *Id.* Lastly, as an additional ground for the OSC/ISO, the Government cites the death of one of the Respondent's patients from an overdose of controlled substances one day after obtaining prescriptions for some of those same controlled substances during a visit to the Respondent at American Pain, and that the investigation determined the deceased patient and two companions obtained those substances "for other than a legitimate medical purpose with the intention of selling the controlled substances in Kentucky." *Id.*

At the hearing, the Government presented the testimony of three witnesses, DEA Miami Field Division (MFD) Group Supervisor (GS) Susan Langston, DEA Special Agent (SA) Michael Burt, and L. Douglas Kennedy, M.D., D.A.B.P.M., Affiliate Clinical Assistant Professor at the University of Miami, Miller School of Medicine.

GS Langston testified that the investigation of the American Pain Clinic had its origins on November 30, 2009, during a routine inspection that she and a subordinate diversion investigator conducted at Appurtenance Biotechnology, LLC, a pharmacy doing business under the name Boca Drugs (Boca Drugs), and located a few blocks away from one of the former locations of American Pain. Tr. at 713, 717–20. According to Langston, an examination of the prescriptions seized from Boca Drugs revealed that the majority of those prescriptions were for oxycodone and alprazolam authorized over the signature of physicians associated with American Pain.[15] *Id.* at 721. Under Langston's supervision, DEA diversion investigators catalogued the prescriptions seized at Boca Drugs (Boca Drugs Prescription Log). Govt. Ex. 118. A review of the data relative to the Respondent on the Boca Drug Prescription Log reveals that from November 2, 2009 through November 25, 2009, 166 controlled substance prescriptions issued over the Respondent's signature, to seventy-five patients, only six of whom resided in Florida. The remainder of the patients had listed addresses in Kentucky, Tennessee, Ohio, Georgia, Indiana, Alabama and West Virginia. The data in the log further reflected that the Respondent issued three prescriptions for non-controlled substances during that time period.

GS Langston also testified that, on March 3, 2010, a criminal search warrant was executed on the American Pain Clinic simultaneously with the OSC/ISO that initiated the present case. Tr. at 735. According to Langston, the items seized from American Pain included a sign that had been posted in what she believes to have served as the urinalysis waiting room. *Id.* at 735–37. The seized sign set forth the following guidance:

ATTENTION PATIENTS

Due to increased fraudulent prescriptions, [i]t's best if you fill your medication in Florida or your regular pharmacy. Don't go to a pharmacy in Ohio when you live in Kentucky and had the scripts written in Florida. The police will confiscate your scripts and hold them while they investigate. This will take up to 6 months. So only fill your meds in Florida or a pharmacy that you have been using for at least 3 months or more.

Govt. Ex. 119 at 1. This sign is attached, apparently by some sort of tape, to the top portion of two other signs, posted at the same location, the first of which reads:

ATTENTION

Patients

Please do *NOT* fill your prescriptions at any *WALGREENS PHARMACY*[16] or *OUTSIDE* the STATE OF FLORIDA.

Id. The final attachment to the composite sign bears the words "24 Hour Camera Surveillance."

Id. A photograph of the composite sign was admitted into evidence.

Langston also testified that while she was present in the American Pain offices, she noticed that each physician's desk was equipped with a group of stamps, each of which depicted a controlled substance medication with a corresponding medication usage instruction (sig). Tr. at 738–39. A photograph of one set of prescription script stamps was admitted as an exhibit.[17] Govt. Ex. 119 at 2.

GS Langston also testified that a great number of medical charts were seized from the American Pain offices, and that she and her staff selected a number of these files to be analyzed by an medical expert procured by the Government. Tr. at 762. According to GS Langston, after the execution of the warrant, the charts from the entire office were placed into piles in alphabetical order, and not separated by physician. Langston testified that she and three of her diversion investigators reviewed the seized files with a view towards choosing approximately fifteen files for each doctor with the aspirational criteria that each would reflect at least three to four visits by that doctor with a patient. Each investigator was empowered to place a chart on the selected pile, and when the target number (or about that number) was reached for each physician, the selection effort relative to that physician was deemed accomplished. *Id.* at 765. Langston credibly testified that there was no effort to specially select files under some prosecution-enhancement or "cherry picking" purpose.[18] *Id.* at 768.

Langston also explained DEA's Automated Record Consolidated Ordering System (ARCOS)[19] and testified that she generated an ARCOS report relative to the Respondent's ordering of controlled substances from January 2009 through February 2010. Govt. Ex. 23.

In the same fashion, Langston explained the purposes of and circumstances behind the generation of state prescription monitoring reports (PMPs) relative to the Respondent maintained by West Virginia, Kentucky and Ohio. Govt. Exs. 24–26. Review of the PMP report data reflects that during the time period of February 1, 2006 through February 11, 2010, pharmacies filled 259 controlled substance prescriptions issued over the Respondent's signature to sixty-eight patients located in West Virginia, 173 similar prescriptions provided to seventy-nine Kentucky-based patients were filled between January 1, 2009 and April 4, 2010, and ninety such prescriptions pertaining to sixty-one patients located in Ohio were filled between April 1, 2008 and April 19, 2010. *Id.*

No evidence was introduced at the hearing that would provide any reliable level of context regarding the raw data

[14] A schedule IC controlled substance.

[15] Although GS Langston testified that DEA immediately suspended the COR that had been issued to Boca Drugs, Tr. at 715, and that aq voluntary surrender by that registrant followed a day later, *id.*, at 776, no evidence has been presented that would lend that fact any particular significance related to any issue that must or should be found regarding the disposition of the present case.

[16] GS Langston testified that she was unaware of the location of the closest Walgreens to American Pain's offices. Tr. at 779. No evidence was presented that would tend to establish that any Walgreens or any other pharmacy has taken a position regarding its willingness to fill prescriptions authorized by American Pain.

[17] Although GS Langston testified that she did not actually take the photographs during the search warrant execution at American Pain, she did provide sufficient, competent evidence to support the admission of the photographs that were ultimately received into evidence. Tr. at 737, 739–41.

[18] In his Discussion and Proposed Findings of Fact and Conclusions of Law (Respondent's Brief), the Respondent argues that the selection criteria employed by Langston deprived him of due process and somehow created an inaccurate portrayal of his practice. Respt's Br. at 4. However, the Respondent never explains the casual connection between the manner in which the files were selected, which was not based on any manner of targeting derogatory information regarding his patient care and why any due process right was compromised.

[19] Langston explained that through the ARCOS system, "[d]rug manufacturers and distributors are required to report the sale of certain controlled substances to DEA," and the system "shows the history of a drug from the point of manufacture through the distribution chain to the retail dispensing level." Tr. at 685–86.

set forth in the databases received into evidence at the Government's request. Other than the observations noted above, no witness who testified at the hearing ever explained the significance of the data set forth in any of these databases to any issue that must or should be considered in deciding the present case.

GS Langston provided evidence that was sufficiently detailed, consistent and plausible to be deemed credible in this recommended decision.

SA Michael Burt testified that he has been employed by DEA since March 2004 and has been stationed with the Miami Field Division (MFD) since September 2004. Tr. at 813–14. Burt testified that he is the lead case agent for DEA in the investigation of American Pain Clinic and has participated in the investigation since the latter part of 2008. According to Burt, American Pain, which was previously known by the name South Florida Pain, has conducted business at four different locations, and he surveilled the Boca Raton and Lake Worth locations both in person and by periodic live review of video captured via pole cameras [20] set up outside the clinic. *Id.* at 815–17. These pole cameras, which were in operation during a three week period from January to February 2010, were initially in operation on a 24-hour basis, but Burt testified that they were later activated only between the hours of 7 a.m. through 6 p.m. due to an observed lack of activity at the clinic outside of that time period. *Id.* at 820–21. The pole camera recordings were not offered into evidence at the hearing or made available to opposing counsel.

Based on these surveillance efforts, SA Burt testified concerning various activities he observed occurring outside the Boca and Lake Worth clinic locations, which were open to the public from 8 a.m. to 5 p.m. At the Boca location, Burt stated that on any given day, beginning at 7 a.m. in the morning, automobiles could be seen pulling into the parking lot and approximately twenty to thirty people were routinely lined up outside of the clinic waiting to gain admittance. Additionally, there was a steady stream of automobile and foot traffic in and out of the clinic throughout the day. *Id.* at 817, 821. Burt testified that in his estimation, approximately 80–90 percent of the automobiles had out-of-state tags, predominantly from Kentucky, Ohio, West Virginia and Tennessee. *Id.* at 817–18. Burt also observed security personnel with "staff" written on their shirts [21] riding around the exterior of the building in golf carts and who, in Burt's assessment, appeared to be directing patients into the American Pain facility. Burt indicated his surveillance of the Lake Worth location yielded similar observations. *Id.* at 818.

Based on his review of some (but not all) [22] of the audio and video tapes made by agents and informers sent into the clinic by the Government at various times, SA Burt also testified about his understanding of the process by which patients obtained controlled substance prescriptions at American Pain. According to Burt, after entering the clinic, a patient would meet with the receptionist, who would determine if the patient had an MRI. If not, the receptionist would issue that individual an MRI prescription in exchange for a $50 cash payment, and the patient "would be directed to a place to obtain an MRI." *Id.* at 822. Burt testified that one such MRI location was Faye Imaging, which was a mobile MRI trailer located behind a gentlemen's club several miles away from American Pain. *Id.* at 822–23. The cost for the MRI was $250, and the patient could pay an additional fee "to have the MRI expedited and faxed over to American Pain." *Id.* at 823–24. Once the MRI was procured and faxed to American Pain, the patient would return to the clinic and be seen by a doctor. According to Burt, the clinic accepted what he referred to as "*predominantly* cash only" [23] for these office visits, and the six doctors at the clinic saw "anywhere from 200 upward to 375 patients a day" [24] in this manner.[25] *Id.* at 882–83 (emphasis supplied).

SA Burt also testified regarding his review of some [26] of the video and audio recordings made by an undercover agent (UC) who assumed the name Luis Lopez capturing activity inside of American Pain.[27] In those recordings, Burt observed who he believed to be an American Pain employee inside the facility standing up in a waiting room full of patients and directing them "not to have their prescriptions filled out of state, not to go out into the parking lot and snort their pills," and directing the patients to have their prescriptions filled "in house" (meaning at American Pain), at "a pharmacy they have in Orlando, Florida," or at "a pharmacy they have down the street," which, in Bart's view, was a reference to Boca Drugs. *Id.* at 825–26. Burt further testified that the purported employee on the recording told the patients to "obey all the traffic laws; do not give the police a reason to pull you over." *Id.* Although Burt testified as to the contents of these recordings, the physical recordings were not offered into evidence by the Government or made available to opposing counsel.

Although noticed in SA Burt's proposed testimony identified in the Government's prehearing statement, testimony regarding the specifics of the UC's visits to see the Respondent at American Pain was not elicited by the Government during its direct examination, but was brought out on cross-examination to meet the Government's admitted evidence consisting of a patient file kept by the Respondent relative to the UC and the accompanying expert report and testimony concerning that file provided by Dr. Kennedy. *Id.* at 985–86; Govt. Exs. 46 (Patient File for Luis Lopez), 131 (Supplemental Expert Report Regarding Undercover Patient Luis Lopez). Burt testified that he did not have the UC examined by a physician to determine his physical condition prior to going to the clinic, he did not ask him whether he had any prior back problems, and he did not ask him whether he had any past problems that caused a doctor to prescribe him controlled substances; instead, Burt relied solely on the UC's representations he was not currently in any pain before sending him into the clinic. Tr. at 987–89. According to Burt, the only instructions he provided to the

[20] SA Burt described the pole cameras as "covert cameras that are installed to observe the activity in the clinic." Tr. 816. Burt testified that he was able to use a laptop to access the live video feed from the cameras after inputting a username and password. The camera video was also recirded to DVR. *Id.* at 821.

[21] Tr. at 910.

[22] SA Burt conceded that although he is the designated lead case agent for DEA, he did not review all the audio and video tapes made in the case or even review the transcripts. Tr. at 1002–05.

[23] Later on cross-examination, SA Burt admitted that the clinic also accepted payment via credit card. Tr. at 916. The parameters of what the witness meant by "predominantly" was not the subject of further explanation.

[24] Inasmuch as the Government provided no information from which any specific number of patients seen by any given clinic doctor on any day could be derived, or any expert testimony regarding a reasonable number of pain patients that could or should be seen per day, the value of providing the raw number of patients walking through the door at the clinic is negligible.

[25] Burt further testified that the doctors were paid $75.00 per patient visit, *id.* at 884, but because he indicated that he could not disclose his basis of knowledge for this information, this portion of his testimony can be afforded no weight. *See Richardson* v. *Perales*, 402 U.S. 389, 402 (1971); *J.A.M. Builders* v. *Herman,* 233 F.3d 1350, 1354 (11th Cir. 2000); *Kelly* v. *Sullivan*, 928 F.2d 227, 230 (7th Cir. 1991); *Calhoun* v. *Bailar*, 626 F.2d 145, 149 (9th Cir. 1980).

[26] Tr. at 1002–05.

[27] The fact that these recordings were made during the course of seven different office visits by an undercover agent to both the Boca Raton and Lake Worth locations was established on cross-examination. Tr. at 900, 985.

UC were to be "very vague regarding the pain," to "point to a general area" when asked about it, and to provide a urine sample if so requested by clinic staff. *Id.* at 989–90, 1001. It was further established that an MRI was taken of the UC at Faye Imaging prior to his seeing the Respondent. *Id.* at 990–91. Burt related that the UC's first visit to the clinic was approximately an hour and fifteen minutes, and his visit with the Respondent was ten to thirteen minutes long. *Id.* at 998–99. Although these encounters between the UC and the Respondent were recorded either via audio or video, the Government did not offer the recordings as evidentiary exhibits at the hearing, and opposing counsel did not have access to them.[28]

More troubling by far is the revelation during SA Burt's cross examination that in addition to UC Luis Lopez, a second UC went into American Pain during July 2009 and recorded his encounters with the Respondent. Those encounters by the second UC did not culminate with the Respondent prescribing controlled substances.[29] *Id.* at 1027, 1029.

SA Burt also testified that he received information from Dr. Eddie Sollie, a former physician employed during the time period American Pain was doing business as South Florida Pain, who terminated his employment at the Oakland Park clinic location in November or December 2008 after working there for approximately two and a half to three months. *Id.* at 827, 898. During the course of an interview where Burt was present, Dr. Sollie related various "concerns about how the practice was being handled or managed." *Id.* at 827–28. These concerns included medical records being, in his opinion, annotated inadequately by the doctors, and what he perceived as a lack of supervision during patient urinalysis testing, where patients would "go[] to the bathrooms together, bringing items with them to the bathrooms that could possibly disguise the urinalysis." According to Burt, Sollie explained that he perceived that patients were substituting urine produced by other persons that contained the metabolites for controlled substances that the patients claimed to be legitimately taking, with a view towards falsely providing evidence to the American Pain doctors showing that they were actually taking prescribed medications and not diverting them. *Id.* at 828–29. During cross-examination, Burt explained that Dr. Sollie told him he had raised these concerns with Christopher George, the owner of American Pain, and that Burt had no evidence that the deficient practices that Sollie had objected to continued through 2010. *Id.* at 900, 906. Burt also acknowledged that he was aware Dr. Sollie had been involved in litigation with Mr. George and that their relationship was strained. *Id.* at 1009. Dr. Sollie was not called as a witness by either party.

SA Burt also provided testimony concerning three confidential sources (only one of whom was seen by the Respondent) and their contacts with doctors at American Pain. Relative to the Respondent, the first confidential source (CS1) discussed by Burt was arrested in Washington, DC after transporting upwards of 3,000 oxycodone pills from south Florida to Massachusetts, and at the time of his arrest, Burt testified that an empty prescription pill bottle from American Pain with the Respondent's name on it was found on his person. *Id.* at 829. Burt relayed that at the time CS1 was searched, he had the 3,000 pills secreted in a jock strap strapped to the inside of his leg, and they were not in any type of bottle with the Respondent's name on it. The individual told Burt during a July 2009 interview[30] that he was a member of a Boston-based drug trafficking organization that would obtain oxycodone in southern Florida and transport it back to Boston for resale. *Id.* at 831. CS1 told Burt that he did not have a legitimate medical need for drugs when he saw the Respondent at American Pain, and that during his office visit, the doctor did not physically touch him, but did tell him to bend over and touch his toes. *Id.* at 832–33. The Government did not submit evidence of, or provide opposing counsel access to, a patient file reflecting CS1's visit to the Respondent, a copy of the prescription allegedly issued, or the empty pill bottle described.[31] Burt's testimony divulged the fact that CS1's cooperation with authorities was being provided in relation to his July 2009 arrest and that a record check revealed CS1 had arrests prior to that incident, though Burt was unable to recall information of any detail concerning the nature and disposition of those arrests. *Id.* at 1018–20. Burt declined to disclose the name of CS1 when queried on cross-examination.[32] *Id.* at 1017.

SA Burt also testified regarding the drug overdose deaths of TY and SM after obtaining controlled substances from American Pain.[33] Burt's record testimony indicates that DEA Task Force Officer[34] (TFO) Barry Adams informed him that a Kentucky resident named TY overdosed in Kentucky from oxycodone intoxication induced by medication procured at American Pain. Burt testified that this information was furnished pursuant to a working law enforcement relationship between the Kentucky State Police, Kentucky FBI, Kentucky DEA and Miami DEA aimed at addressing "the brunt of the pill problem" centered within the state of Kentucky relative to illegal use and resale of prescription pain medications. *Id.* at 833–35. However, in his testimony, Burt was unable to recall the name of the doctor from whom TY obtained his pills, and, thus, no admissible evidence was presented by the Government with respect to TY's death.[35] Likewise, the record evidence concerning SM did not implicate prescribing activity by the Respondent.

Perhaps among the more striking aspects of SA Burt's performance on the witness stand is the anticipated testimony which he did not provide. When viewed in its entirety, SA Burt's record testimony was stunningly sparse when compared with his proposed

[28] In fact, as addressed *infra*, SA Burt did not review the recordings or read the history and physical examination form contained in the UC's patient file with an eye towards determining if the audio corroborated the information on the forms. Furthermore, Burt admitted these recordings were not provided to Dr. Kennedy for his use in formulating his expert testimony and reports. Tr. at 1007.

[29] As discussed in more detail anon, this development was particularly troubling in light of the Respondent's prehearing motion practice where he sought the disclosure of precisely this variety of evidence.

[30] Tr. at 1012.

[31] SA Burt testified that he has never actually seen the described pill bottle. Tr. at 830. Burt also revealed on cross-examination that he has never reviewed a patient file relative to CS1, and that said patient file was not reviewed by a doctor to determine the propriety of the controlled substance prescriptions purportedly issued by the Respondent. *Id.* at 1015.

[32] In light of the inability to identify the name of this source of information to opposing counsel, and the lack of detail and corroborating evidence related to the information derived from him, no weight can be assigned to SA Burt's testimony concerning information provided by CS1, other than the fact that it may have informed DEA's investigation. To proceed otherwise would deny the Respondent the ability guaranteed by the APA "to conduct such cross-examination as may be required for a full and true disclosure of the facts." 5 U.S.C. 556(d); *see Richardson* v. *Perales,* 402 U.S. 389, 402 (1971); *J.A.M. Builders* v. *Herman,* 233 F.3d 1350, 1354 (11th Cir. 2000); *Keller* v. *Sullivan,* 928 F.2d 227, 230 (7th Cir. 1991); *Calhoun* v. *Bailar,* 626 F.2d 145, 149 (9th Cir. 1980).

[33] Although similar testimony concerning the overdose death of a third individual, OB, was noticed in the Government's prehearing statement, it was not offered by the Government at the hearing. ALJ Ex. 6 at 8.

[34] According to SA Burt, a "task force officer" is a local police officer or sheriff's deputy that is assigned to work on a DEA task force, rather than a sworn DEA criminal investigator. Tr. at 1031.

[35] *See* Tr. at 836–53 (addressing exclusion of Govt. Ex. 27 and associated testimony).

testimony as noticed in the Government's prehearing statement.[36] That certain information may be unavailable for reasons related to other litigation forums or other equally valid reasons are of no moment with respect to the evaluation that must be made at this administrative forum. Equally important, such considerations do not alter the burdens imposed upon the respective parties. Simply put, the admitted evidence must succeed or fail on its own merits, irrespective of extraneous considerations.

Even apart from the marked contrast between the Burt testimony as proffered and as realized, his testimony was marred by periodic memory failures on significant issues and an inability to supply details to an extent that it could arguably have diminished the weight that could be fairly attached to those aspects of his own investigation that he did manage to recollect. During his testimony, SA Burt acknowledged his own marked lack of preparation and unfamiliarity with the investigation and confessed simply that "[t]here's no excuse * * *." *Id.* at 1003–05.

Even acknowledging its obvious suboptimal aspects, SA Burt's testimony had no apparent nefarious motivation or indicia of intentional deceit. Burt came across as an earnest and believable witness, who, regarding the aspects of the case that he did recall, was able to impart substantial information about the investigation and activities involving American Pain and its doctors. While frequently lacking in detail, his testimony was not internally inconsistent or facially implausible, and although the legal weight I have assigned to certain portions of Burt's testimony varies given the issues described, I find his testimony to be credible overall.

The Government presented the bulk of its case through the report and testimony of its expert, L. Douglas Kennedy, M.D., D.A.B.P.M., Affiliate Clinical Assistant Professor at the University of Miami, Miller School of Medicine.[37] Dr. Kennedy was offered by the Government and accepted as an expert in the field of pain medicine. *Id.* at 39. In Dr. Kennedy's expert opinion, based on a documentary review of the patient charts from the Respondent's practice that he reviewed, the Respondent's prescribing practices fell below the standards set forth by the Florida Medical Board. *Id.* at 176–77, 365. Dr. Kennedy stated that

> there was no true doctor/patient relationship established for the prescription of controlled substances at the first or any visit, and [] it was grossly deficient and medically dangerous to prescribe in the fashion it was prescribed for the same reasons.

Id. Furthermore, Dr. Kennedy testified that after reviewing the charts, he concluded that the prescribing of controlled substances by the Respondent to the patients named in the charts was not for a legitimate medical purpose. *Id.* at 182.

During the course of his testimony, Dr. Kennedy explained that he took professional issue with several aspects of the Respondent's patient care as reflected in the charts regarding the prescribing of controlled substances. It is apparent from his testimony that Dr. Kennedy's analysis is restricted to those matters which can be gleaned from an examination of the written word in that subset of the Respondent's patient files provided by the Government for his review, and that limitation perforce circumscribes the breadth of his testimony. That being said, Dr. Kennedy highlighted numerous features in the Respondent's chart documentation that he found wanting, or at least remarkable.

While, during his testimony, Dr. Kennedy acknowledged that some level of standardization and utilization of forms is not, standing alone, improper,[38] Dr. Kennedy took issue with what he perceived as flaws in the forms utilized by the Respondent to document patient care. Dr. Kennedy even acknowledged that the Respondent's possession and use of stamps to affix prescription descriptions and doses on scripts, was not, standing alone, improper. *Id.* at 178. However, according to Dr. Kennedy, the forms employed by the Respondent were "grossly deficient in that [they] didn't really justify why the individual was given the high doses of narcotics or controlled substances that they were." *Id.* at 177.

Dr. Kennedy explained that there are basic elements to practicing pain medicine. The acquisition of a thorough history and physical examination is important. *Id.* at 41–42. He also stressed the vital importance of obtaining past medical records to evaluate what treatments, therapies, medications, and dosages have been utilized in the past so that correct current treatment decisions can be made. *Id.* at 45–46. Reliance upon the patient's memory of these elements without the prior medical records, in Dr. Kennedy's view is not reliable or acceptable. *Id.* at 46–47. Dr. Kennedy acknowledged that physicians customarily accept patients at their word, but on the subject of verifying a patient's subjective complaint and medication history, Dr. Kennedy explained that

> [s]ometimes you have to help people understand why they're suffering or what their problems are. A person with an addiction or drug abuse problem is no worse a human being than me. I'm not any better than them. But it's your job as a doctor to sit down and find out what the truth is as well as you reasonably can under the circumstances. That wasn't done here, in my opinion.

Id. at 357.

Kennedy also explained the importance of establishing a differential or working diagnosis on the first visit, and modifying and reviewing that diagnosis as more information and results become available. *Id.* at 49. Similarly, a diagnostic plan is a systematic methodology of eliminating possible causes of symptoms to allow the treating physician to accurately determine what is causing them so that a successful treatment plan can be developed. *Id.* at 49–50. In other words, the diagnostic plan allows the treating doctor to eliminate or confirm items on the differential diagnosis. *Id.* at 50–52.

Dr. Kennedy testified that in his expert opinion, the Respondent's histories and physical examinations were "grossly deficient in that [the documentation] didn't really justify why the [patient] was given the high doses of narcotics or controlled substance that they were." *Id.* at 177. Kennedy stated that, in his view, the treatment plans evident in the charts were also defective because there was no individualized consideration apparent, that "[e]verybody got essentially the same thing," and that the treatment plans for all patients were invariably limited to a single option, *i.e.,* "the treatment plan was to give controlled substances, and that was essentially it."[39] *Id.* at 78.

[36] ALJ Ex. 6.

[37] Dr. Kennedy's CV was admitted into evidence. Govt. Ex. 117.

[38] Tr. at 74.

[39] At the consolidated hearing in this matter, the Government elicited testimony from Dr. Kennedy regarding additional aspects of practice that he found deficient regarding the prescribing practices of other respondents. For example, Dr. Kennedy opined that the prescribing of 30 mg of oxycodone to an opioid naïve patient would, in his opinion, be dangerous and improper. Similarly, Dr. Kennedy provided his opinion that the practice of ordering of an MRI prior to a physician meeting with a patient would be improper. However, regarding the charts that Dr. Kennedy reviewed relative to this Respondent, the government adduced no testimonial evidence regarding issues such as opioid naïveté or the timing of MRI scripts, and it would be unfair, improper and illogical for an Administrative Law Judge to extrapolate the

Although Dr. Kennedy had earlier conceded that it is the judgment of the examining physician that is generally relied upon in determining the necessity and appropriateness of diagnostic testing,[40] he also testified that, at least in his view, exclusive reliance on MRI procedures as the sole diagnostic tool is suboptimal, because they are not always required and not always appropriate. *Id.* at 75–77, 165–66. Kennedy characterized MRIs as the Respondent's principal diagnostic tool. *Id.* at 177.

Dr. Kennedy prepared two reports in connection with the Government's case against the Respondent, both of which are dated April 30, 2010, and both of which were admitted into evidence during his testimony. Govt. Exs. 28, 131; Tr. at 174, 194. One of the reports describes a general analysis of seventeen charts that the Respondent maintained on as many patients, that were (selected by and) provided to Dr. Kennedy by the Government from among patient files seized pursuant to a criminal search warrant executed at the Respondent's practice on March 3, 2010 (Patient Charts Analysis).[41] Govt. Ex. 28. Although this report purports to describe practices common to all seventeen files reviewed by Dr. Kennedy, much of the analysis is directed toward a chart prepared in connection with RZ,[42] one of the Respondent's patients. A second report (Supplemental Chart Analysis) prepared by Dr. Kennedy focuses on the chart maintained under the name Luis Lopez, which was the assumed name of a law enforcement officer who visited the Respondent's practice in an undercover capacity. Govt. Ex. 131; Tr. at 188, 335.

Many of the observations and conclusions contained within the two reports are remarkably similar. Dr. Kennedy's report makes it unambiguously clear that, at least in his opinion, all eighteen of the Respondent's charts that he reviewed suffered from the same shortcomings. The Patient Charts Analysis states that the Respondent's patient charts that Dr. Kennedy reviewed "are essentially the same with regard to review issues; as stated in the report of [RZ] referenced and discussed in this report in detail, [and that] there were no significant differences that affected [his] conclusions and summary." Govt. Ex. 28 at 2. A like-worded proviso accompanies Dr. Kennedy's analysis of the chart prepared in connection with the undercover officer's (Luis Lopez's) interaction in the Supplemental Chart Analysis. Govt. Ex. 131 at 1.

In Dr. Kennedy's opinion, the patient charts he reviewed that were prepared by the Respondent reflected care that fell below the applicable standard on multiple levels. In his report, Dr. Kennedy noted that the treatment notes in the charts: (1) contained no typewritten clinical notes and were "very brief, difficult to read (often impossible) and not within the standard of care due to their brevity and quality";[43] (2) reflected prescriptions, right from the initial patient visit, that "were almost entirely for controlled substances, most often one or two immediate release oxycodone pills with Xanax," and which were, in Dr. Kennedy's view, inappropriate and more powerful than justified by the objective signs documented in the written notes;[44] (3) showed that "the same or very similar 'drug cocktails' were prescribed [among all patients in the reviewed files] in the same or very similar doses, [directions] * * * with a 30-day supply," and were affixed to the prescription scripts with a few prepared stamps utilized by all American Pain physicians that reflected "drug, dose, sig (directions) and quantity dispensed;"[45] (4) contained medication contracts that were "not always signed" and "listed criteria that was not followed by the doctors at American Pain;[46] (5) failed to document the efficacy of the prescribed medication; (6) did not set forth a "diagnostic plan, except to obtain an occasional MRI, the results of which made no difference in the 'treatment'";[47] (7) reflected "no therapeutic plan, except to use controlled substances to 'treat' the subjective complaint of 'pain' which was inadequately described;[48] (8) did not reflect "real therapeutic goals * * * for improvement of quality of life (activities of daily living, work, sleep, mood)";[49] (9) did not reflect "consultations with other physicians or specialists outside the American Pain group [which] could have and in some cases should have included orthopedics, neurology, neurosurgery, psychiatry, addiction medicine and psychology";[50] (10) reflected "a gross lack of past medical records in all charts reviewed and in some cases none at all";[51] and, (11) demonstrated controlled substance patient monitoring practices that were "not within the standard of care and outside the boundaries of professional practice."[52]

Dr. Kennedy found the Respondent's controlled substance patient monitoring to be deficient in numerous respects. From the reviewed patient charts, Dr. Kennedy gleaned that an initial, in-office urine drug screen was frequently executed during the patients' initial visit to the office but repeated only occasionally.[53] Govt. Ex. 28 at 14; Tr. at

testimony elicited relative to the patients of other physician(s) to this Respondent. *See Gregg & Son Distribs.,* 74 FR 17517 n.1 (2009) (data should be provided while record is open, and "[t]o make clear, it is the Government's obligation as part of its burden of proof and not the ALJ's responsibility to sift through the records and highlight that information which is probative of the issues in the proceeding") citing *Southwood Pharms., Inc.,* 72 FR 36487, 36503 n.25 (2007). The absence of testimonial support by Dr. Kennedy on these issues relative to this Respondent does not adversely affect the weight to be attached to the conclusions set forth in the reports he prepared in connection with this Respondent which were received into evidence. Govt. Exs. 28, 131.

[40] Tr. at 63.

[41] During the prehearing proceedings, the Respondent moved for an order compelling production of, *inter alia,* all patient files seized from his office by the Government. The request (which was opposed by the Government) was denied in a separate order as *ultra vires.* ALJ Ex. 20; s*ee Nicholas A. Sychak, d/b/a Medicap Pharmacy,* 65 FR 75959, 75961 (2000); *Roy E. Berkowitz, M.D.,* 74 FR 3678, 36760 (2009).

[42] At the request of the Government, a protective order was issued that is designed to minimize the risk of the dissemination of identifying information related to patients and their relatives associated with this case. Accordingly, initials have been substituted for the names of individuals within the protection of the protective order throughout the body of this decision. ALJ Ex. 17.

[43] Govt. Ex. 28 at 4.

[44] In Dr. Kennedy's opinion, the Respondent "prescribed, at the first visit, very high initial doses of controlled substance combinations despite not being within the standard of care for histories, physical examinations and/or absent past medical records [with] no apparent consideration given to patient safety with initial or subsequent prescription of controlled substance[s]." Govt. Ex. 28 at 7.

[45] Govt. Ex. 28 at 4.

[46] As an example of the failure to adhere to the terms of the medication contract, Dr. Kennedy cites a contract term that provides notice that the physician may stop prescribing opioids or change treatment if pain or activity improvement is not demonstrated, and points out that pain and activity levels are routinely not documented in treatment notes. Govt. Ex. 28 at 4. Similarly, Dr. Kennedy references a medication contract warning that termination of services may result from failure to make regular follow-up appointments with primary care physicians, and notes that the American Pain charts contain no notes from primary care physicians or medical records generated by them. *Id.*

[47] Govt. Ex. 28 at 7. In Dr. Kennedy's opinion, Respondent in effect, acted as a "barrier" for [RZ] to receive appropriate medical evaluation and treatment. In other words, the very potent, high doses of opioids (oxycodone) and benzodiazepine (Xanax) may have masked or cover[ed] up [RZ's] underlying disease process(s), making them more difficult to diagnose, and allowing the disease(s) to unnecessarily worsen. Without an accurate diagnosis, all [the Respondent] was doing was, again, masking or covering up the symptoms. *Id.* at 10.

[48] Govt. Ex. 28 at 7.

[49] Govt. Ex. 28 at 8.

[50] Govt. Ex. 28 at 7.

[51] Govt. Ex. 28 at 15. RZ's chart did not contain a request for past medical records. *Id.* at 8.

[52] Govt. Ex. 28 at 14.

[53] However, when pressed on the issue, Dr. Kennedy declined to identify any specific instance

Continued

179–80. It was Dr. Kennedy's observation that even a drug screen anomaly did not alter the seemingly inexorable continuation of controlled substance prescribing from the Respondent. *Id.* Dr. Kennedy also noted that the Respondent did not utilize out-of-office toxicology tests, or obtain out-of-state prescription monitoring program or outside pharmacy drug profiles. Furthermore, the charts contained only rare evidence of contact with primary care physicians, treating physicians, pharmacists, or other health care providers. *Id.*

The identified shortcomings of controlled substance patient monitoring systems was of particular significance where Dr. Kennedy identified specific evidence that he identified as "red flags" of possible or likely diversion. In addition to providing incomplete information on his patient questionnaires, the undercover officer (a/k/a Luis Lopez) admitted to the Respondent that he had previously purchased oxycodone on the street. Govt. Exs. 46 at 9, 131 at 3. Other red flags noted by Dr. Kennedy in the reviewed charts included the relatively young age (in Kennedy's view) of the Respondent's chronic pain patients,[54] incomplete history information provided by the patients, periodically significant gaps between office visits,[55] referrals from friends, relatives, or advertising, but not other physicians,[56] and the fact that a relatively high number of patients were traveling significant distances to American Pain for pain treatment, although no physician employed at that facility had any specialized training in pain management.[57]

At the hearing, Dr. Kennedy testified that the entries in some of the charts that reflected that the patients were acquiring controlled substances "off the street," and urine drug screen results that were inconsistent with patient disclosures, were red flags that should have motivated a prudent physician to perform additional due-diligence steps, that, in addition to discussing the matter with the patient, could include reaching out to family members, previous treating physicians and pharmacists, obtaining past medical records, and additional testing. Tr. at 359–60, 362. Dr. Kennedy testified that his evaluation revealed that these red flags were present in the charts and precipitated no due-diligence actions on the Respondent's part. *Id.* at 360–64, 368–69.

On the issue of red flags, WA's patient file contains the Respondent's handwritten notation indicating the patient acquired oxycodone and Xanax "off [the] streets," yet the Respondent authorized prescriptions for Roxicodone, Xanax, and Percocet to WA during his initial and subsequent visits. Govt. Ex. 29 at 11, 23–33. Like scenarios were also apparent in the charts of numerous other patients who had informed the Respondent that they had previously acquired such substances in this illegal manner, including the undercover law enforcement officer (Luis Lopez). *See* Govt. Exs. 30 at 7; 33 at 4; 34 at 5; 37 at 1; 39 at 4; 40 at 1; 46 at 9 (notations indicating patients acquiring controlled substances "off the street"). Another patient file contained a similar note that the patient had received oxycodone "from [a] friend." Govt. Ex. 44 at 13.

KA's patient file contains a form indicating a positive UDS for opiates and oxycodone from 7/9/09, yet on the same date, the patient comfort assessment guide and medication contract signed by KA are both blank in the section where a patient is supposed to list any medications he or she is currently taking. Govt. Ex. 30 at 14–15, 33; *see also* Govt. Exs. 33 at 8–9, 23; 43 at 10–11, 27 (similar issues). Patient JR's 5/27/[09] UDS indicates a negative test for all listed substances, yet on her signed medication contract from the same date, she indicates she is currently taking three substances which, though misspelled, appear to refer to oxycodone, Percocet, and Xanax, a discrepancy which raises questions about the validity of the testing procedures and/or the patient's candor. Govt. Ex. 35 at 12, 26. Patient AZ's [58] UDS form, on the other hand, lists positive test results for oxycodone and opiates only on 11/12/09, yet the patient claims on two different documents from the same date that, in addition to two different strengths of Roxicodone, she is also currently taking clonazepam, a benzodiazepine that should have triggered a positive reading for that substance on her drug screen.[59] Govt. Ex. 45 at 9–10, 24. A prescribed controlled substance that is not reflected in a drug screen should have raised a sufficient suspicion of diversion to merit further inquiry by the registrant reflected in the patient file. At a minimum, these observations support the conclusion there was a general lack of vigilance on the part of the Respondent regarding his obligations as a registrant to minimize the risk of controlled substance diversion.

Dr. Kennedy also found it remarkable that each American Pain patient file provided notice to its patients that American Pain did not accept any form of health care insurance. Govt. Ex. 28 at 3–4, 16. Dr. Kennedy's report set forth his opinion that this practice was designed to "effectively keep [the physicians at American Pain] 'off the radar' from monitoring by any private health care insurance company as well as all state and federal agencies (Medicaid and Medicare respectively). Govt. Ex. 28 at 16. Significantly, however, when asked, Dr. Kennedy acknowledged that he conducts his own current medical practice on a cash-only basis. Tr. at 151.

Notwithstanding the discomfiture that Dr. Kennedy expressed regarding non-physician referrals in his report, during his testimony at the hearing he clarified that it was not unusual for a physician to treat patients that have been referred by relatives and friends. *Id.* at 154. Further, Kennedy conceded while in the course of his own medical practice he has treated patients referred by family and friends, and that in his report he was focusing on what he perceived as a lack of any referrals by physicians in the files he reviewed, or what he perceived as "trends" or "patterns." *Id.* at 154–55. Given Dr. Kennedy's acknowledgement that such referrals are not unusual, coupled with the absence of any record-evidence way to measure the relative percentage of physician referrals in the Respondent's practice based on this limited sample of charts, the observations regarding referral sources are of limited value here.[60]

A review of the 18 patient files that informed the analysis, findings and

regarding any of Respondent's charts where he would have ordered an additional drug screen. Tr. at 180.

[54] Govt. Ex. 28 at 15.

[55] Govt. Ex. 28 at 13.

[56] Govt. Ex. 28 at 8, 15.

[57] Govt. Ex. 28 at 16.

[58] Given the testimony of SA Burt regarding the level of activity outside American Pain parking area as observed through the pole cam, it is remarkable that one patient actually indicated that one of the reasons she left the previous pain clinic she frequented was because of "people hanging outside place approaching patients for their medications." Govt. Ex. 45 at 20.

[59] Although a mathematically conceivable explanation for this discrepancy could be that the patient exhausted her prescribed clonazepam stock sufficiently in advance of the 11/12/09 testing so as to not register a positive reading, the chart should have reflected that the physician recognized, addressed, and documented this red flag regarding a potential abuse or diversion issue.

[60] Dr. Kennedy did not testify that a referral that emanated from a source other than a physician could or should be a basis for a diversion red flag on a given case. His opinion was limited to culling some manner of a trend or pattern. In view of the fact that the record contains no development of the numbers of files with non-physician referrals versus the total number of files, or even an acceptable metric upon which the issue could be evaluated, there is very little useful analysis that can come from Dr. Kennedy's observation regarding the files he reviewed.

conclusions offered in Dr. Kennedy's written report and testimony does reflect the presence of at least some of the red flag issues he identified therein, but there was not the unanimity among the files that he repeatedly urges. A review of the files reveals other treatment modalities beyond the exclusive regimen of controlled substances reflected in the selected patient charts urged by Kennedy in his report.[61] Govt. Exs. 30 at 1; 34 at 1; 35 at 1; 36 at 7; 38 at 3; 43 at 2; 44 at 2; 36 at 6, 27.

Dr. Kennedy concluded his report regarding the Respondent's prescribing practices with the following summary:

[The Respondent] was not engaged in the practice of medicine, rather he was engaged in an efficient, "[a]ssembly [l]ine" business. His "patients" were revenue streams, not true patients. This business allowed him to collect cas[h] for office visits as well as being a "[d]ispensing [p]hysician" for controlled substances. He prescribed controlled substances so that "patients" would return to his office on a regular basis, allowing him to generate further revenue. [The Respondent's] routine and excessive prescription of multiple controlled substances (oxycodone and Xanax) and lack of arriving at a valid medical diagnosis and treatment most likely caused harm to the "patients" he saw. Drug diversion most likely caused a "mushroom" effect of increased drug abuse, drug addiction, drug overdoses, serious bodily injury and death in those communities spread over several different states. [The Respondent's] continued ability to prescribe controlled substances will only perpetuate the suffering and be a threat to the public.

Govt. Ex. 28 at 16.

On cross examination at the hearing, Dr. Kennedy's attention was directed to what would seem, at least to a lay person, to present as including a significant level of detail set forth in the charts he reviewed relative to the Respondent's patient documentation, including both subjective complaints of discomfort and objective signs of medical anomalies. Tr. at 214–27, 230, 233–38, 243–44, 246–56, 262–66, 269–70, 273–87, 289–98, 305–08, 311–18, 320–29, 332–47, 366. Even the file prepared in connection with the undercover officer's interaction with the Respondent reflects recorded subjective complaints coupled with a remarkable MRI and other objective signs indicating some medical pathology. *Id.* at 335–47. Undaunted, Dr. Kennedy (the sole expert to testify at the hearing), remained committed to his position that the manner in which the documentation was completed was fundamentally insufficient for a physician to adequately proceed to treat the patients with controlled substances. *Id.* at 226–29, 231–32, 238–41, 258, 262, 264, 267–68, 286, 290, 299–301, 309–11, 342–43, 366–67. Dr. Kennedy, more than once, succinctly stated that "[i]t's not even close." *Id.* at 268, 310.

The Government's presentation of Dr. Kennedy's testimony at the hearing was substantially consistent with the conclusions included in the Patient Charts Analysis, but Dr. Kennedy's presentation was clearly not without its blemishes. Although he testified that he was familiar with prescribing practices in Florida, and that he utilized the medical standards applicable to Florida practice,[62] he was unable to identify the documentation standard in the Florida Administrative code with any degree of particularity, and he also acknowledged that he was not aware of what the standard is in Florida Medical Board administrative decisions regarding the overprescribing of medication or what constitutes an adequate medical history. *Id.* at 149–51, 233, 304. While, overall, Kennedy presented testimony that appeared candid and knowledgeable, there were areas in his written report that rang of hyperbole and over-embellishment. The reasoning behind some of the seemingly critical observations in the written report, such as the "cash basis" of the Respondent's practice and the absence of doctor referrals among the reviewed patient files, did not well survive the crucible of cross examination at the hearing. However, overall, Dr. Kennedy's testimony was sufficiently detailed, plausible, and internally consistent to be considered credible, and, consistent with his qualifications, he spoke persuasively and with authority on some relevant issues within his expertise, and notwithstanding the Respondent's objections relative to his Florida-related experience, he is currently an assistant professor teaching at a Florida Medical School. It may well be that the greatest and most significant aspect of Dr. Kennedy's opinion is that on the current record, it stands unrefuted. Thus, his opinion is the only expert opinion available for reliance in this action.[63] Consistent with his written report, Dr. Kennedy testified that from what he could glean in the charts he examined, the physical examinations were "grossly deficient in that [the physical examination] didn't really justify why the individual was given the high doses of narcotics or controlled substances that they were," that MRIs were the primary diagnostic tools and they should not have been, that the treatment plans were improperly "rubber stamped" with few modifications, and "there was no true doctor/patient relationship established for the prescription of controlled substances at the first of any visit, and that it was grossly deficient and medically dangerous to prescribe in the fashion it was prescribed for the same reasons." *Id.* at 177–79. Accordingly, Dr. Kennedy's expert opinion that the Respondent's controlled substance prescribing practices, at least as evidenced through his examination of the patient charts he reviewed, fell below the standards applicable in Florida, and that the controlled substance prescriptions contained in those files were not issued for a legitimate medical purpose is unrefuted on this record and (although by no means overwhelming) is sufficiently reliable to be accepted and relied upon in this recommended decision.

The Analysis

Pursuant to 21 U.S.C. 824(a)(4), the Deputy Administrator[64] may revoke a registrant's DEA Certificate of Registration if persuaded that the registrant "has committed such acts that would render * * * registration under section 823 * * * inconsistent with the public interest * * * " The following factors have been provided by Congress in determining "the public interest":

(1) The recommendation of the appropriate State licensing board or professional disciplinary authority.

(2) The applicant's experience in dispensing, or conducting research with respect to controlled substances.

(3) The applicant's conviction record under Federal or State laws relating to the manufacture, distribution, or dispensing of controlled substances.

(4) Compliance with applicable State, Federal or local laws relating to controlled substances.

(5) Such other conduct which may threaten the public health and safety.

[61] The Government's tactical decision to essentially unload a pile of charts that are explained only by the representations and generalizations in a report, with no attempt whatsoever to have its expert witness explain the applicable aspects of most charts to this tribunal or any future reviewing body is clearly at odds with the directive provided by the Deputy Administrator in *Gregg & Son Distributors* that "it is the Government's obligation as part of its burden of proof and not the ALJ's responsibility to sift through the records and highlight that information which is probative of the issues in the proceeding." 74 FR 17517 n.1.

[62] Tr. at 628.

[63] The Respondent did not testify on his own behalf.

[64] This authority has been delegated pursuant to 28 CFR 0.100(b) and 0.104.

21 U.S.C. 823(f).

"[T]hese factors are considered in the disjunctive." *Robert A. Leslie, M.D.,* 68 FR 15227, 15230 (2003). Any one or a combination of factors may be relied upon, and when exercising authority as an impartial adjudicator, the Deputy Administrator may properly give each factor whatever weight she deems appropriate in determining whether an application for a registration should be denied. *JLB, Inc., d/b/a Boyd Drugs,* 53 FR 43945 (1988); *England Pharmacy,* 52 FR 1674 (1987); *see also David H. Gillis, M.D.,* 58 FR 37507, 37508 (1993); *Joy's Ideas,* 70 FR 33195, 33197 (2005); *Henry J. Schwarz, Jr., M.D.,* 54 FR 16422 (1989). Moreover, the Deputy Administrator is "not required to make findings as to all of the factors * * * " *Hoxie* v. *DEA,* 419 F.3d 477, 482 (6th Cir. 2005); *see also Morall* v. *DEA,* 412 F.3d 165, 173–74 (D.C. Cir. 2005). The Deputy Administrator is not required to discuss consideration of each factor in equal detail, or even every factor in any given level of detail. *Trawick* v. *DEA,* 861 F.2d 72, 76 (4th Cir. 1988) (the Administrator's obligation to explain the decision rationale may be satisfied even if only minimal consideration is given to the relevant factors and remand is required only when it is unclear whether the relevant factors were considered at all). The balancing of the public interest factors "is not a contest in which score is kept; the Agency is not required to mechanically count up the factors and determine how many favor the Government and how many favor the registrant. Rather, it is an inquiry which focuses on protecting the public interest * * * " *Jayam Krishna-Iyer, M.D.,* 74 FR 459, 462 (2009).

In an action to revoke a registrant's DEA COR, the DEA has the burden of proving that the requirements for revocation are satisfied. 21 CFR 1301.44(e). Once DEA has made its *prima facie* case for revocation of the registrant's DEA Certificate of Registration, the burden of production then shifts to the Respondent to show that, given the totality of the facts and circumstances in the record, revoking the registrant's registration would not be appropriate. *Morall,* 412 F.3d at 174; *Humphreys* v. *DEA,* 96 F.3d 658, 661 (3d Cir. 1996); *Shatz* v. *U.S. Dept. of Justice,* 873 F.2d 1089, 1091 (8th Cir. 1989); *Thomas E. Johnston,* 45 FR 72, 311 (1980). Further, "to rebut the Government's *prima facie* case, [the Respondent] is required not only to accept responsibility for [the established] misconduct, but also to demonstrate what corrective measures [have been] undertaken to prevent the reoccurrence of similar acts." *Jeri Hassman, M.D.,* 75 FR 8194, 8236 (2010).

Where the Government has sustained its burden and established that a registrant has committed acts inconsistent with the public interest, that registrant must present sufficient mitigating evidence to assure the Deputy Administrator that he can be entrusted with the responsibility commensurate with such a registration. *Steven M. Abbadessa, D.O.,* 74 FR 10077 (2009); *Medicine Shoppe-Jonesborough,* 73 FR 364, 387 (2008); *Samuel S. Jackson, D.D.S.,* 72 FR 23848, 23853 (2007). Normal hardships to the practitioner, and even the surrounding community, that are attendant upon the lack of registration are not a relevant consideration. *Abbadessa,* 74 FR at 10078; *see also Gregory D. Owens, D.D.S.,* 74 FR 36751, 36757 (2009).

The Agency's conclusion that past performance is the best predictor of future performance has been sustained on review in the courts, *Alra Labs.* v. *DEA,* 54 F.3d 450, 452 (7th Cir. 1995), as has the Agency's consistent policy of strongly weighing whether a registrant who has committed acts inconsistent with the public interest has accepted responsibility and demonstrated that he or she will not engage in future misconduct. *Hoxie,* 419 F.3d at 483; *George C. Aycock, M.D.,* 74 FR 17529, 17543 (2009); *Abbadessa,* 74 FR at 10078; *Krishna-Iyer,* 74 FR at 463; *Medicine Shoppe,* 73 FR at 387.

While the burden of proof at this administrative hearing is a preponderance-of-the-evidence standard, *see Steadman* v. *SEC,* 450 U.S. 91, 100–01 (1981), the Deputy Administrator's factual findings will be sustained on review to the extent they are supported by "substantial evidence." *Hoxie,* 419 F.3d at 481. While "the possibility of drawing two inconsistent conclusions from the evidence" does not limit the Deputy Administrator's ability to find facts on either side of the contested issues in the case, *Shatz,* 873 F.2d at 1092; *Trawick,* 861 F.2d at 77, all "important aspect[s] of the problem," such as a respondent's defense or explanation that runs counter to the Government's evidence, must be considered. *Wedgewood Vill. Pharmacy* v. *DEA,* 509 F.3d 541, 549 (D.C. Cir. 2007); *Humphreys,* 96 F.3d at 663. The ultimate disposition of the case must be in accordance with the weight of the evidence, not simply supported by enough evidence to justify, if the trial were to a jury, a refusal to direct a verdict when the conclusion sought to be drawn from it is one of fact for the jury. *Steadman,* 450 U.S. at 99 (internal quotation marks omitted).

Regarding the exercise of discretionary authority, the courts have recognized that gross deviations from past agency precedent must be adequately supported, *Morall,* 412 F.3d at 183, but mere unevenness in application does not, standing alone, render a particular discretionary action unwarranted. *Chein* v. *DEA,* 533 F.3d 828, 835 (D.C. Cir. 2008) (citing *Butz* v. *Glover Livestock Comm. Co., Inc.,* 411 U.S. 182, 188 (1973)), *cert. denied,* __ U.S. __, 129 S.Ct. 1033 (2009). It is well-settled that since the Administrative Law Judge has had the opportunity to observe the demeanor and conduct of hearing witnesses, the factual findings set forth in this recommended decision are entitled to significant deference, *Universal Camera Corp.* v. *NLRB,* 340 U.S. 474, 496 (1951), and that this recommended decision constitutes an important part of the record that must be considered in the Deputy Administrator's decision, *Morall,* 412 F.3d at 179. However, any recommendations set forth herein regarding the exercise of discretion are by no means binding on the Deputy Administrator and do not limit the exercise of that discretion. 5 U.S.C. 557(b); *River Forest Pharmacy, Inc.* v. *DEA,* 501 F.2d 1202, 1206 (7th Cir. 1974); *Attorney General's Manual on the Administrative Procedure Act* 8 (1947).

Factors 1 and 3: The Recommendation of the Appropriate State Licensing Board or Professional Disciplinary Authority and Conviction Record Under Federal or State Laws Relating to the Manufacture, Distribution, or Dispensing of Controlled Substances

In this case, it is undisputed that the Respondent holds a valid and current state license to practice medicine. The record contains no evidence of a recommendation regarding the Respondent's medical privileges by any cognizant state licensing board or professional disciplinary authority. However, that a state has not acted against a registrant's medical license is not dispositive in this administrative determination as to whether continuation of a registration is consistent with the public interest. *Patrick W. Stodola, M.D.,* 74 FR 20727, 20730 (2009); *Jayam Krishna-Iyer,* 74 FR at 461. It is well-established Agency precedent that a "state license is a necessary, but not a sufficient condition for registration." *Leslie,* 68 FR at 15230; *John H. Kennedy, M.D.,* 71 FR 35705, 35708 (2006). Even the reinstatement of a state medical license does not affect the DEA's independent responsibility to

determine whether a registration is in the public interest. *Mortimer B. Levin, D.O.,* 55 FR 9209, 8210 (1990). The ultimate responsibility to determine whether a registration is consistent with the public interest has been delegated exclusively to the DEA, not to entities within state government. *Edmund Chein, M.D.,* 72 FR 6580, 6590 (2007), *aff'd, Chein* v. *DEA,* 533 F.3d 828 (D.C. Cir. 2008), *cert. denied,* __U.S.__, 129 S.Ct. 1033 (2009). Congress vested authority to enforce the CSA in the Attorney General and not state officials. *Stodola,* 74 FR at 20375. Thus, on these facts, the fact that the record contains no evidence of a recommendation by a state licensing board does not weigh for or against a determination as to whether continuation of the Respondent's DEA certification is consistent with the public interest.

Similarly, regarding Factor 3, while testimony was received at the hearing that indicated that a criminal search warrant was executed regarding the Respondent and American Pain, the record contains no evidence that the Respondent has ever been convicted of any crime or even arrested in connection with any open criminal investigation. Thus, consideration of the record evidence under the first and third factors does not militate in favor of revocation.

Factors 2, 4 and 5: The Respondent's Experience in Dispensing Controlled Substances, Compliance with Applicable State, Federal or Local Laws Relating to Controlled Substances, and Such Other Conduct Which May Threaten the Public Health and Safety

In this case, the gravamen of the allegations in the OSC, as well as the factual concentration of much of the evidence presented, share as a principal focus the manner in which the Respondent has managed that part of his practice relative to prescribing and dispensing controlled substances and acts allegedly committed in connection with his practice at American Pain. Thus, it is analytically logical to consider public interest factors two, four and five together. That being said, factors two, four and five involve analysis of both common and distinct considerations.

Regarding Factor 2, the qualitative manner and the quantitative volume in which a registrant has engaged in the dispensing of controlled substances, and how long he has been in the business of doing so are factors to be evaluated in reaching a determination as to whether he should be entrusted with a DEA certificate. In some cases, viewing a registrant's actions against a backdrop of how he has performed activity within the scope of the certificate can provide a contextual lens to assist in a fair adjudication of whether continued registration is in the public interest.

There are two principal considerations embedded within a consideration of this public interest factor. In considering a similar factor under the List I chemical context, the Agency has recognized that the level of experience held by those who will be charged with recognizing and taking steps to minimize diversion factors greatly in determining whether entrusting a COR will be in the public interest. *See Volusia Wholesale,* 69 FR 69409, 69410 (2004); *Xtreme Enters., Inc.,* 67 FR 76195, 76197–98 (2004); *Prachi Enters.,* 69 FR 69407, 69409 (2004); *J&S Distribs.,* 69 FR 62089, 62090 (2004); *K.V.M. Enters.,* 67 FR 70968, 70969 (2002). The Agency has also recognized that evidence that a registrant may have conducted a significant level of sustained activity within the scope of the registration for a sustained period is a relevant and correct consideration, which must be accorded due weight. However, this factor can be outweighed by acts held to be inconsistent with the public interest. Experience which occurred prior and subsequent to proven allegations of malfeasance may be relevant. Evidence that precedes proven misconduct may add support to the contention that, even acknowledging the gravity of a particular registrant's transgressions, they are sufficiently isolated and/or attenuated that adverse action against its registration is not compelled by public interest concerns. Likewise, evidence presented by the Government that the proven allegations are consistent with a consistent past pattern of poor behavior can enhance the Government's case.

In this case, notwithstanding the Respondent's *Krishna-Iyer*-based [65] protestation in his brief that he has been somehow denied the ability to present "positive experience in dispensing controlled substances,"[66] the Respondent introduced no evidence regarding his level of knowledge and experience, or even the quality or length of his experience as a physician-registrant. The Government, on the other hand did elect to present evidence on the subject.

Regarding the Government's presentation, Agency precedent has long held that in DEA administrative proceedings that "the parameters of the hearing are determined by the prehearing statements." *CBS Wholesale Distribs.,* 74 FR 36746, 36750 (2009) (citing *Darrel Risner, D.M.D.,* 61 FR 728, 730 (1996); *see also Roy E. Berkowitz, M.D.,* 74 FR 36758, 36759–60 (2009) ("pleadings in administrative proceedings are not judged by the standards applied to an indictment at common law" and "the rules governing DEA hearings do not require the formality of amending a show cause order to comply with the evidence"). That being said, however, the marked difference between the amount of evidence that the Government noticed in its OSC/ISO and the amount that it ultimately introduced at the hearing is striking. For example, contrary to its allegations, there was no evidence that the Respondent "prescribe[d] and dispense[d] *inordinate* amounts of controlled substances," that the "*majority*" of the Respondent's patients were "from states other than Florida," there was no evidence that American Pain patients were issued "*pre-signed* prescriptions to obtain MRI[s]," nor was there evidence that individuals positioned outside the American Pain building were there to "monitor the activity of patients in the parking lot *to prevent patients from selling their recently obtained controlled substances*." Likewise, no evidence was introduced at the hearing that could support the allegations that "employees of American Pain [] *frequently* ma[d]e announcements to patients in the clinic advising them on how to avoid being stopped by law enforcement upon departing the pain clinic" and "*frequently* ma[d]e announcements [] advising [patients], among other things, not to attempt to fill their prescriptions at out-of state pharmacies and warning them against trying to fill their prescriptions at particular local retail pharmacies." ALJ Ex. 1 (emphasis supplied).

In like fashion, the Government's prehearing statement proffered that SA Burt would testify to several of the items described but not established in the OSC/ISO. Among the list of allegations that were *not supported by any evidence introduced at the hearing,* were representations that SA Burt would testify concerning the following:

Law enforcement in Florida and [other states that correspond to license plates seen in the American Pain parking lot] frequently arrest people for illegal possession and/or illegal distribution of controlled substances who have obtained the controlled substances from American Pain;

[65] The Respondent cites the Agency's decision in *Krishna-Iyer,* 74 FR at 459–01 and the unpublished 11th Circuit remand related to that case. *Krishna-Iyer* v. *DEA,* No. 06–15034 (11th Cir. 2007), Slip Op. at 3.

[66] Respt's Br. at 3.

American Pain hired individuals to "roam" the parking lot of the clinic to dissuade people from selling their recently obtained controlled substances on the property;

[The reason American Pain placed] [t]here are signs within American Pain warning individuals not to have their prescriptions filed at Walgreens pharmacies [is] because Walgreens refuses to dispense the prescriptions;

Walgreens has flagged all American Pain doctors and will not fill any of their prescriptions;

[Physical exams at American Pain are] usually no more than a blood pressure check and some bending and stretching;

Dismissed patients would be routed to other doctors within the clinic;

[There was] co-mingling of [American Pain] physician's drugs;

[American Pain maintained] no inventories of drugs dispensed;

[Details surrounding] the death of [American Pain] patient OB [where] [t]he cause of death was determined to be drug intoxication—opiate and benzodiazepine;

[Information] from a confidential source [who indicated] that she traveled to American Pain in order to obtain controlled substances that were later sold in Kentucky for $25 per pill[,] [that] [the American Pain physician she encountered] did not spend any significant time conducting a physical examination of [her] [,] [that she would simply ask questions regarding [her] well being and would then "stamp" a prescription for [controlled substances][,] * * * that on one visit [during a power failure a] security guard working for the clinic instructed everyone to be patient and that the doctors would be with them shortly to "get your fix."

ALJ Ex. 6 at 3–9.

To be clear, it is not that the evidence was introduced and discredited; no evidence to support these (and other) allegations was introduced at all. To the extent the Government had this evidence, it left it home. While the stunning disparity between the allegations proffered and those that were supported with any evidence does not raise due process concerns, it is worthy of noting, without deciding the issue, that Agency precedent has acknowledged the Supreme Court's recognition of the applicability of the *res judicata* doctrine in DEA administrative proceedings. *Christopher Henry Lister, P.A.,* 75 FR 28068, 28069 (2010) (citing *Univ. of Tenn.* v. *Elliot,* 478 U.S. 788, 797–98 (1986) ("When an administrative agency is acting in a judicial capacity and resolves disputed issues of fact properly before it which the parties have had an adequate opportunity to litigate, the courts have not hesitated to apply *res judicata*[.]")

The evidence the Government did present raises issues regarding not only Factor 2 (experience dispensing[67] controlled substances), but also Factors 4 (compliance with federal and state law relating to controlled substances) and 5 (other conduct which may threaten public health and safety). Succinctly put, the Government's evidence related to the manner in which the Respondent practiced, and whether his practice complied with the law and/or was a threat to the public.

While true that GS Langston convincingly testified about the course of her investigation and laid an adequate foundation for numerous database results, the Government provided no foundational context for any relevant uses for those database results. Without some insight into what types of results from these databases should be expected when compared to similarly-situated registrants engaged in acceptable prescribing practices, the raw data is without use. In short, there was no evidence elicited wherein the percentage of the Respondent's in-state to out-of state patients could be assessed, and no reasonable measuring stick based on sound principles upon which to evaluate such data. Likewise, there was no reliable yardstick upon which to measure the amount of controlled substances reflected in the databases compared to what a reasonable regulator would expect to see regarding a compliant registrant. To the extent Langston possessed this information (and she well may have) it was not elicited from her. The same could be said of the allegation set forth in the Government's Prehearing Statement that alleges that from a given period the Respondent "was the 5th largest practitioner purchaser of oxycodone in the United States."[68] No evidence to support that allegation (or its relevance) was ever brought forth at the hearing. To the extent that fact may have been true or relevant, it was never developed. What's more, the Florida Administrative Code specifically eschews pain medication prescribing analysis rooted only in evaluation of medication quantity. Fla. Admin. Code r. 64B8–9.013(g). Lastly, there was no indication that despite Langston's obvious qualifications to do so, that she or anyone else ever conducted an audit of the controlled-substance-inventory-related recordkeeping practices at American Pain.

SA Burt testified that, during a temporally limited period of time, he observed some of the images captured by a pole camera positioned outside American Pain, and that he observed what in his view was a high percentage of vehicles in the parking lot with out-of-state license tags. This testimony arguably provides some support for the Government's contention that out-of-state patients (or at least patients being dropped off by cars with out-of-state tags) were being seen at the clinic, but his testimony did not provide much else in terms of relevant information. In any event, recent Agency precedent holds that details such as "where [a registrant's] patients were coming from," without additional factual development, can support a "strong suspicion that [a] respondent was not engaged in a legitimate medical practice" but that "under the substantial evidence test, the evidence must 'do more than create a suspicion of the existence of the fact to be established.'" *Alvin Darby, M.D.,* 75 FR 26993, 26999, n.31 (2010) (citing *NLRB* v. *Columbian Enameling & Stamping Co.,* 306 U.S. 292, 300 (1939).

Likewise, without additional details or at least some context, Burt's testimony that individuals with "staff" written on their shirts appeared to be directing patients into the clinic reveals virtually nothing about the Respondent's prescribing practices. Tr. 818, 910. Furthermore, that Burt observed an individual on a videotape, who he believed to be an American Pain employee, on a single occasion, instruct patients not to "snort [their] pills" in the parking lot,[69] or advising them to comply with vehicle and traffic laws,[70] does not shed illumination on the Respondent's prescribing practices. There was neither evidence that the Respondent knew that these isolated incidents occurred, nor was there contextual evidence from which the relevance to these proceedings could be gleaned. Even if this tribunal was inclined to engage in the unsupported assignment of motives to the actions of these employees, under these circumstances, such an exercise could not constitute substantial evidence that could be sustained at any level of appeal.

Burt's testimony regarding his conversations with Dr. Sollie, who was formerly employed by American Pain, was also not received in a manner that could meaningfully assist in the

[67] The statutory definition of the term "dispense" includes the prescribing and administering of controlled substances. 21 U.S.C. 802(10).

[68] ALJ Ex. 6 at 11–12.

[69] Tr. at 825.

[70] Tr. at 826.

decision process. According to Burt, Sollie told him that some (unnamed) physicians at American Pain were inadequately documenting their patient charts in some manner that was apparently never explained to Burt,[71] and that some patients were intentionally evading the American Pain urinalysis process. Sollie did not specifically name any physician as being connected with his allegations of misconduct. Thus, this tribunal is at something of a loss as to how the information, as presented, would tend to establish a fact relevant to whether the continuation of the Respondent's authorization to handle controlled substances is in the public interest.

The Government evidence connected with Burt's testimony concerning the undercover operations focused on the Respondent unfolded in a somewhat disquieting manner when viewed in context with the prior motion practice in this case. As a preliminary matter, it must be acknowledged that Burt's testimony regarding the details of the Luis Lopez evolution, because it lacked detail, was of negligible import. Burt related that the UC told him that American Pain employees made statements and Burt viewed some statements on videotape, but there is no indication as to who the employees were, why Burt or the UC believed them to be employees, or what the basis for the directions to the patients were. For example, American Pain employees advising patients to avoid a particular pharmacy would doubtless have more relevance to these proceedings if the Government had presented any evidence that the pharmacy to be avoided (Walgreens) had some aversion to filling American Pain prescriptions. There was no such evidence. To the extent the Government was seeking to introduce the UC interaction evidence with a view toward reflecting on the Respondent's prescribing practices, evidence regarding the details of the interaction between the Respondent and the UC would seem to have been imperative.[72] This is particularly true here, where an MRI actually showed that the UC had a back impairment that could be treated by the use of the controlled substances prescribed by the Respondent. Thus, other than to provide contextual evidence concerning one of the patient charts reviewed by Dr. Kennedy, Burt's testimony regarding the UC interaction does not advance the Government's case for revocation.

Of somewhat more concern is the procedural context of the UC-related portions of the Government's case. During pre-hearing procedures, the Respondent sought discovery in the form of, *inter alia*, "[a]ll audio and video recordings pertaining to visits to American Pain during which the undercover officer was seen by [the Respondent]." ALJ Ex. 18 at 1. The Government correctly pointed out that, under the Administrative Procedure Act (APA) and Agency precedent, a discovery order is beyond the authority of this tribunal, but went on to argue that under Agency precedent "the only formal discovery required in DEA hearings is the exchange of documents and summarized testimony,"[73] and that the

"Respondent in this matter will be provided the documents and testimony to be used against him, and will be permitted to confront and cross examine witnesses and evidence presented by the Government at hearing."

Id. at 3. In a separate order (Discovery Denial Order),[74] the discovery request was denied as *ultra vires,* and the Respondent's attention was invited to explore other available procedural mechanisms, such as specific subpoena requests (none were submitted), applications to the United States District Court under Fed. R. Crim. P. 41(g), and, if warranted, the pursuit of the application of an evidentiary adverse inference before this tribunal. The Discovery Denial Order contained the following language:

"While discovery beyond the regulations is not a viable option available to the parties in this action, the position taken by the Government, if taken to its natural analytical conclusion, would allow it to intentionally seize exculpatory evidence, render it unavailable, and prevail in an administrative enforcement action that requires a due process hearing [with a footnote that added that] [t]here is no indication that such a scenario has taken place or would take place here. [The Order went on to state that] [w]hile the analytical simplicity of the Government's position is facially appealing, it is unlikely that Congress, in enacting the APA and the Controlled Substances Act, intended such a result."

ALJ Ex. 20 at 7. Ironically, the precise scenario that this tribunal expressed confidence would not likely occur, is exactly the scenario that unfolded at the hearing. The Government seized the Respondent's patient charts and proceeded under a theory that the Respondent inexorably prescribed controlled substances to essentially anyone posing as a patient who made a request. Through an agent who was ill-equipped to provide interaction details, the Government presented testimony that a UC who (at least by its theory) was not a legitimate candidate for a controlled substance prescription, received one from the registrant. It was only through the cross-examination performed by a co-Respondent's counsel present at the consolidated hearing that it was revealed that another UC who attempted to procure controlled substances from this Respondent was refused. The Respondent (and this tribunal) have never been apprised of the details of the interaction or been given access to the patient chart regarding the rebuffed UC.

In *International Union (UAW)* v. *NLRB,*[75] the United States Court of Appeals for the District of Columbia Circuit held that the National Labor Relations Board committed reversible error by declining to apply the "adverse inference rule" where one of the parties had "relevant evidence within his control which he fail[ed] to produce."[76] This precedent was embraced by the Eleventh Circuit in *Callahan* v. *Schultz,* 783 F.2d 1543, 1545 (11th Cir. 1986). The judicious utilization of the adverse inference rule allows an administrative tribunal to use the tools available to it and "permits vindication of the tribunal's authority in situations where vindication might, as a practical matter, be impossible otherwise." *Int'l Union,* 459 F.2d at 1339. Such an inference is appropriate under the circumstances of this case where the evidence of the unsuccessful UC was clearly within the Government's control and should, to maintain the integrity of the proceedings, have been disclosed if not produced. Accordingly, an adverse interference will be applied here to the extent that is will be assumed in this recommended decision that, regarding the unsuccessful UC, his encounter with the Respondent reflected a correct and professional interaction memorialized by documentation that met with the standards set by the Florida Medical Board. Thus, the evidence regarding this unsuccessful UC, even if it had been provided to the Respondent, could have

[71] Tr. at 898.

[72] In fact, the Government actually interposed an objection that exploration of this issue was beyond the scope of the direct examination. Tr. at 986.

[73] ALJ Ex. 19 at 6.

[74] ALJ Ex. 20.

[75] 459 F.2d 1329, 1336 (D.C. Cir. 1972).

[76] The applicability of the adverse inference rule is not dependent upon the issuance of a subpoena seeking to compel production. *Int'l Union* v. *NLRB,* 459 F.2d at 1338.

logically established no greater benefit to his litigation position.

Furthermore, in this case, because SA Burt's testimony regarding the UC's interaction with the Respondent has been afforded no weight, the non-availability of the details regarding the unsuccessful UC has resulted in no adverse impact regarding the Respondent's case. This is ever so much more true where an adverse inference has resulted in the assumption that the only such credited interaction in the record was in all ways appropriate. Put another way, the Government's attempt to show that the Respondent's interaction with the successful UC demonstrated his proclivity to dole out controlled substances for insufficient reasons was not persuasive.[77] However, if the testimonial vessel had delivered the testimony in a more effective fashion and the testimony regarding the successful UC had been credited, it seems that there was at least the potential for a significant compromise to the fairness of the adjudication. To the extent that a strained interpretation of the APA and existing DEA regulations have empowered the Government in espousing the position that it should rightfully be permitted to seize all potential evidence and dole back only those portions that adversely implicate the Respondent, that course is likely to result in precedent on judicial review that could impose unintended appellate consequences that could (and perhaps should) severely curtail its options in future enforcement actions. The point raised in the Respondent's brief that "[t]he Due Process Clause forbids an agency from using evidence in a way that forecloses an opportunity for a party to offer a contrary presentation," Respt's Br. at 3 (citing *Volkman* v. *DEA,* 567 F.3d 215, 220 (6th Cir. 2009), is well taken. The APA guarantees that "[a] party is entitled to present his case or defense." 5 U.S.C. 556(d). Irrespective of the number of assurances provided by the Government that a respondent will be afforded all the rights to which he is entitled, the practice of seizing all evidence from a Respondent, presenting a selective compilation of that which tends to disparage his case, while denying access to information from which he could meaningfully defend against the allegations, does not have a strong likelihood of ratification on appeal. More importantly, when brought to its logical end, it could tend to undermine the integrity of the adjudication in the eyes of the public. That no cognizable prejudice was realized to this Respondent's ability to present his case here does not enhance the wisdom of the procedural course embarked upon. That being said, no prejudice resulted to the Respondent here.

The Government's evidence at the hearing targeted not only the Respondent's experience practicing under Factor 2, but also his compliance with applicable state and federal laws relating to controlled substances under Factor 4. To effectuate the dual goals of conquering drug abuse and controlling both legitimate and illegitimate traffic in controlled substances, "Congress devised a closed regulatory system making it unlawful to manufacture, distribute, dispense, or possess any controlled substance except in a manner authorized by the CSA." *Gonzales* v. *Raich,* 545 U.S. 1, 13 (2005). Consistent with the maintenance of that closed regulatory system, subject to limited exceptions not relevant here, a controlled substance may only be dispensed upon a prescription issued by a practitioner, and such a prescription is unlawful unless it is "issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice." 21 U.S.C. 829; 21 CFR 1306.04(a). Furthermore, "an order purporting to be a prescription issued not in the usual course of professional treatment * * * is not a prescription within the meaning and intent of [21 U.S.C. 829] and the person knowingly * * * issuing it, shall be subject to the penalties provided for violations of the provisions of law related to controlled substances." *Id.*

A registered practitioner is authorized to dispense,[78] which the CSA defines as "to deliver a controlled substance to an ultimate user[79] * * * by, or pursuant to the lawful order of a practitioner." 21 U.S.C. 802(10); *see also Rose Mary Jacinta Lewis,* 72 FR 4035, 4040 (2007). The prescription requirement is designed to ensure that controlled substances are used under the supervision of a doctor, as a bulwark against the risk of addiction and recreational abuse. *Aycock,* 74 FR at 17541 (citing *Gonzales* v. *Oregon,* 546 U.S. 243, 274 (2006); *United States* v. *Moore,* 423 U.S. 122, 135, 142–43 (1975) (noting that evidence established that a physician exceeded the bounds of professional practice when he gave inadequate examinations or none at all, ignored the results of the tests he did make, and took no precautions against misuse and diversion)). The prescription requirement likewise stands as a proscription against doctors "peddling to patients who crave the drugs for those prohibited uses." *Id.* The courts have sustained criminal convictions based on the issuing of illegitimate prescriptions where physicians conducted no physical examinations or sham physical examinations. *United States* v. *Alerre,* 430 F.3d 681, 690–91 (4th Cir. 2005), *cert. denied,* 574 U.S. 1113 (2006); *United States* v. *Norris,* 780 F.2d 1207, 1209 (5th Cir. 1986).

While true that the CSA authorizes the "regulat[ion] of medical practice so far as it bars doctors from using their prescription-writing powers as a means to engage in illicit drug dealing and trafficking as conventionally understood," *Gonzales,* 546 U.S. at 266–67, an evaluation of cognizant state standards is essential. *Joseph Gaudio, M.D.,* 74 FR 10083, 10090 (2009); *Kamir Garces-Mejias, M.D.,* 72 FR 54931, 54935 (2007); *United Prescription Servs., Inc.,* 72 FR 50397, 50407 (2007). In this adjudication, the evaluation of the Respondent's prescribing practices must be consistent with the CSA's recognition of state regulation of the medical profession and its bar on physicians from peddling to patients who crave drugs for prohibited uses. The analysis must be "tethered securely" to state law and federal regulations in application of the public interest factors, and may not be based on a mere disagreement between experts as to the most efficacious way to prescribe controlled substances to treat chronic pain sufferers. *Volkman,* 567 F.3d at 223 (citing *Gonzales,* 546 U.S. at 272, 274).

Under the CSA, it is fundamental that a practitioner must establish a bonafide doctor-patient relationship in order to act "in the usual course of * * * professional practice" and to issue a prescription for a legitimate medical purpose." *Stodola,* 74 FR at 20731; *Shyngle,* 74 FR at 6057–58 (citing *Moore,* 423 U.S. at 141–43). The CSA looks to state law to determine whether a bonafide doctor-patient relationship existed. *Stodola,* 74 FR at 20731; *Shyngle,* 74 FR at 6058; *Garces-Mejias,* 72 FR at 54935; *United Prescription Servs.,* 72 FR at 50407. It was Dr. Kennedy's uncontroverted opinion that his evaluation of chart entries convinced him that they were so defective that the Respondent did not establish a sufficient doctor-patient

[77] As evidenced by the ultimate disposition of this recommended decision, other evidence of record relating to the chart analysis by Dr. Kennedy was more successful in this regard.

[78] 21 U.S.C. 823(f).

[79] "Ultimate user" is defined as "a person who has lawfully obtained, and who possesses, a controlled substance for his own use or for the use of a member of his household or for an animal owned by him or by a member of his household." 21 U.S.C. 802(27).

relationship to justify the prescribing of controlled substances, and that "this was not the practice of medicine in [his] opinion. Tr. at 160–61.

Under Florida law, grounds for disciplinary action or denial of state licensure include "prescribing * * * any controlled substance, other than in the course of the physician's professional practice," and prescribing such substances "inappropriately or in excessive or inappropriate quantities is not in the best interest of the patient and is not in the course of the physician's professional practice, without regard to his or her intent." Fla. Stat. § 458.331(q) (2009). Florida law further provides that grounds for such disciplinary action also include:

Failing to keep legible, as defined by department rule in consultation with the board, medical records that identify the licensed physician * * * and that justify the course of treatment of the patient, including, but not limited to, patient histories; examination results; test results; records of drugs prescribed, dispensed, or administered; and reports of consultations and hospitalizations.

Id. § 458.331(m).

In exercising its rulemaking function,[80] the Florida Board of Medicine (Florida Board) promulgated a regulation addressing "Standards for Adequacy of Medical Records" applicable to all physicians. Fla. Admin. Code r. 64B8–9.003 (2009). That regulation provides, in pertinent part:

(2) A licensed physician shall maintain patient medical records in English, in a legible manner and with sufficient detail to clearly demonstrate why the course of treatment was undertaken.

(3) The medical record shall contain sufficient information to identify the patient, support the diagnosis, justify the treatment and document the course and results of treatment accurately, by including, at a minimum, patient histories; examination results; test results; records of drugs prescribed, dispensed or administered; reports of consultations and hospitalizations; and copies of records or reports or other documentation obtained from other health care practitioners at the request of the physician and relied upon by the physician in determining the appropriate treatment of the patient.

(4) All entries made into the medical records shall be accurately dated and timed. Late entries are permitted, but must be clearly and accurately noted as late entries and dated and timed accurately when they are entered in to the record * * *.

Fla. Admin. Code r. 64B8–9.003 (2009).

With respect to defining the parameters of what constitutes "professional practice" in the context of pain management prescribing, Florida state law provides:

Notwithstanding any other provision of law, a physician may prescribe or administer any controlled substance under Schedules II–V * * * to a person for the treatment of intractable pain,[81] provided the physician does so in accordance with that level of care, skill, and treatment recognized by a reasonably prudent physician under similar conditions and circumstances. Fla. Stat. § 458.326 (2009). Moreover, the Florida Board has adopted,[82] albeit in modified version, the *Model Policy for the Use of Controlled Substances for the Treatment of Pain* (*Model Policy*) a document drafted by the Federation of State Medical Boards (FSMB) to provide professional guidelines for the treatment of pain with controlled substances. The standards adopted by Florida share the key tenants of the *Model Policy's* standards for pain management prescribing, including the emphasis on diligent efforts by physicians to prevent drug diversion, prescribing based on clear documentation of unrelieved pain and thorough medical records, and compliance with applicable Federal and State law.

Like the *Model Policy,* which was promulgated "to encourage the legitimate medical uses of controlled substances for the treatment of pain while stressing the need to safeguard against abuse and diversion," Florida's regulation providing "Standards for the Use of Controlled Substances for Treatment of Pain," Fla. Admin. Code r. 64B8–9.013 (2009) (Florida Standards), recognizes that "inappropriate prescribing of controlled substances * * * may lead to drug diversion and abuse by individuals who seek them for other than legitimate medical use." The language employed by the regulation under the preamble section titled "Pain Management Principles" makes clear that the standards "are not intended to define *complete or best practice,* but rather to communicate what the [Florida Board] considers to be *within the boundaries of professional practice*" (emphasis supplied), *id.* at 9.013(1)(g); thus, the plain text supports an inference that the standards provide the *minimum* requirements for establishing conduct that comports with the professional practice of controlled substance-based pain management within the state. Likewise, the level of integral range of acceptable practice that is built into the regulation underscores the importance of seeking an expert professional opinion in reaching a correct adjudication of whether a registrant has met the applicable Florida standard. It is clear that in assessing whether the controlled substance prescribing practices of a Florida practitioner fall within the acceptable range of what constitutes being within the bounds of being "issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice," [83] resort must be had to an expert.

The Florida Standards direct that "[p]hysicians should be diligent in preventing the diversion of drugs for illegitimate purposes," *id.* at 9.013(1)(d), and provide that the prescribing of controlled substances for pain will be considered

to be for a legitimate medical purpose if based on accepted scientific knowledge of the treatment of pain or if based on sound clinical grounds. All such prescribing must be based on *clear documentation* of unrelieved pain and in compliance with applicable State or Federal law.

Id. at 9.013(1)(e) (emphasis supplied).

The Florida Standards further provide that the validity of prescribing will be judged "based on the physician's treatment of the patient and *on available documentation,* rather than on the quantity and chronicity of prescribing" (emphasis supplied). *Id.* at 9.013(1)(g). Furthermore, the Standards advise that physicians should not fear disciplinary action for "prescribing controlled substances * * * for a legitimate medical purpose and that is supported by *appropriate documentation* establishing a valid medical need and treatment plan" (emphasis supplied), or "for failing to adhere strictly to the provisions of these standards, *if good cause is shown for such deviation*" (emphasis supplied). *Id.* at 9.013(1)(b),(f).

Although, as discussed above, the Florida Board instituted general guidance applicable to all physicians regarding medical records, it also

[80] Rulemaking authority regarding the practice of medicine within the state of Florida has been delegated to the Florida Board of Medicine (Florida Board). Fla. Stat. § 458.309(1) (2009).

[81] Florida defines "intractable pain" to mean "pain for which, in the generally accepted course of medical practice, the cause cannot be removed and otherwise treated." Fla. Stat. § 458.326 (2009).

[82] Pursuant to authority vested in the Florida Board by the Florida legislature to promulgate rules regarding state standards for pain management clinical practice specifically. Fla. Stat. § 458.309(5) (2009).

[83] 21 CFR 306.04(a).

promulgated a separate set of documentation requirements in the Florida Standards applicable specifically to those physicians who prescribe controlled substances in the pain-management context. The Florida Standards, under the subheading "Medical Records," state that "[t]he physician is required to keep *accurate and complete records*" (emphasis supplied) including, though not limited to:

1. The medical history and physical examination, including history of drug abuse or dependence, as appropriate;
2. Diagnostic, therapeutic, and laboratory results;
3. Evaluations and consultations;
4. Treatment objectives;
5. Discussion of risks and benefits;
6. Treatments;
7. Medications (including date, type, dosage, and quantity prescribed);
8. Instructions and agreements; and
9. Periodic reviews.

Id. at 9.013(3)(f). The same section directs that "[r]ecords must remain current and be maintained in an acceptable manner and readily available for review. *Id.*

The Florida Standards similarly emphasize the need for proper documentation in the patient evaluation context by specifying:

A complete [84] medical history and physical examination must be conducted and documented in the medical record. The medical record should document the nature and intensity of the pain, current and past treatments for pain, underlying or coexisting diseases or conditions, the effect of the pain on physical and psychological function, and history of substance abuse. The medical record also should document the presence of one or more recognized medical indications for the use of a controlled substance.

Id. at 9.013(3)(a).

Furthermore, the Florida Standards require a written treatment plan that "should state objectives that will be used to determine treatment success, such as pain relief and improved physical and psychosocial function, and should indicate if any further diagnostic evaluations or other treatments are planned." *Id.* at 9.013(3)(b). Subsequent to the initiation of treatment, "the physician should *adjust* drug therapy to the individual medical needs of each patient. Other treatment modalities or a rehabilitation program may be necessary depending on the etiology of the pain and the extent to which the pain is associated with physical and psychosocial impairment." (emphasis supplied). *Id.*

Another standard adopted by the Florida Board, under the subheading "Informed Consent and Agreement for Treatment," is the directive that

> [t]he physician should discuss the risks and benefits of the use of controlled substances with the patient, persons designated by the patient, or with the patient's surrogate or guardian if the patient is incompetent. The patient should receive prescriptions from one physician and one pharmacy where possible. If the patient is determined to be at high risk for medication abuse or have a history of substance abuse, the physician should employ the use of a written agreement between the physician and patient outlining patient responsibilities, including, but not limited to:
>
> 1. Urine/serum medication levels screening when requested;
> 2. Number and frequency of all prescription refills; and
> 3. Reasons for which drug therapy may be discontinued (*i.e.,* violation of agreement.

Id. at 9.003(3)(c).

The Florida Standards contain a further requirement to periodically review "the course of pain treatment and any new information about the etiology of the pain or the patient's state of health." *Id.* at 9.013(3)(d) The Florida Standards explain the importance of periodic review in the following manner:

> Continuation or modification of therapy depends on the physician's evaluation of the patient's progress. If treatment goals are not being achieved, despite medication *adjustments,* the physician should reevaluate the appropriateness of continued treatment. The physician should monitor patient compliance in medication usage and related treatment plans.

Id.

Under the subheading "Consultation," the Florida Board promulgated the instruction that

> [t]he physician should be willing to refer the patient as necessary for additional evaluation and treatment in order to achieve treatment objectives. Special attention should be given to those pain patients who are at risk for misusing their medications and those whose living arrangements pose a risk for medication misuse or diversion. The management of pain in patients with a history of substance abuse or with a comorbid psychiatric disorder requires extra care, monitoring, and documentation, and may require consultation with or referral to an expert in the management of such patients.

Id. at 9.003(3)(e).

It is abundantly clear from the plain language of the Florida Standards that the Florida Board places critical emphasis on physician implementation of adequate safeguards in their practice to minimize diversion and the need to document the objective signs and rationale employed in the course of pain treatment utilizing the prescription of controlled substances. Conscientious documentation is repeatedly emphasized as not just a ministerial act, but a key treatment tool and a vital indicator to evaluate whether the physician's prescribing practices are "within the usual course of professional practice." Here, the uncontroverted expert opinion of Dr. Kennedy, the only expert witness to testify at these proceedings, reflects that the documentation he reviewed in the Respondent's patient charts reflected care that was markedly below the standard of care set by the Florida Medical Board. Dr. Kennedy's expert assessment was consistent with the state statutory and regulatory guidance. In Kennedy's view, the Respondent's charts demonstrated minimalistic, incomplete, and otherwise medically inadequate documentation of his contacts with patients, and the prescribing rationale for his issuance of controlled substance prescriptions to those patients for alleged pain management purposes. The boilerplate-style, "one high-dosage controlled substances treatment plan fits all" nature of nearly all of the patient medical records at issue, at least in the view of the uncontroverted expert, evidences a failure on the part of the Respondent to conduct his practice of medicine in a manner to minimize the potential of controlled substance abuse and diversion, and supports a conclusion that he failed to even substantially comply with the minimum obligations for professional practice imposed under the Florida Standards—and without "good cause [] shown for such deviation." *Id.* at 9.013(1)(f).

The Respondent, who was in a unique position to conclusively refute Dr. Kennedy's views and explain the format and nuances of the reviewed documentation, elected not to testify in this matter. At a DEA administrative hearing, it is permissible to draw an adverse inference from the silence of the Respondent, even in the face of a Fifth Amendment invocation. *Hoxie* v. *DEA,* 419 F.3d 477, 483 (6th Cir. 2005) (citing *United States* v. *Hale,* 422 U.S. 171, 176

[84] The original *Model Policy* version of the guidelines does not contain a reference to the need for a *complete* medical history, instead only requiring a medical history generally. Thus, the Florida Board has adopted a higher standard than the measure that has been set in the *Model Policy* by the FSMB.

(1975) ("silence gains more probative weight where it persists in the face of accusation, since it is assumed in such circumstances that the accused would be more likely than not to dispute an untrue accusation.")); *Joseph Baumstarck, M.D.,* 74 FR 17525, 17528, n.3 (2009) (citing *Ohio Adult Parole Auth.* v. *Woodward,* 523 U.S. 272, 286 (1998)). On the facts of this case, where the allegations are of a nature that a registrant would be more likely than not to dispute them if untrue, an adverse inference based on the Respondent's silence is appropriate. Where, as here, the Government, through its expert, has alleged that the Respondent's charts do not reflect genuine analysis, but rather (at least in its view and the opinion of its expert), a sort of sham-by-check-box form designed specifically to present a false impression of a compliant registrant, it is precisely the type of allegation that would naturally all but oblige a registrant to spring to offer a contradictory account. The Respondent's choice to remain silent in the face of such allegations, where he could have related his version of his practice as a registrant, adds at least some additional credence to the factual and analytical views of the Government's expert in this regard.

In the Social Security context, where an Administrative Law Judge has received expert medical opinions on the issue of the claimant's ability to work and they are not repudiated in any respect by substantial evidence, an adverse decision should be set aside as based on "suspicion and speculation." *Miracle* v. *Celebrezze,* 351 F.2d 361, 378 (6th Cir. 1965); *see also Hall* v. *Celebrezze,* 314 F.2d 686, 689–90 (6th Cir. 1963); *cf. Harris* v. *Heckler,* 756 F.2d 431, 436 (6th Cir. 1985) (improper to reject uncontroverted evidence supporting complaints of pain simply because of claimant's demeanor at hearing). When an administrative tribunal elects to disregard the uncontradicted opinion of an expert, it runs the risk of improperly declaring itself as an interpreter of medical knowledge. *Ross* v. *Gardner,* 365 F.2d 554 (6th Cir. 1966). While in this case it is ironically true, much like in the Social Security context, that the opinion of a treating physician should be afforded greater weight than the opinion of an expert whose opinion is limited to a review of the patient file, *see Magallenes* v. *Bowen,* 881 F.2d 747, 751 (9th Cir. 1989), the treating-source Respondent in this case offered no evidence, not even his own opinion, regarding the treatment rendered. Thus, in this adjudication, the record contains no dispute between experts to be resolved; instead, there is but one, unrefuted, uncontroverted, credible expert opinion. To ignore that expert opinion on this record and replace it with the opinion of this tribunal, Respondent's counsel, or any other lay source would be a dangerous course and more importantly, a plainly erroneous one.

Accordingly, after carefully balancing the admitted evidence, even applying an adverse inference that permits the assumption that the Respondent was approached by an undercover agent and acted appropriately, the evidence establishes, by a preponderance, that the prescriptions the Respondent issued in Florida were not issued within "the usual course of [the Respondent's] professional practice." 21 CFR 1306.04(a). Consideration of the evidence under the second and fourth factors support the COR revocation sought by the Government in this case.

To the extent that the Respondent's prescribing practices fell below the requisite standard in Florida, that conduct also impacts upon the Fifth statutory factor. Under Factor 5, the Deputy Administrator is authorized to consider "other conduct which may threaten the public health and safety." 21 U.S.C. 823(f)(5). Although this factor authorizes consideration of a somewhat broader range of conduct reaching beyond those activities typically associated with a registrant's practice, an adverse finding under this factor requires some showing that the relevant conduct actually constituted a threat to public safety. *See Holloway Distrib.,* 72 FR 42118, 42126 (2007).

The evidence establishes that the Respondent engaged in a course of practice wherein he prescribed controlled substances to patients irrespective of the patients' need for such medication and ignoring any and all red flags that could or did indicate likely paths of diversion. The testimony of Dr. Kennedy, the DEA regulations, and the Florida Standards make clear that physicians prescribing controlled substances do so under an obligation to monitor the process to minimize the risk of diversion. The patient charts reflect that the Respondent, contrary to his obligations as a DEA registrant, did not follow up in the face of multiple red flags. The Respondent's disregard of his obligations as a DEA registrant and Federal and State laws related to controlled substances militate in favor of revocation.

By ignoring his responsibilities to monitor the controlled substance prescriptions he was authorizing to minimize diversion, and by participating in an insufficiently documented and thoughtful process for the issuance of potentially dangerous controlled substances, the Respondent created a significant potential conduit for the unchecked diversion of controlled substances. *See Holloway Distrib.,* 72 FR at 42124 (a policy of "see no evil, hear no evil" is fundamentally inconsistent with the obligations of a DEA registrant). Agency precedent has long recognized that "[l]egally, there is absolutely no difference between the sale of an illicit drug on the street and the illicit dispensing of a licit drug by means of a physician's prescription." *EZRX, LLC,* 69 FR 63178, 63181 (1988); *Floyd A. Santner, M.D.,* 55 FR 37581 (1988).

Agency precedent has consistently held that where, as here, the Government has met its burden to establish a prima facie case that a registrant has committed acts demonstrating that continued registration is inconsistent with the public interest, acceptance of responsibility is a condition precedent to continued registration. *Jeri Hassman, M.D.,* 75 FR 8194, 8236 (2010); *Medicine Shoppe,* 73 FR at 387. The record contains no evidence that the Respondent has either acknowledged or accepted responsibility for the misconduct at issue in these proceedings.

Recommendation

Based on the foregoing, the evidence supports a finding that the Government has established that the Respondent has committed acts that are inconsistent with the public interest. A balancing of the statutory public interest factors supports the revocation of the Respondent's Certificate of Registration and a denial of his application to renew. The Respondent has not accepted responsibility for his actions, expressed remorse for his conduct at any level, or presented evidence that could reasonably support a finding that the Deputy Administrator should continue to entrust him with a Certificate of Registration. Accordingly, the Respondent's Certificate of Registration should be *revoked* and any pending applications for renewal should be *denied.*

Dated: August 10, 2010.

John J. Mulrooney II,

U.S. Administrative Law Judge.

[FR Doc. 2011–8344 Filed 4–6–11; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 10–40]

Michael J. Aruta, M.D.; Decision and Order

On August 10, 2010, Administrative Law Judge (ALJ) John J. Mulrooney, II, issued the attached recommended decision.[1] The Respondent did not file exceptions to the decision.

Having reviewed the record in its entirety including the ALJ's recommended decision, I have decided to adopt the ALJ's rulings, findings of fact,[2] conclusions of law,[3] and recommended Order.

Order

Pursuant to the authority vested in me by 21 U.S.C. 823(f) and 824(a), as well as 21 CFR 0.100(b) and 0.104, I order that DEA Certificate of Registration, BA6733578, issued to Michael J. Aruta, M.D., be, and it hereby is revoked. I further order that any pending application of Michael J. Aruta, M.D., to renew or modify his registration, be, and it hereby is, denied. This Order is effective immediately.

Dated: March 31, 2011.

Michele M. Leonhart,

Administrator.

Larry P. Cote., Esq., for the Government.
Bernard M. Cassidy., Esq., for the Respondent.

Recommended Rulings, Findings of Fact, Conclusions of Law, and Decision of the Administrative Law Judge

John J. Mulrooney, II, Administrative Law Judge. On February 25, 2010, the Deputy Administrator, Drug Enforcement Administration (DEA or Government), issued an Order to Show Cause and Immediate Suspension of Registration (OSC/ISO), immediately suspending the DEA Certificate of Registration (COR), Number BA6733578, of Michael J. Aruta, M.D. (Respondent), as a practitioner, pursuant to 21 U.S.C. 824(d), alleging that such registration constitutes an imminent danger to the public health and safety. The OSC/ISO also seeks revocation of the Respondent's registration, pursuant to 21 U.S.C. 824(a)(4), and denial of any pending applications for renewal or modification of such registration, pursuant to 21 U.S.C. 823(f), alleging that the Respondent's continued registration is inconsistent with the public interest, as that term is used in 21 U.S.C. 823(f). On March 24, 2010, the Respondent timely requested a hearing, which was conducted in Miami, Florida, on July 7, 2010 through July 9, 2010.[4] The immediate suspension of the Respondent's COR has remained in effect throughout these proceedings.

The issue ultimately to be adjudicated by the Deputy Administrator, with the assistance of this recommended decision, is whether the record as a whole establishes by substantial evidence that Respondent's registration with the DEA should be revoked as inconsistent with the public interest as that term is used in 21 U.S.C. 823(f) and 824(a)(4). The Respondent's DEA practitioner registration expires by its terms on June 30, 2012.

After carefully considering the testimony elicited at the hearing, the admitted exhibits, the arguments of counsel, and the record as a whole, I have set forth my recommended findings of fact and conclusions below.

The Evidence

The OSC/ISO issued by the Government alleges that the Respondent, through the medical practice he had been conducting at American Pain, LLC (American Pain), has prescribed and dispensed inordinate amounts of controlled substances, primarily oxycodone,[5] under circumstances wherein he knew, or should have known, that the controlled substances were not prescribed and/or dispensed for a legitimate medical purpose. ALJ Ex. 1. The OSC/ISO

[1] All citations to the ALJ's Decision (ALJ) are to the slip opinion as issued on August 10, 2010, and not to the attached decision which has been reformatted.

[2] The ALJ found that there is "no evidence that the Respondent 'prescribe[d] and dispense[d] *inordinate* amounts of controlled substances." ALJ at 26. While there is no evidence as to the amounts that Respondent directly dispensed, there is evidence, which is unrefuted, that Respondent prescribed inordinate amounts of controlled substances. In his report, an Expert witness explained that the usual starting dose of Xanax is .25 to .5 mg. once to twice per day and yet Respondent prescribed Xanax 2 mg. twice per day to patients "who had not had Xanax before or recently," and that he did so without documenting that he had considered any of the possible underlying causes of his patients' complaint that they had anxiety; moreover, Respondent did not refer the patients to a mental health professional. GX 5, at 9–10. As the Expert explained, "[t]he treatment was with a very high dose of the controlled substance Xanax. This was clearly not within the boundaries of professional practice." *Id.* at 10. There is also unrefuted evidence that Respondent's prescribing of drug cocktails of oxycodone and Xanax lacked a legitimate medical purpose. *Id.* at 13. In this manner, Respondent did prescribe inordinate amounts.

[3] I do not, however, adopt the ALJ's discussion of the standards applied by the Agency in assessing a practitioner's experience in dispensing controlled substances, which cites cases involving list chemical I distributors, a different category of registrant. *See* ALJ at 25–26. As the Agency has previously made clear, DEA can revoke based on a single act of intentional diversion and "evidence that a practitioner has treated thousands of patients" in circumstances that do not constitute diversion "does not negate a *prima facie* showing that the practitioner has committed acts inconsistent with the public interest." *Jayam Krishna-Iyer,* 74 FR 459, 463 (2009). *See also Dewey C. MacKay,* 75 FR 49956, 49977 (2010); *Medicine Shoppe-Jonesborough,* 73 FR 364, 386 & n.56 (noting that pharmacy "had 17,000 patients," but that "[n]o amount of legitimate dispensings can render * * * flagrant violations [acts which are] 'consistent with the public interest'"), *aff'd, Medicine Shoppe-Jonesborough* v. *DEA,* 300 Fed. Appx. 409 (6th Cir. 2008). As I further explained, "[w]hile such evidence may be [entitled to] some weight in assessing whether a practitioner has credibly shown that [he] has reformed his practices," it is entitled to no weight where a practitioner fails to acknowledge his wrongdoing. *Krishna-Iyer,* 74 FR at 463.

In any event, Respondent offered no evidence on the issue of his experience in dispensing controlled substances and the ALJ's ultimate conclusions that Respondent violated the CSA's prescription requirement because he dispensed controlled substance prescriptions that were not "within 'the usual course of [his] professional practice,'" ALJ at 39 (quoting 21 CFR 1306.04(a)), and that "the evidence under the [experience] * * * factor[] support[s]" the revocation of his registration, is consistent with Agency precedent. *Id.*

With respect to factor five, "[s]uch other conduct which may threaten public health and safety," 21 U.S.C. 823(f)(5), the ALJ opined that "an adverse finding under this factor requires some showing that the relevant conduct *actually constituted* a threat to public safety." ALJ at 39 (emphasis added). Contrary to the ALJ's reasoning, Congress, by inserting the word "may" in factor five, clearly manifested its intent to grant the Agency authority to consider conduct which creates a probable or possible threat (and not only an actual) threat to public health and safety. *See Webster's Third New Int'l Dictionary* 1396 (1976) (defining "may" in relevant part as to "be in some degree likely to"); *see also The Random House Dictionary of the English Language* 1189 (1987) (defining "may" in relevant part as "used to express possibility"). While the ALJ misstated the applicable standard, his conclusion that Respondent repeatedly ignored "red flags" indicative of likely diversion and thus "created a significant potential conduit for the unchecked diversion of controlled substances," ALJ at 39, is clearly supported by substantial evidence and warrants an adverse finding under factor five.

The ALJ also opined that "[i]t is clear that in assessing whether the controlled substance prescribing practices of a Florida practitioner fall within the acceptable range of what constitutes being within the bounds of being 'issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice,' resort must be had to an expert." ALJ at 34 (quoting 21 CFR 1306.04(a)). While the ALJ properly noted the importance of expert testimony in this case, in which the Government primarily relied on a review of the medical charts, whether expert testimony is needed in any case necessarily depends on the nature of the allegations and the other evidence in the case. Where, for example, the Government produces evidence of undercover visits showing that a physician knowingly engaged in outright drug deals, expert testimony adds little to the proof necessary to establish a violation of Federal law.

[4] Pursuant to an order issued on April 15, 2010, the hearing in this matter was consolidated with the cases of four other registrants who were working at the same clinic as the Respondent and who were also issued OSC/ISOs on February 25, 2010, alleging similar and related conduct.

[5] A schedule II controlled substance.

further charges that these prescriptions were issued outside the usual course of professional practice based on a variety of circumstances [6] surrounding the manner in which American Pain has been operated and the manner in which its physicians, to include the Respondent, has engaged in the practice of medicine. *Id.* The OSC/ISO also sets forth the Government's allegation that Respondent's former patients have apprised law enforcement personnel that "they were able to obtain prescriptions for controlled substances from [the Respondent] for other than a legitimate medical purpose and with little or no medical examination." *Id.*

At the hearing, the Government presented the testimony of three witnesses, DEA Miami Field Division (MFD) Group Supervisor (GS) Susan Langston, DEA Special Agent (SA) Michael Burt, and L. Douglas Kennedy, M.D., D.A.B.P.M., Affiliate Clinical Assistant Professor at the University of Miami, Miller School of Medicine.

GS Langston testified that the investigation of the American Pain Clinic had its origins on November 30, 2009, during a routine inspection that she and a subordinate diversion investigator conducted at Appurtenance Biotechnology, LLC, a pharmacy doing business under the name Boca Drugs (Boca Drugs), and located a few blocks away from one of the former locations of American Pain. Tr. at 713, 717–20. According to Langston, an examination of the prescriptions seized from Boca Drugs revealed that the majority of those prescriptions were for oxycodone and alprazolam authorized over the signature of physicians associated with American Pain.[7] *Id.* at 721. Under Langston's supervision, DEA diversion investigators catalogued the prescriptions seized at Boca Drugs (Boca Drugs Prescription Log). Govt. Ex. 118. A review of the data relative to the Respondent on the Boca Drug Prescription Log reveals that from November 2, 2009 through November 25, 2009, 175 controlled substance prescriptions issued over the Respondent's signature, to eighty-nine patients, only five of whom resided in Florida. The remainder of the patients had listed addresses in Kentucky, Tennessee, Ohio, Georgia, Massachusetts, West Virginia, North Carolina, Virginia, and South Carolina.

GS Langston also testified that, on March 3, 2010, a criminal search warrant was executed on the American Pain Clinic simultaneously with the OSC/ISO that initiated the present case. Tr. at 735. According to Langston, the items seized from American Pain included a sign that had been posted in what she believes to have served as the urinalysis waiting room. Tr. at 735–37. The seized sign set forth the following guidance:

ATTENTION PATIENTS

Due to increased fraudulent prescriptions, [i]t's best if you fill your medication in Florida or your regular pharmacy. Don't go to a pharmacy in Ohio when you live in Kentucky and had the scripts written in Florida. The police will confiscate your scripts and hold them while they investigate. This will take up to 6 months. So only fill your meds in Florida or a pharmacy that you have been using for at least 3 months or more.

Govt. Ex. 119 at 1. This sign is attached, apparently by some sort of tape, to the top portion of two other signs, posted at the same location, the first of which reads:

ATTENTION:

Patients

Please do *NOT* fill your prescriptions at any *WALGREENS PHARMACY* [8] or *OUTSIDE* the STATE OF FLORIDA.

Id. The final attachment to the composite sign bears the words "24 Hour Camera Surveillance."

Id. A photograph of the composite sign was admitted into evidence.

Langston also testified that while she was present in the American Pain offices, she noticed that each physician's desk was equipped with a group of stamps, each of which depicted a controlled substance medication with a corresponding medication usage instruction (sig). Tr. at 738–39. A photograph of one set of prescription script stamps was admitted as an exhibit.[9] Govt. Ex. 119 at 2.

GS Langston also testified that a great number of medical charts were seized from the American Pain offices, and that she and her staff selected a number of these files to be analyzed by a medical expert procured by the Government. Tr. at 762. According to GS Langston, after the execution of the warrant, the charts from the entire office were placed into piles in alphabetical order, and not separated by physician. Langston testified that she and three of her diversion investigators reviewed the seized files with a view towards choosing approximately fifteen files for each doctor with the aspirational criteria that each would reflect at least three to four visits by that doctor with a patient. Each investigator was empowered to place a chart on the selected pile, and when the target number (or about that number) was reached for each physician, the selection effort relative to that physician was deemed accomplished. *Id.* at 765. Langston credibly testified that there was no effort to specially select files under some prosecution-enhancement or "cherry picking" purpose. *Id.* at 768.

Langston also explained DEA's Automated Record Consolidated Ordering System (ARCOS) [10] and testified that she generated an ARCOS report relative to the Respondent's ordering of controlled substances from January 2009 through February 2010.[11] Govt. Ex. 2.

In the same fashion, Langston explained the purposes of and circumstances behind the generation of State prescription monitoring reports (PMPs) relative to the Respondent maintained by West Virginia and Kentucky. Govt. Exs. 3, 4. Review of the PMP report data reflects that during the time period of February 1, 2006 through February 11, 2010, pharmacies filled 210 controlled substance prescriptions issued over the Respondent's signature to fifty-five patients located in West Virginia, and 182 similar prescriptions provided to seventy-eight Kentucky-based patients were filled between January 1, 2009 and April 4, 2010. *Id.*

No evidence was introduced at the hearing that would provide any reliable level of context regarding the raw data set forth in the databases received into evidence at the Government's request. Other than the observations noted above, no witness who testified at the hearing ever explained the significance

[6] The majority of which are supported by no evidence introduced by the Government during the course of these proceedings.

[7] Although GS Langston testified that DEA immediately suspended the COR that had been issued to Boca Drugs, Tr. at 715, and that a voluntary surrender by that registrant followed a day later, *id.* at 776, no evidence has been presented that would lend that fact any particular significance related to any issue that must or should be found regarding the disposition of the present case.

[8] GS Langston testified that she was unaware of the location of the closest Walgreens to American Pain's offices. Tr. at 779. No evidence was presented that would tend to establish that any Walgreens or any other pharmacy has taken a position regarding its willingness to fill prescriptions authorized by American Pain.

[9] Although GS Langston testified that she did not actually take the photographs taken during the search warrant execution at American Pain, she did provide sufficient, competent evidence to support the admission of the photographs that were ultimately received into evidence. Tr. at 737, 739–41.

[10] GS Langston explained that through the ARCOS system, "[d]rug manufacturers and distributors are required to report the sale of certain controlled substances to DEA," and the system "shows the history of a drug from the point of manufacture through the distribution chain to the retail dispensing level." Tr. at 685–86.

[11] For reasons that were never made clear, the ARCOS report begins with a 2006 entry. Govt. Ex. 2 at 1.

of the data set forth in any of these databases to any issue that must or should be considered in deciding the present case.

GS Langston provided evidence that was sufficiently detailed, consistent and plausible to be deemed credible in this recommended decision.

SA Michael Burt testified that he has been employed by DEA since March 2004 and has been stationed with the Miami Field Division (MFD) since September 2004. Tr. at 813–14. Burt testified that he is the lead case agent for DEA in the investigation of American Pain Clinic and has participated in the investigation since the latter part of 2008. According to Burt, American Pain, which was previously known by the name South Florida Pain, has conducted business at four different locations, and he surveilled the Boca Raton and Lake Worth locations both in person and by periodic live review of video captured via pole cameras [12] set up outside the clinic. *Id.* at 815–17. These pole cameras, which were in operation during a three week period from January to February 2010, were initially in operation on a 24 hour basis, but Burt testified that they were later activated only between the hours of 7 a.m. through 6 p.m. due to an observed lack of activity at the clinic outside of that time period. *Id.* at 820–21. The pole camera recordings were not offered into evidence at the hearing or made available to opposing counsel.

Based on these surveillance efforts, SA Burt testified concerning various activities he observed occurring outside the Boca and Lake Worth clinic locations, which were open to the public from 8 a.m. to 5 p.m. At the Boca location, Burt stated that on any given day, beginning at 7 a.m. in the morning, automobiles could be seen pulling into the parking lot and approximately twenty to thirty people were routinely lined up outside of the clinic waiting to gain admittance. Additionally, there was a steady stream of automobile and foot traffic in and out of the clinic throughout the day. *Id.* at 817, 821. Burt testified that in his estimation, approximately 80–90 percent of the automobiles had out-of-State tags, predominantly from Kentucky, Ohio, West Virginia and Tennessee. *Id.* at 817–18. Burt also observed security personnel with "staff" written on their shirts [13] riding around the exterior of the building in golf carts and who, in Burt's assessment, appeared to be directing patients into the American Pain facility. Burt indicated his surveillance of the Lake Worth location yielded similar observations. *Id.* at 818.

Based on his review of some (but not all) [14] of the audio and video tapes made by agents and informers sent into the clinic by the Government at various times, SA Burt also testified about his understanding of the process by which patients obtained controlled substance prescriptions at American Pain. According to Burt, after entering the clinic, a patient would meet with the receptionist, who would determine if the patient had an MRI. If not, the receptionist would issue that individual an MRI prescription in exchange for a $50 cash payment, and the patient "would be directed to a place to obtain an MRI." *Id.* at 822. Burt testified that one such MRI location was Faye Imaging, which was a mobile MRI trailer located behind a gentlemen's club several miles away from American Pain. *Id.* at 822–23. The cost for the MRI was $250, and the patient could pay an additional fee "to have the MRI expedited and faxed over to American Pain." *Id.* at 823–24. Once the MRI was procured and faxed to American Pain, the patient would return to the clinic and be seen by a doctor. According to Burt, the clinic accepted what he referred to as "*predominantly* cash only" [15] for these office visits, and the six doctors at the clinic saw "anywhere from 200 upward to 375 patients a day" [16] in this manner.[17] *Id.* at 882–83 (emphasis supplied).

SA Burt also testified regarding his review of some [18] of the video and audio recordings made by an undercover agent (UC) who assumed the name Luis Lopez capturing activity inside of American Pain.[19] In those recordings, Burt observed who he believed to be an American Pain employee inside the facility standing up in a waiting room full of patients and directing them "not to have their prescriptions filled out of State, not to go out into the parking lot and snort their pills," and directing the patients to have their prescriptions filled "in house" (meaning at American Pain), at "a pharmacy they have in Orlando, Florida," or at "a pharmacy they have down the street," which, in Burt's view, was a reference to Boca Drugs. *Id.* at 825–26. Burt further testified that the purported employee on the recording told the patients to "obey all the traffic laws; do not give the police a reason to pull you over." *Id.* Although Burt testified as to the contents of these recordings, the physical recordings were not offered into evidence by the Government or made available to opposing counsel.

SA Burt also testified that he received information from Dr. Eddie Sollie, a former physician employed during the time period American Pain was doing business as South Florida Pain, who terminated his employment at the Oakland Park clinic location in November or December 2008 after working there for approximately two and a half to three months.[20] *Id.* at 827, 898. During the course of an interview where Burt was present, Dr. Sollie related various "concerns about how the practice was being handled or managed." *Id.* at 827–28. These concerns included medical records being, in his opinion, annotated inadequately by the doctors, and what he perceived as a lack of supervision during patient urinalysis testing, where patients would "go[] to the bathrooms together, bringing items with them to the bathrooms that could possibly disguise the urinalysis." According to Burt, Sollie explained that he perceived that patients were substituting urine produced by other persons that contained the metabolites

[12] SA Burt described the pole cameras as "covert cameras that are installed to observe the activity in the clinic." Tr. at 816. Burt testified that he was able to use a laptop to access the live video feed from the cameras after inputting a username and password. The camera video was also recorded to DVR. *Id.* at 821.

[13] Tr. at 910.

[14] SA Burt conceded that although he is the designated lead case agent for DEA, he did not review all the audio and video tapes made in the case or even review the transcripts. Tr. at 1002–05.

[15] Later on cross-examination, SA Burt admitted that the clinic also accepted payment via credit card. Tr. at 916.

[16] Inasmuch as the Government provided no information from which any specific number of patients seen by any given clinic doctor on any day could be derived, or any expert testimony regarding a reasonable number of pain patients that could or should be seen per day, the value of providing the raw number of patients walking through the door at the clinic is negligible.

[17] Burt further testified that the doctors were paid $75.00 per patient visit, *id.* at 884, but because he indicated that he could not disclose his basis of knowledge for this information, this portion of his testimony can be afforded no weight. To proceed otherwise would deny the Respondent the ability guaranteed by the APA "to conduct such cross-examination as may be required for a full and true disclosure of the facts." 5 U.S.C. 556(d); *see Richardson* v. *Perales,* 402 U.S. 389, 402 (1971); *J.A.M. Builders* v. *Herman,* 233 F.3d 1350, 1354 (11th Cir. 2000); *Keller* v. *Sullivan,* 928 F.2d 227, 230 (7th Cir. 1991); *Calhoun* v. *Bailar,* 626 F.2d 145, 149 (9th Cir. 1980).

[18] Tr. at 1002–05.

[19] The fact that these recordings were made during the course of seven different office visits by an undercover agent to both the Boca Raton and Lake Worth locations was established on cross-examination. Tr. at 900, 985.

[20] On cross-examination, SA Burt stated that he did not know whether it was true that the Respondent began working at the clinic in 2009 (a representation made by Respondent's counsel, but not in evidence), which (at least according to the question posed) would have been after Sollie's employment at the clinic had already ended. Tr. at 898.

for controlled substances that the patients claimed to be legitimately taking, with a view towards falsely providing evidence to the American Pain doctors showing that they were actually taking prescribed medications and not diverting them. *Id.* at 828–29. During cross-examination, Burt explained that Dr. Sollie told him he had raised these concerns with Christopher George, the owner of American Pain, and that Burt had no evidence that the deficient practices that Sollie had objected to continued through 2010. *Id.* at 900, 906. Burt also acknowledged that he was aware Dr. Sollie had been involved in litigation with Mr. George and that their relationship was strained. *Id.* at 1009. Dr. Sollie was not called as a witness by either party.

SA Burt also provided testimony concerning three confidential sources (only one of whom was seen by the Respondent) and their contacts with doctors at American Pain. Relative to the Respondent, Burt testified concerning his April 2009 debriefing of a confidential source of information (CS2) based in Kentucky who came to Burt's attention through his Kentucky law enforcement contacts. *Id.*at 866–67. Burt assisted the source's Kentucky handlers with arranging for CS2 to visit American Pain, at which time she was able to obtain a prescription for oxycodone from the Respondent. Burt testified that during the debriefing, CS2 told him the Respondent instructed her "not to go out of the State of Florida and try to get this pain medication [prescription] filled," and that it should instead be filled within Florida. *Id.* at 869. According to Burt, CS2 also indicated that she did not have a legitimate medical need for the controlled substances when they were acquired from the Respondent. The Government did not submit evidence of, or provide opposing counsel access to, a patient file reflecting CS2's visit with the Respondent, or a copy of the prescription allegedly issued.[21] Burt indicated CS2's cooperation in this investigation was as a result of "working off" criminal charges she was subject to. *Id.* at 895. Burt also declined to disclose the name of CS2 when queried on cross-examination. *Id.* at 893.[22]

SA Burt also testified regarding the drug overdose deaths of TY and SM after obtaining controlled substances from American Pain.[23] Burt's record testimony indicates that DEA Task Force Officer[24] (TFO) Barry Adams informed him that a Kentucky resident named TY overdosed in Kentucky from oxycodone intoxication induced by medication procured at American Pain. Burt testified that this information was furnished pursuant to a working law enforcement relationship between the Kentucky State Police, Kentucky FBI, Kentucky DEA and Miami DEA aimed at addressing "the brunt of the pill problem" centered within the State of Kentucky relative to illegal use and resale of prescription pain medications. *Id.* at 833–35. However, in his testimony, Burt was unable to recall the name of the doctor from whom TY obtained his pills, and, thus, no admissible evidence was presented by the Government with respect to TY's death.[25] Likewise, the record evidence concerning SM did not implicate prescribing activity by the Respondent.

Perhaps among the more striking aspects of SA Burt's performance on the witness stand is the anticipated testimony which he did not provide. When viewed in its entirety, SA Burt's record testimony was stunningly sparse when compared with his proposed testimony as noticed in the Government's prehearing statement.[26] That certain information may be unavailable for reasons related to other litigation forums, or other equally valid reasons, are of no moment with respect to the evaluation that must be made at this administrative forum. Equally important, such considerations do not alter the burdens imposed upon the respective parties. Simply put, the admitted evidence must succeed or fail on its own merits, irrespective of extraneous considerations.

Even apart from the marked contrast between the Burt testimony as proffered and as realized, his testimony was marred by periodic memory failures on significant issues and an inability to supply details to an extent that it could arguably have diminished the weight that could be fairly attached to those aspects of his own investigation that he did manage to recollect. During his testimony, SA Burt acknowledged his own marked lack of preparation and unfamiliarity with the investigation and confessed simply that "[t]here's no excuse * * *" *Id.* at 1003–05.

Even acknowledging its obvious suboptimal aspects, SA Burt's testimony had no apparent nefarious motivation or indicia of intentional deceit. Burt came across as an earnest and believable witness, who, regarding the aspects of the case that he did recall, was able to impart substantial information about the investigation and activities involving American Pain and its doctors. While frequently lacking in detail, his testimony was not internally inconsistent or facially implausible, and although the legal weight I have assigned to certain portions of Burt's testimony varies given the issues described, I find his testimony to be credible overall.

The Government presented the bulk of its case through the report and testimony of its expert, L. Douglas Kennedy, M.D., D.A.B.P.M., Affiliate Clinical Assistant Professor at the University of Miami, Miller School of Medicine.[27] Dr. Kennedy, who testified that he is board certified by the American Board of Pain Medicine and the American Board of Anesthesiology,[28] was offered and accepted as an expert in the field of pain medicine. Tr. at 39.

Dr. Kennedy prepared a report in connection with the Government's case against the Respondent, which is dated April 30, 2010, and was admitted into evidence during his testimony. Govt. Ex. 5. The report describes a general analysis of fifteen charts that the Respondent maintained on as many patients, that were (selected by and) provided to Dr. Kennedy by the Government[29] from among an

[21] On cross-examination, SA Burt responded in the negative when asked if he had "anywhere" in his possession a copy of the prescription at issue and whether he had supplied Government counsel with a copy of this individual's patient file. Tr. at 894.

[22] In light of the inability to identify the name of this source of information to opposing counsel, and the lack of detail and corroborating evidence related to the information derived from her, no weight can be assigned to SA Burt's testimony concerning information provided by CS2, beyond the fact that this interaction may have informed the course of DEA's investigation. To proceed otherwise would deny the Respondent the ability guaranteed by the APA "to conduct such cross-examination as may be required for a full and true disclosure of the facts." 5 U.S.C. § 556(d); *see Richardson* v. *Perales,* 402 U.S. 389, 402 (1971); *J.A.M. Builders* v. *Herman,* 233 F.3d 1350, 1354 (11th Cir. 2000); *Keller* v. *Sullivan,* 928 F.2d 227, 230 (7th Cir. 1991); *Calhoun* v. *Bailar,* 626 F.2d 145, 149 (9th Cir. 1980).

[23] Although similar testimony concerning the overdose death of a third individual, OB, was noticed in the Government's prehearing statement, it was not offered by the Government at the hearing. ALJ Ex. 6 at 8.

[24] According to SA Burt, a "task force officer" is a local police officer or sheriff's deputy that is assigned to work on a DEA task force, rather than a sworn DEA criminal investigator. Tr. at 1031.

[25] *See* Tr. at 836–53 (addressing exclusion of Govt. Ex. 27 and associated testimony).

[26] ALJ Ex. 6.

[27] Dr. Kennedy's CV was admitted into evidence. Govt. Ex. 117.

[28] Tr. at 17.

[29] Dr. Kennedy testified that he asked that the charts be selected randomly and not be "cherry picked" or selected with a view towards influencing his conclusions. Tr. at 214. As discussed, above, GS Langston testified that the reviewed charts were not selected with a view toward influencing Dr. Kennedy's opinion. Tr. at 768.

unspecified number of patient files seized pursuant to a criminal search warrant executed at the Respondent's practice on March 3, 2010 (Patient Charts Analysis).

In Dr. Kennedy's expert opinion, based on a documentary review of the patient charts from the Respondent's practice that he reviewed, the Respondent's prescribing practices fell below the standards set forth by the Florida Medical Board. Tr. at 118. Furthermore, Dr. Kennedy testified that after reviewing the charts, he was unable to identify any legitimate basis for prescribing any of the controlled substance medications prescribed to the patients named in the charts. *Id.*

During the course of his testimony, Dr. Kennedy explained that he took professional issue with several aspects of the Respondent's patient care as reflected in the charts regarding the prescribing of controlled substances. It is apparent from his testimony that Dr. Kennedy's analysis is restricted to those matters which can be gleaned from an examination of the written word in that subset of the Respondent's patient charts provided by the Government for his review, and that limitation perforce circumscribes the breadth of his testimony. That being said, Dr. Kennedy highlighted numerous features in the Respondent's chart documentation that he found wanting, or at least remarkable.

While acknowledging that some standardization and utilization of forms is not, standing alone, improper,[30] Dr. Kennedy took issue with what he perceived as flaws in the forms utilized by the Respondent to document patient care. According to Dr. Kennedy, the forms inadequately distinguished between the history and physical examinations, and failed to sufficiently document an adequate pain assessment. *Id.* at 79–80, 128–31. According to Dr. Kennedy, the charts also did not document activities that improved or exacerbated pain symptoms, and did not document self-described patient limits, neurological signs and objective observations, such as gait and station. *Id.* at 81. Dr. Kennedy testified that the chart entries were so defective that the Respondent did not establish a sufficient doctor-patient relationship to justify the prescribing of controlled substances, and that "this was not the practice of medicine in [his] opinion. *Id.* at 160–61.

Dr. Kennedy explained that there are basic elements to practicing pain medicine. The acquisition of a thorough history and physical examination is important. *Id.* at 44. He also stressed the vital importance of obtaining past medical records to evaluate what treatments, therapies, medications, and dosages have been utilized in the past so that correct current treatment decisions can be made. *Id.* at 47–48. Reliance upon the patient's memory of these elements without the prior medical records, in Dr. Kennedy's view, is not reliable or acceptable. *Id.* at 49–51. Although the Respondent's charts routinely contained a form which purports to require patients to see their primary care physicians, Dr. Kennedy testified that none of the files contained any record of any communication with any primary care physician from any patient. *Id.* at 114–16.

Kennedy also explained the importance of establishing a differential or working diagnosis on the first visit and modifying and reviewing that diagnosis as more information and results become available. *Id.* at 52. Similarly, a diagnostic plan is a systematic methodology of eliminating possible causes of symptoms to allow the treating physician to accurately determine what is causing them so that a successful treatment plan can be developed. *Id.* at 52–53. In other words, the diagnostic plan allows the treating doctor to eliminate or confirm items on the differential diagnosis. *Id.* at 54.

Dr. Kennedy testified that, in his expert opinion, the medical histories taken by the Respondent in the reviewed files were insufficiently detailed to meet the standards set by the Florida Board of Medicine to justify the prescribing of controlled substances. *Id.* at 81–82. The histories and pain assessment evaluations, as documented in the charts, were also "not adequate on the initial or ongoing basis," because the forms used and the manner in which they were completed did not sufficiently catalogue key aspects, such as

> [the] particular pain level, where the pain was located, what it felt like, when was it worse, what made it better, what it made it worse, what have you done to alleviate or past treatments, and what can you not do with the pain? Observations on physical examination about how the person walks, gait and station. Consistency of neurologic and inadequacy of pathologic reflexes particularly, presence or absence, and adequate sensory examination. Musculoskeletal examination. And height and weight many times were not present.

Id. at 80–81, *see also id.* at 128–32.

Similarly, Dr. Kennedy opined that Respondent's treatment plans, as they were reflected in the reviewed records, were "grossly inadequate" in that the use of controlled substances was the single option considered and employed, "[s]o everybody got essentially the same treatment regardless of their complaint, severity, physical examination [and] history." *Id.* at 82–83. In Kennedy's view, combining controlled substance medications that were utilized in the charts was not "bad by itself, but it was done across the board with everybody. * * * [with] essentially the same drugs at the same doses for all the individuals" *Id.* at 98. In Dr. Kennedy's view, there were a panoply of other treatment options that could and should have been documented and discussed with the Respondent's pain patients. *Id.* 162–64.

Dr. Kennedy also made the ironic observation that although to the "extremely rare" [31] extent controlled substance medication adjustments were ever effected by the Respondent, they went up, and the forms utilized by the Respondent (and the practice in general) only provided a checkbox for reduction, or weaning. *Id.* at 95–96. This is essentially inconsistent with the normal practice of starting controlled substance treatment at the lowest dose possible to attain the desired result and adjusting upwards. *Id.* The form used by the Respondent seems to presume that the controlled substance doses would generally progress downward. Dr. Kennedy testified that he saw no evidence of medication adjustment to accommodate treatment, or "titration," in any of the charts he examined. *Id.* at 174.

Although Dr. Kennedy conceded that it is the judgment of the examining physician that is generally relied upon in determining the necessity and appropriateness of diagnostic testing,[32] he also testified that the Respondent's practice of routinely ordering magnetic resonance imaging (MRI) procedures before he met with the patients was inappropriate because an MRI is not always required and not always appropriate. *Id.* at 71–73, 153–54. In Kennedy's opinion, a physician has an obligation to meet with the patient before including this procedure as part of the utilized diagnostic tools. *Id.*

Dr. Kennedy opined that the Respondent's prescribing of opioids lacked a legitimate medical purpose in that he routinely prescribed oxycodone in initial 30 milligram (mg) doses that significantly exceeded the recommended 0.5 to 2.5 mg starting dosage.[33] *Id.* at 86–87. Kennedy

[30] Tr. at 74.

[31] Tr. at 96.

[32] Tr. at 59.

[33] Dr. Kennedy testified that the recommended starting dosages are found in the medication product insert and divined through clinical knowledge. Tr. at 100.

explained that a patient who has never had opioids, or has been off them for two to four weeks is classified as "opioid naïve" and would feel the affects of the medication with smaller doses that can be increased as needed. *Id.* at 83–86. The dosage levels prescribed by the Respondent, in Dr. Kennedy's view, would always require significant monitoring of the medication's effect on the patient, generally done in an office or hospital, and not an outpatient setting. *Id.* at 86–88.

In this regard, Dr. Kennedy highlighted the chart of patient JR.[34] Govt. Ex. 7. JR's patient chart reflects his disclosures that he had not been prescribed pain medication within the twenty-eight days preceding his first appointment with the Respondent. *Id.* at 20. A notation on JR's pain contract indicates that he was not currently taking any medications at the time of his appointment. *Id.* at 23. Notwithstanding the fact that JR, at least by his representations, presented as an opioid naïve patient, the Respondent issued prescription scripts for 30 mg of Roxicodone and 2 mg of Xanax. *Id.* at 17. Kennedy characterized prescribing these controlled substances as "absolutely dangerous if [the patient] took that as prescribed. There would be a significant incident of respiratory depression, drug overdose and potentially death." Tr. at 90. When pressed on the relative likelihood of adverse effects, Dr. Kennedy responded this way:

> If the records that the patient filled out themselves [sic] are correct, then that especially given with the Xanax, which is a benzodiazepine like Valium[,] [i]ts generic name is alprazolam[,] [a]nd that's a high dose of Xanax as well. [] [T]he typical starting dose of Xanax is .25 to 0.5 [mg]. So, that's four to eight times higher than the usual dose on that, and that's given twice daily. Given that they work different areas in the nervous system and they both can cause sedation and potentially respiratory depression, there's at least an additive if not a synergistic effect between when you mix different components of an opioid like oxycodone, a narcotic pain reliever, with a benzodiazepine like Xanax, alprazolam, especially at those doses in a naïve person for both drugs, that makes it even more dangerous.

Id. at 91. Dr. Kennedy was asked to clarify whether this was an area where reasonable medical professionals could differ and provided this emphatic clarification:

> No sir, this isn't even close. There's no room, wiggle room on this. This is absolutely beyond the pale.

Id. at 92.

Notwithstanding his expressed concerns over the potency of some of the controlled substances prescribed by the Respondent, Dr. Kennedy was struck by the fact the charts of several of the Respondent's patients reflected no indication that any acceptable measure of mental status, cognitive ability and response time was undertaken. *Id.* at 102–07.

On cross-examination, Dr. Kennedy agreed that the reviewed charts reflected objective signs that arguably supported medically determinable impairments that could cause chronic pain conditions, and that the controlled substance medications that were prescribed by the Respondent were among those that could be correctly employed to treat chronic pain. *Id.* at 132–33, 135–37, 140–42, 144–45, 148–51. However, Dr. Kennedy remained steadfast in his dual views that the Respondent's medical records simply did not contain enough information for a physician to reach the conclusion that the prescribing was appropriate and that the medication doses were simply too high. *Id.* at 123, 126–27, 166. Kennedy was also consistent in his position that MRI results, standing alone, are not a reliable indicator of an impairment indicating the utilization of controlled substance medications. *Id.* at 55–63, 130–31, 164–66.

In his Patient Charts Analysis, Dr. Kennedy focuses on a patient chart related to GA, one of the Respondent's patients, and opines that the flaws identified in GA's chart are common to all fifteen of the Respondent's files that he reviewed. Specifically, the Patient Charts Analysis states that the charts he reviewed "are essentially the same with regard to review issues; as stated in the report of [GA] referenced and discussed in this report in detail, [and that] there were no significant differences that affected [his] conclusions and summary." Govt. Ex. 5 at 2.

In Dr. Kennedy's opinion, the patient charts he reviewed that were prepared by the Respondent reflected care that fell below the applicable standard on multiple levels. In his report, Dr. Kennedy noted that the treatment notes in the charts: (1) Contained no typewritten clinical notes and were "very brief, difficult to read (often impossible) and not within the bounds of professional practice due to their brevity and quality";[35] (2) reflected prescriptions, right from the initial patient visit, that "were almost entirely for controlled substances, most often one or two immediate release oxycodone pills with Xanax," and which were, in Dr. Kennedy's view, inappropriate and more powerful than justified by the objective signs documented in the written notes;[36] (3) showed that "the same or very similar 'drug cocktails' were prescribed [among all patients in the reviewed files] in the same or very similar doses, [directions] * * * with a 30-day supply," and were affixed to the prescription scripts with a few prepared stamps utilized by all American Pain physicians that reflected "drug, dose, sig (directions) and quantity dispensed";[37] (4) contained medication contracts that were "not always signed" and "listed criteria that was not followed by the doctors at American Pain;[38] (5) failed to adequately document the efficacy of the prescribed medication; (6) did not set forth a "diagnostic plan except to obtain an occasional MRI, the results of which made no difference in the 'treatment' ";[39] (7) reflected "no therapeutic plan, except to use controlled substances to 'treat' the subjective complaint of 'pain' which was inadequately described;[40] (8) reflected "inadequate therapeutic goals * * * for improvement of quality of life (activities of daily living, work, sleep, mood) with the prescription of

[34] At the request of the Government, a protective order was issued that is designed to minimize the risk of the dissemination of identifying information related to patients and their relatives associated with this case. Accordingly, initials have been substituted for the names of individuals within the protection of the protective order throughout the body of this decision. ALJ Ex. 15.

[35] Govt. Ex. 5 at 4.

[36] Govt. Ex. 5 at 4. In Dr. Kennedy's opinion, the Respondent "prescribed, at the first visit, very high initial doses of controlled substance combinations despite being outside the bounds of professional practice for histories and physical examinations and absent past medical records." *Id.* at 7.

[37] Govt. Ex. 5 at 4.

[38] Govt. Ex. 5 at 3. As an example of the failure to adhere to the terms of the medication contract, Dr. Kennedy cites a contract term that provides notice that the physician may stop prescribing opioids or change treatment if pain or activity improvement is not demonstrated, and points out that pain and activity levels are routinely not documented in treatment notes. *Id.* at 4. Similarly, Dr. Kennedy references a medication contract warning that termination of services may result from failure to make regular follow-up appointments with primary care physicians, and notes that the American Pain charts contain no notes from primary care physicians or medical records generated by them. *Id.*

[39] Govt. Ex. 5 at 7. In Dr. Kennedy's opinion, Respondent "in effect, acted as a 'barrier' for [GA] to receive appropriate medical evaluation and treatment. In other words, the very potent, high doses of opioids (oxycodone) and benzodiazepine (Xanax) could mask or cover up [GA's] underlying disease process(s), making them more difficult to diagnose, and allowing the disease(s) to unnecessarily worsen. Without an accurate diagnosis, all [the Respondent] was doing was, again, masking or covering up the symptoms." *Id.* at 10.

[40] Govt. Ex. 5 at 7.

controlled substance 'cocktails'";[41] (9) did not reflect "consultations with other physicians or specialists outside the American Pain group [which] could have and in some cases should have included orthopedics, neurology, neurosurgery, psychiatry, addiction medicine and/or psychology";[42] (10) reflected "a gross lack of past medical records in all charts reviewed and in some cases none at all";[43] and, (11) demonstrated controlled substance patient monitoring practices that were "not within the standard of care and outside the boundaries of professional practice."[44]

Dr. Kennedy found the Respondent's controlled substance patient monitoring to be deficient in numerous respects. From the reviewed patient charts, Dr. Kennedy gleaned that an initial, in-office urine drug screen was frequently executed during the patients' initial visit to the office but repeated only occasionally. Govt. Ex. 5 at 14. It was Dr. Kennedy's observation that even a drug screen anomaly did not alter the seemingly inexorable continuation of controlled substance prescribing from the Respondent. *Id.* Dr. Kennedy also noted that the Respondent did not utilize out-of-office toxicology tests, or obtain out-of-State prescription monitoring program or outside pharmacy drug profiles, and expressed concern that the in-house urinalysis documentation that was maintained did not provide sufficient detail regarding the procuring and maintaining of the sample to meaningfully gauge its reliability. *Id.;* Tr. at 107–111. Kennedy expressed his view that the whole drug testing process at the Respondent's office was inadequate. Furthermore, the charts contained only rare evidence of contact with primary care physicians, treating physicians, pharmacists, or other health care providers. *Id.*

The identified shortcomings of controlled substance patient monitoring systems was of particular significance where Dr. Kennedy identified specific evidence that he identified as "red flags" of possible or likely diversion. Red flags noted by Dr. Kennedy in the reviewed charts included the relatively young age of the Respondent's chronic pain patients,[45] incomplete history information provided by the patients, periodically significant gaps between office visits,[46] referrals from friends, relatives, or advertising, but not other physicians,[47] and the fact that a relatively high number of patients were traveling significant distances to American Pain for pain treatment, although no physician employed at that facility had any specialized training in pain management.[48] During his testimony, Dr. Kennedy conceded that, standing alone, the Respondent's treating out-of-State patients has no particular significance, and that when he was engaged in the practice of medicine in Kentucky he had patients who traveled to his office from Florida.[49] Tr. at 116. Regarding the Respondent's Kentucky patients, Dr. Kennedy observed that there were numerous medical and osteopathic schools that were much closer to the homes of these patients that could have provided pain management. *Id.* at 116–17.

Although Dr. Kennedy's report and testimony appear to attach some significance to referrals that originated in family and friends, he later clarified that it was not unusual for a physician to treat patients that have been referred by relatives and friends. *Id.* at 154. Further, Kennedy conceded while in the course of his own medical practice he has treated patients referred by family and friends, and that in his report he was focusing on what he perceived as a lack of any referrals by physicians in the files he reviewed, or what he perceived as "trends" or "patterns." *Id.* at 154–55. Given Dr. Kennedy's acknowledgement that such referrals are not unusual, coupled with the absence of any way to measure the relative percentage of physician referrals in the Respondent's practice based on the record evidence, the observations regarding referral sources are of limited value here.[50]

During his testimony as well as his report, Dr. Kennedy highlighted several features of particular charts that, at least in his view, bore the indicia of some red flags that should have signaled an increased risk of controlled substance diversion. Kennedy detailed several controls that should have been, but were apparently not utilized by the Respondent to monitor diversion risks in a pain management practice. *Id.* at 111. Some examples of expected diversion controls that were available to, yet absent from the Respondent's practice included random pill counts, communication with family members, blood tests to supplement urinalysis drug screens, communication with patient pharmacists and the acquisition of pharmacy readout sheets to evaluate the prescriptions filled and sources of those prescriptions, and the acquisition of printouts from prescription monitoring programs (PMPs) in some of the States[51] where his patients resided. *Id.* at 111–13.

Although not touched upon by Dr. Kennedy in his testimony or report,[52] there were other indications of potential red flags and related anomalies among the charts admitted into evidence. For example, patient JR's chart contains a form indicating a positive UDS for oxycodone and opiates from 12/30/09, yet on the same date, the medication contract signed by JR reflects a handwritten "N/A" notation in the section where a patient is supposed to list any medications they are currently taking. Govt. Ex. 7 at 10, 23; *see also* Govt. Ex. 19 at 10–11, 23 (similar issue). Patient MR's file, on the other hand, indicates a positive UDS for oxycodone only, yet the patient indicates he is currently taking Xanax (a benzodiazepine that should have triggered a positive UDS reading) on two different documents, a discrepancy which raises questions about the validity of the testing procedures and/or the patient's candor. Govt. Ex. 8 at 13–14, 28; *see also* Govt. Exs. 10 at 9, 22; 12 at 12, 26; 17 at 12–13 (similar discrepancies present in other patient

[41] Govt. Ex. 5 at 7.

[42] Govt. Ex. 5 at 7.

[43] Govt. Ex. 5 at 15. The only past medical record contained in GA's chart was a report from an MRI conducted one day prior to the patient's initial office visit at American Pain. *Id.* at 8.

[44] Govt. Ex. 5 at 14.

[45] Govt. Ex. 5 at 15.

[46] Govt. Ex. 5 at 13.

[47] Govt. Ex. 5 at 7, 15.

[48] Govt. Ex. 5 at 15; Tr. at 67–68.

[49] Although the Government elicited testimony from Dr. Kennedy concerning his perceived significance to a "majority" of patients coming from out of State, Tr. at 116–17, since there was no evidence regarding what percentage of the Respondent's patients were from outside Florida, this inquiry and its responses have been given no weight.

[50] Dr. Kennedy did not testify that a referral that emanated from a source other than a physician could or should be a basis for a diversion red flag on a given case. His opinion was limited to culling some manner of a trend or pattern. In view of the fact that the record contains no development of the numbers of files with non-physician referrals versus the total number of files, or even an acceptable metric upon which the issue could be evaluated, there is very little useful analysis that can come from Dr. Kennedy's observation regarding the files he reviewed.

[51] Dr. Kennedy testified that although Florida does not have a PMP, several of the States where some of the Respondent's patients resided did have such programs, and that the Respondent would have had access to obtain information about his patients in this manner. Tr. at 113.

[52] The Government's tactical decision to essentially unload a pile of charts that are explained only by the representations and generalizations in a report, with no attempt whatsoever to have its expert witness explain the applicable aspects of most charts to this tribunal or any future reviewing body is clearly at odds with the directive provided by the Deputy Administrator in *Gregg & Son Distributors* that "it is the Government's obligation as part of its burden of proof and not the ALJ's responsibility to sift through the records and highlight that information which is probative of the issues in the proceeding." 74 FR 17517 n.1.

files with respect to those drugs present on UDS in comparison to current medications listed in medication contract and other forms). Patient BS's UDS indicates a negative test for all listed substances, yet on two different forms she indicates she is currently taking two strengths of Roxycodone along with Xanax. Govt. Ex. 16 at 6–7, 18. A prescribed controlled substance that is not reflected in a drug screen should have raised a sufficient suspicion of diversion to merit further inquiry by the registrant reflected in the patient file. The UDS form in patient TS's file reflects circled positive results for benzodiazepines, opiates, and oxycodone on "2/12," yet the words "Neg Test" is handwritten and circled in the margin. Govt. Ex. 13 at 9. Numerous patient files also reflected notations that patients "requested" specific types and/or strengths of controlled substances. Govt. Exs. 6 at 6; 7 at 2; 8 at 4; 17 at 2; 20 at 3; 21 at 3. At a minimum, these observations support the conclusion there was a general lack of vigilance on the part of the Respondent regarding his obligations as a registrant to minimize the risk of controlled substance diversion.

Interestingly, in his report, Dr. Kennedy also found it remarkable that each American Pain patient file provided notice to its patients that American Pain did not accept any form of health care insurance. Govt. Ex. 5 at 3, 16. The report reflected Kennedy's view that this practice was designed to "effectively keep [the physicians at American Pain] 'off the radar' from monitoring by any private health care insurance company as well as all State and Federal agencies (Medicaid and Medicare respectively)." *Id.* at 16. Significantly, however, when asked, Dr. Kennedy acknowledged that he conducts his own current medical practice on a cash-only basis. Tr. at 151.

Dr. Kennedy concluded his report regarding the Respondent's prescribing practices with the following summary:

> [The Respondent] was not engaged in the practice of medicine, rather he was engaged in an efficient, "[a]ssembly [l]ine" business. His "patients" were revenue streams, not true patients. This business allowed him to collect cas[h] for office visits as well as being a "[d]ispensing [p]hysician" for controlled substances. He prescribed controlled substances so that "patients" would return to his office on a regular basis, allowing him to generate further revenue. [The Respondent's] routine and excessive prescription of multiple controlled substances (oxycodone and Xanax) and lack of arriving at a valid medical diagnosis and treatment most likely caused harm to the "patients" he saw. Drug diversion most likely caused a "mushroom" effect of increased drug abuse, drug addiction, drug overdoses, serious bodily injury and death in those communities spread over several different states. [The Respondent's] continued ability to prescribe controlled substances will only perpetuate the suffering and be a threat to the public.

Govt. Ex. 5 at 16.

The Government's presentation of Dr. Kennedy's testimony at the hearing was substantially consistent with the conclusions included in the Patient Charts Analysis, but Dr. Kennedy's presentation was clearly not without its blemishes. Although he testified that he was familiar with prescribing practices in Florida, and that he utilized the medical standards applicable to Florida practice,[53] he was unable to identify the documentation standard in the Florida Administrative code with any degree of particularity, and he also acknowledged that he was not aware of what the standard is in Florida Medical Board administrative decisions regarding the overprescribing of medication or what constitutes an adequate medical history. Tr. at 149–51, 233, 304. While, overall, Kennedy presented testimony that appeared candid and knowledgeable, there were areas in his written report that rang of hyperbole and over-embellishment. The reasoning behind some of the seemingly critical observations in the written report, such as the "cash basis" of the Respondent's practice and the absence of doctor referrals among the reviewed patient files, did not well survive the crucible of cross examination at the hearing. However, overall, Dr. Kennedy's testimony was sufficiently detailed, plausible, and internally consistent to be considered credible, and, consistent with his qualifications, he spoke persuasively and with authority on some relevant issues within his expertise, and notwithstanding the Respondent's objections relative to his Florida-related experience, he is currently an assistant professor teaching at a Florida Medical School. It may well be that the greatest and most significant aspect of Dr. Kennedy's opinion is that on the current record, it stands unrefuted. Thus, his opinion is the only expert opinion available for reliance in this action.[54] Dr. Kennedy testified that based on his review of the selected patient charts from the Respondent's medical practice, in his expert opinion, he "couldn't find any legitimate basis for [the Respondent] prescribing medications to any of the [patients] and that the Respondent's prescribing practices "were not in compliance at all from the very first visit on" with the standards set forth by the Florida Medical Board. *Id.* at 118. Accordingly, Dr. Kennedy's expert opinion that the Respondent's controlled substance prescribing practices, at least as evidenced through his examination of the patient charts he reviewed, fell below the standards applicable in Florida, and that the controlled substance prescriptions contained in those files were not issued for a legitimate medical purpose is unrefuted on this record and (although by no means overwhelming) is sufficiently reliable to be accepted and relied upon in this recommended decision.

The Analysis

Pursuant to 21 U.S.C. 824(a)(4), the Deputy Administrator[55] may revoke a registrant's DEA Certificate of Registration if persuaded that the registrant "has committed such acts that would render * * * registration under section 823 * * * inconsistent with the public interest * * *." The following factors have been provided by Congress in determining "the public interest":

> (1) The recommendation of the appropriate State licensing board or professional disciplinary authority.
>
> (2) The applicant's experience in dispensing, or conducting research with respect to controlled substances.
>
> (3) The applicant's conviction record under Federal or State laws relating to the manufacture, distribution, or dispensing of controlled substances.
>
> (4) Compliance with applicable State, Federal or local laws relating to controlled substances.
>
> (5) Such other conduct which may threaten the public health and safety.

21 U.S.C. 823(f).

"[T]hese factors are considered in the disjunctive." *Robert A. Leslie, M.D.,* 68 FR 15227, 15230 (2003). Any one or a combination of factors may be relied upon, and when exercising authority as an impartial adjudicator, the Deputy Administrator may properly give each factor whatever weight she deems appropriate in determining whether an application for a registration should be denied. *JLB, Inc., d/b/a Boyd Drugs,* 53 FR 43945 (1988); *England Pharmacy,* 52 FR 1674 (1987); *see also David H. Gillis, M.D.,* 58 FR 37507, 37508 (1993); *Joy's Ideas,* 70 FR 33195, 33197 (2005); *Henry J. Schwarz, Jr., M.D.,* 54 FR 16422 (1989). Moreover, the Deputy Administrator is "not required to make findings as to all of the factors * * *." *Hoxie* v. *DEA,* 419 F.3d 477, 482 (6th Cir. 2005); *see also Morall* v. *DEA,* 412 F.3d 165, 173–74 (DC Cir. 2005). The

[53] Tr. at 628.

[54] The Respondent did not testify on his own behalf.

[55] This authority has been delegated pursuant to 28 CFR 0.100(b) and 0.104.

Deputy Administrator is not required to discuss consideration of each factor in equal detail, or even every factor in any given level of detail. *Trawick* v. *DEA,* 861 F.2d 72, 76 (4th Cir. 1988) (the Administrator's obligation to explain the decision rationale may be satisfied even if only minimal consideration is given to the relevant factors and remand is required only when it is unclear whether the relevant factors were considered at all). The balancing of the public interest factors "is not a contest in which score is kept; the Agency is not required to mechanically count up the factors and determine how many favor the Government and how many favor the registrant. Rather, it is an inquiry which focuses on protecting the public interest * * *." *Jayam Krishna-Iyer, M.D.,* 74 FR 459, 462 (2009).

In an action to revoke a registrant's DEA COR, the DEA has the burden of proving that the requirements for revocation are satisfied. 21 CFR 1301.44(e). Once DEA has made its *prima facie* case for revocation of the registrant's DEA Certificate of Registration, the burden of production then shifts to the Respondent to show that, given the totality of the facts and circumstances in the record, revoking the registrant's registration would not be appropriate. *Morall,* 412 F.3d at 174; *Humphreys* v. *DEA,* 96 F.3d 658, 661 (3d Cir. 1996); *Shatz* v. *U.S. Dept. of Justice,* 873 F.2d 1089, 1091 (8th Cir. 1989); *Thomas E. Johnston,* 45 FR 72, 311 (1980). Further, "to rebut the Government's *prima facie* case, [the Respondent] is required not only to accept responsibility for [the established] misconduct, but also to demonstrate what corrective measures [have been] undertaken to prevent the reoccurrence of similar acts." *Jeri Hassman, M.D.,* 75 FR 8194, 8236 (2010).

Where the Government has sustained its burden and established that a registrant has committed acts inconsistent with the public interest, that registrant must present sufficient mitigating evidence to assure the Deputy Administrator that he or she can be entrusted with the responsibility commensurate with such a registration. *Steven M. Abbadessa, D.O.,* 74 FR 10077 (2009); *Medicine Shoppe-Jonesborough,* 73 FR 364, 387 (2008); *Samuel S. Jackson, D.D.S.,* 72 FR 23848, 23853 (2007). Normal hardships to the practitioner, and even the surrounding community, that are attendant upon the lack of registration are not a relevant consideration. *Abbadessa,* 74 FR at 10078; *see also Gregory D. Owens, D.D.S.,* 74 FR 36751, 36757 (2009).

The Agency's conclusion that past performance is the best predictor of future performance has been sustained on review in the courts, *Alra Labs.* v. *DEA,* 54 F.3d 450, 452 (7th Cir. 1995), as has the Agency's consistent policy of strongly weighing whether a registrant who has committed acts inconsistent with the public interest has accepted responsibility and demonstrated that he or she will not engage in future misconduct. *Hoxie,* 419 F.3d at 483; *George C. Aycock, M.D.,* 74 FR 17529, 17543 (2009); *Abbadessa,* 74 FR at 10078; *Krishna-Iyer,* 74 FR at 463; *Medicine Shoppe,* 73 FR at 387.

While the burden of proof at this administrative hearing is a preponderance-of-the-evidence standard, *see Steadman* v. *SEC,* 450 U.S. 91, 100–01 (1981), the Deputy Administrator's factual findings will be sustained on review to the extent they are supported by "substantial evidence." *Hoxie,* 419 F.3d at 481. While "the possibility of drawing two inconsistent conclusions from the evidence" does not limit the Deputy Administrator's ability to find facts on either side of the contested issues in the case, *Shatz,* 873 F.2d at 1092; *Trawick,* 861 F.2d at 77, all "important aspect[s] of the problem," such as a respondent's defense or explanation that runs counter to the Government's evidence, must be considered. *Wedgewood Vill. Pharmacy* v. *DEA,* 509 F.3d 541, 549 (DC Cir. 2007); *Humphreys,* 96 F.3d at 663. The ultimate disposition of the case must be in accordance with the weight of the evidence, not simply supported by enough evidence to justify, if the trial were to a jury, a refusal to direct a verdict when the conclusion sought to be drawn from it is one of fact for the jury. *Steadman,* 450 U.S. at 99 (internal quotation marks omitted).

Regarding the exercise of discretionary authority, the courts have recognized that gross deviations from past agency precedent must be adequately supported, *Morall,* 412 F.3d at 183, but mere unevenness in application does not, standing alone, render a particular discretionary action unwarranted. *Chein* v. *DEA,* 533 F.3d 828, 835 (DC Cir. 2008) (citing *Butz* v. *Glover Livestock Comm. Co., Inc.,* 411 U.S. 182, 188 (1973)), *cert. denied,* __ U.S. __, 129 S.Ct. 1033 (2009). It is well-settled that since the Administrative Law Judge has had the opportunity to observe the demeanor and conduct of hearing witnesses, the factual findings set forth in this recommended decision are entitled to significant deference, *Universal Camera Corp.* v. *NLRB,* 340 U.S. 474, 496 (1951), and that this recommended decision constitutes an important part of the record that must be considered in the Deputy Administrator's decision, *Morall,* 412 F.3d at 179. However, any recommendations set forth herein regarding the exercise of discretion are by no means binding on the Deputy Administrator and do not limit the exercise of that discretion. 5 U.S.C. 557(b); *River Forest Pharmacy, Inc.* v. *DEA,* 501 F.2d 1202, 1206 (7th Cir. 1974); *Attorney General's Manual on the Administrative Procedure Act* 8 (1947).

Factors 1 and 3: The Recommendation of the Appropriate State Licensing Board or Professional Disciplinary Authority and Conviction Record Under Federal or State Laws Relating to the Manufacture, Distribution, or Dispensing of Controlled Substances

In this case, it is undisputed that the Respondent holds a valid and current State license to practice medicine. The record contains no evidence of a recommendation regarding the Respondent's medical privileges by any cognizant State licensing board or professional disciplinary authority. However, that a State has not acted against a registrant's medical license is not dispositive in this administrative determination as to whether continuation of a registration is consistent with the public interest. *Patrick W. Stodola, M.D.,* 74 FR 20727, 20730 (2009); *Jayam Krishna-Iyer,* 74 FR at 461. It is well-established Agency precedent that a "state license is a necessary, but not a sufficient condition for registration." *Leslie,* 68 FR at 15230; *John H. Kennedy, M.D.,* 71 FR 35705, 35708 (2006). Even the reinstatement of a State medical license does not affect the DEA's independent responsibility to determine whether a registration is in the public interest. *Mortimer B. Levin, D.O.,* 55 FR 9209, 8210 (1990). The ultimate responsibility to determine whether a registration is consistent with the public interest has been delegated exclusively to the DEA, not to entities within State government. *Edmund Chein, M.D.,* 72 FR 6580, 6590 (2007), *aff'd, Chein* v. *DEA,* 533 F.3d 828 (DC Cir. 2008), *cert. denied,* __ U.S. __, 129 S.Ct. 1033 (2009). Congress vested authority to enforce the CSA in the Attorney General and not State officials. *Stodola,* 74 FR at 20375. Thus, on these facts, the fact that the record contains no evidence of a recommendation by a State licensing board does not weigh for or against a determination as to whether continuation of the Respondent's DEA certification is consistent with the public interest.

Similarly, regarding Factor 3, while testimony was received at the hearing

that indicated that a criminal search warrant was executed regarding the Respondent and American Pain, the record contains no evidence that the Respondent has ever been convicted of any crime or even arrested in connection with any open criminal investigation. Thus, consideration of the record evidence under the first and third factors does not militate in favor of revocation.

Factors 2, 4 and 5: The Respondent's Experience in Dispensing Controlled Substances, Compliance With Applicable State, Federal or Local Laws Relating to Controlled Substances, and Such Other Conduct Which May Threaten the Public Health and Safety

In this case, the gravamen of the allegations in the OSC, as well as the factual concentration of much of the evidence presented, share as a principal focus the manner in which the Respondent has managed that part of his practice relative to prescribing and dispensing controlled substances and acts allegedly committed in connection with his practice at American Pain. Thus, it is analytically logical to consider public interest factors two, four and five together. That being said, factors two, four and five involve analysis of both common and distinct considerations.

Regarding Factor 2, the qualitative manner and the quantitative volume in which a registrant has engaged in the dispensing of controlled substances, and how long he has been in the business of doing so are factors to be evaluated in reaching a determination as to whether he should be entrusted with a DEA certificate. In some cases, viewing a registrant's actions against a backdrop of how he has performed activity within the scope of the certificate can provide a contextual lens to assist in a fair adjudication of whether continued registration is in the public interest.

There are two principal considerations embedded within a consideration of this public interest factor. In considering a similar factor under the List I chemical context, the Agency has recognized that the level of experience held by those who will be charged with recognizing and taking steps to minimize diversion factors greatly in determining whether entrusting a COR will be in the public interest. *See Volusia Wholesale,* 69 FR 69409, 69410 (2004); *Xtreme Enters., Inc.,* 67 FR 76195, 76197–98 (2004); *Prachi Enters.,* 69 FR 69407, 69409 (2004); *J&S Distribs.,* 69 FR 62089, 62090 (2004); *K.V.M. Enters.,* 67 FR 70968, 70969 (2002). The Agency has also recognized that evidence that a registrant may have conducted a significant level of sustained activity within the scope of the registration for a sustained period is a relevant and correct consideration, which must be accorded due weight. However, this factor can be outweighed by acts held to be inconsistent with the public interest. Experience which occurred prior and subsequent to proven allegations of malfeasance may be relevant. Evidence that precedes proven misconduct may add support to the contention that, even acknowledging the gravity of a particular registrant's transgressions, they are sufficiently isolated and/or attenuated that adverse action against its registration is not compelled by public interest concerns. Likewise, evidence presented by the Government that the proven allegations are consistent with a consistent past pattern of poor behavior can enhance the Government's case.

In this case, the Respondent introduced no evidence regarding his level of knowledge and experience, or even the quality or length of his experience as a physician-registrant, but the Government has elected to do so.

Regarding the Government's presentation, Agency precedent has long held that in DEA administrative proceedings "the parameters of the hearing are determined by the prehearing statements." *CBS Wholesale Distribs.,* 74 FR 36746, 36750 (2009) (citing *Darrel Risner, D.M.D.,* 61 FR 728, 730 (1996); *see also Roy E. Berkowitz, M.D.,* 74 FR 36758, 36759–60 (2009) ("pleadings in administrative proceedings are not judged by the standards applied to an indictment at common law" and "the rules governing DEA hearings do not require the formality of amending a show cause order to comply with the evidence"). That being said, however, the marked difference between the amount of evidence that the Government noticed in its OSC/ISO and the amount that it introduced at the hearing is striking. For example, contrary to its allegations, there was no evidence that the Respondent "prescribe[d] and dispense[d] *inordinate* amounts of controlled substances," that the "*majority*" of the Respondent's patients were "from states other than Florida," and there was no evidence that American Pain patients were issued "*pre-signed* prescriptions to obtain MRI[s]," nor was there evidence that individuals positioned outside the American Pain building were there to "monitor the activity of patients in the parking lot *to prevent patients from selling their recently obtained controlled substances*." Likewise, no evidence was introduced at the hearing that could support the allegations that "employees of American Pain [] *frequently* ma[d]e announcements to patients in the clinic advising them on how to avoid being stopped by law enforcement upon departing the pain clinic" and "*frequently* ma[d]e announcements [] advising [patients], among other things, not to attempt to fill their prescriptions at out-of State pharmacies and warning them against trying to fill their prescriptions at particular local retail pharmacies." ALJ Ex. 1 (emphasis supplied).

In like fashion, the Government's prehearing statement proffered that SA Burt would testify to several of the items described but not established in the OSC/ISO. Among the list of allegations that were *not supported by any evidence introduced at the hearing,* were representations that SA Burt would testify concerning the following:

> Law enforcement in Florida and [other states that correspond to license plates seen in the American Pain parking lot] frequently arrest people for illegal possession and/or illegal distribution of controlled substances who have obtained the controlled substances from American Pain;
>
> American Pain hired individuals to "roam" the parking lot of the clinic to dissuade people from selling their recently obtained controlled substances on the property;
>
> [The reason American Pain placed] signs within American Pain warning individuals not to have their prescriptions filled at Walgreens pharmacies [is] because Walgreens refuses to dispense the prescriptions;
>
> Walgreens has flagged all American Pain doctors and will not fill any of their prescriptions;
>
> [Physical exams at American Pain are] usually no more than a blood pressure check and some bending and stretching;
>
> Dismissed patients would be routed to other doctors within the clinic;
>
> [There was] co-mingling of [American Pain] physician's drugs;
>
> [American Pain maintained] no inventories of drugs dispensed;
>
> [Details surrounding] the death of [American Pain] patient OB [where] [t]he cause of death was determined to be drug intoxication—opiate and benzodiazepine;
>
> [Information] from a confidential source [who indicated] that she traveled to American Pain in order to obtain controlled substances that were later sold in Kentucky for $25 per pill[,] [that] [the American Pain physician she encountered] did not spend any significant time conducting a physical examination of [her] [,] [that she would simply ask questions regarding [her] well being and would then "stamp" a prescription for [controlled substances][,] * * * that on one visit [during a power failure a] security guard working for the clinic instructed everyone to be patient and that the doctors would be with them shortly to "get your fix."

ALJ Ex. 6 at 3–9.

The Government's Prehearing Statement also represented that it would

be presenting the testimony of Intelligence Analyst (IA) Janet Hines, who would relate her encounter with a confidential source who allegedly obtained controlled substances from the Respondent with minimal or no physical examinations and intentionally diverted them. ALJ Ex. 6. The Government never called IA Hines and never offered an explanation for the differences between the expansive proffers and the less-expansive ultimate presentation.

To be clear, it is not that the evidence was introduced and discredited; no evidence to support these (and other) allegations was introduced at all. To the extent the Government had this evidence, it left it home. While the stunning disparity between the allegations proffered and those that were supported with any evidence does not raise due process concerns, it is worthy of noting, without deciding the issue, that Agency precedent has acknowledged the Supreme Court's recognition of the applicability of the *res judicata* doctrine in DEA administrative proceedings. *Christopher Henry Lister, P.A.,* 75 FR 28068, 28069 (2010) (citing *University of Tennessee* v. *Elliot,* 478 U.S. 788, 797–98 (1986) ("When an administrative agency is acting in a judicial capacity and resolves disputed issues of fact properly before it which the parties have had an adequate opportunity to litigate, the courts have not hesitated to apply *res judicata*[.]")

The evidence the Government did present raises issues regarding not only Factor 2 (experience dispensing [56] controlled substances), but also Factors 4 (compliance with Federal and State law relating to controlled substances) and 5 (other conduct which may threaten public health and safety). Succinctly put, the Government's evidence related to the manner in which the Respondent practiced, and whether his practice complied with the law and/or was a threat to the public.

While true that GS Langston convincingly testified about the course of her investigation and laid an adequate foundation for numerous database results, the Government provided no foundational context for any relevant uses for those database results. Without some insight into what types of results from these databases should be expected when compared to similarly-situated registrants engaged in acceptable prescribing practices, the raw data is without use. In short, there was no evidence elicited wherein the percentage of the Respondent's in-State to out-of State patients could be assessed, and no reasonable measuring stick based on sound principles upon which to evaluate such data. Likewise, there was no reliable yardstick upon which to measure the amount of controlled substances reflected in the databases compared to what a reasonable regulator would expect to see regarding a compliant registrant. To the extent Langston possessed this information (and she well may have) it was not elicited from her. The same could be said of the allegation set forth in the Government's Prehearing Statement that alleges that from a given period the Respondent "was the 16th largest practitioner purchaser of oxycodone in the United States." [57] No evidence to support that allegation (or its relevance) was ever brought forth at the hearing. To the extent that fact may have been true or relevant, it was never developed. What's more, as ably pointed out by Respondent's counsel,[58] the Florida Administrative Code specifically eschews pain medication prescribing analysis rooted only in evaluation of medication quantity. Fla. Admin. Code r. 64B8–9.013(g).[59] Lastly, there was no indication that despite Langston's obvious qualifications to do so, that she or anyone else ever conducted an audit of the controlled-substance-inventory-related recordkeeping practices at American Pain.

SA Burt testified that, during a temporally limited period of time, he observed some of the images captured by a pole camera positioned outside American Pain, and that he observed what in his view was a high percentage of vehicles in the parking lot with out-of-State license tags. This testimony arguably provides some support for the Government's contention that out-of-State patients (or at least patients being dropped off by cars with out-of-State tags) were being seen at the clinic, but his testimony did not provide much else in terms of relevant information. In any event, recent Agency precedent holds that details such as "where [a registrant's] patients were coming from," without additional factual development, can support a "strong suspicion that [a] respondent was not engaged in a legitimate medical practice" but that "under the substantial evidence test, the evidence must 'do more than create a suspicion of the existence of the fact to be established.'" *Alvin Darby, M.D.,* 75 FR 26993, 26999, n.31 (2010) (citing *NLRB* v. *Columbian Enameling & Stamping Co.,* 306 U.S. 292, 300 (1939).

Likewise, without additional details or at least some context, Burt's testimony that individuals with "staff" written on their shirts appeared to be directing patients into the clinic reveals virtually nothing about the Respondent's prescribing practices. Tr. 818, 910. Furthermore, that Burt observed an individual on a videotape, who he believed to be an American Pain employee, on a single occasion, instruct patients not to "snort [their] pills" in the parking lot,[60] or advising them to comply with vehicle and traffic laws,[61] does not shed illumination on the Respondent's prescribing practices. There was no evidence that the Respondent knew that these isolated incidents occurred, nor was there contextual evidence from which the relevance to these proceedings could be gleaned. Even if this tribunal was inclined to engage in the unsupported assignment of motives to the actions of these employees, under these circumstances, such an exercise could not constitute substantial evidence that could be sustained at any level of appeal.

Burt's testimony regarding his conversations with Dr. Sollie, who was formerly employed by American Pain, were also not received in a manner that could meaningfully assist in the decision process. According to Burt, Sollie told him that some (unnamed) physicians at American Pain were inadequately documenting their patient charts in some manner that was apparently never explained to Burt,[62] and that some patients were intentionally evading the American Pain urinalysis process. Sollie did not work at American Pain at the same time the Respondent did, and did not specifically name any physician as being connected with his allegations of misconduct. Thus, this tribunal is at something of a loss as to how the information, as presented, would tend to establish a fact relevant to whether the continuation of the Respondent's authorization to handle controlled substances is in the public interest.

The Government's evidence targeted not only the Respondent's experience practicing under Factor 2, but also his compliance with applicable State and Federal laws relating to controlled substances under Factor 4. To effectuate the dual goals of conquering drug abuse and controlling both legitimate and

[56] The statutory definition of the term "dispense" includes the prescribing and administering of controlled substances. 21 U.S.C. 802(10).

[57] ALJ Ex. 6 at 11–12.

[58] Respt's Br. at 20.

[59] The Respondent's brief incorrectly sites subsection (f).

[60] Tr. at 825.

[61] Tr. at 826.

[62] Tr. at 898.

illegitimate traffic in controlled substances, "Congress devised a closed regulatory system making it unlawful to manufacture, distribute, dispense, or possess any controlled substance except in a manner authorized by the CSA." *Gonzales* v. *Raich,* 545 U.S. 1, 13 (2005). Consistent with the maintenance of that closed regulatory system, subject to limited exceptions not relevant here, a controlled substance may only be dispensed upon a prescription issued by a practitioner, and such a prescription is unlawful unless it is "issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice." 21 U.S.C. 829; 21 CFR 1306.04(a). Furthermore, "an order purporting to be a prescription issued not in the usual course of professional treatment * * * is not a prescription within the meaning and intent of [21 U.S.C. 829] and the person knowingly * * * issuing it, shall be subject to the penalties provided for violations of the provisions of law related to controlled substances." *Id.*

A registered practitioner is authorized to dispense,[63] which the CSA defines as "to deliver a controlled substance to an ultimate user[64] * * * by, or pursuant to the lawful order of a practitioner." 21 U.S.C. 802(10); *see also Rose Mary Jacinta Lewis,* 72 FR 4035, 4040 (2007). The prescription requirement is designed to ensure that controlled substances are used under the supervision of a doctor, as a bulwark against the risk of addiction and recreational abuse. *Aycock,* 74 FR at 17541 (citing *Gonzales* v. *Oregon,* 546 U.S. 243, 274 (2006); *United States* v. *Moore,* 423 U.S. 122, 135, 142–43 (1975) (noting that evidence established that a physician exceeded the bounds of professional practice when he gave inadequate examinations or none at all, ignored the results of the tests he did make, and took no precautions against misuse and diversion)). The prescription requirement likewise stands as a proscription against doctors "peddling to patients who crave the drugs for those prohibited uses." *Id.* The courts have sustained criminal convictions based on the issuing of illegitimate prescriptions where physicians conducted no physical examinations or sham physical examinations. *United States* v. *Alerre,* 430 F.3d 681, 690–91 (4th Cir. 2005), *cert. denied,* 574 U.S. 1113 (2006); *United States* v. *Norris,* 780 F.2d 1207, 1209 (5th Cir. 1986).

While true that the CSA authorizes the "regulat[ion] of medical practice so far as it bars doctors from using their prescription-writing powers as a means to engage in illicit drug dealing and trafficking as conventionally understood," *Gonzales,* 546 U.S. at 266–67, an evaluation of cognizant State standards is essential. *Joseph Gaudio, M.D.,* 74 FR 10083, 10090 (2009); *Kamir Garces-Mejias, M.D.,* 72 FR 54931, 54935 (2007); *United Prescription Servs., Inc.,* 72 FR 50397, 50407 (2007). In this adjudication, the evaluation of the Respondent's prescribing practices must be consistent with the CSA's recognition of State regulation of the medical profession and its bar on physicians from peddling to patients who crave drugs for prohibited uses. The analysis must be "tethered securely" to State law and Federal regulations in application of the public interest factors, and may not be based on a mere disagreement between experts as to the most efficacious way to prescribe controlled substances to treat chronic pain sufferers. *Volkman* v. *DEA,* 567 F.3d 215, 223 (6th Cir. 2009) (citing *Gonzales,* 546 U.S. at 272, 274).

Under the CSA, it is fundamental that a practitioner must establish a bonafide doctor-patient relationship in order to act "in the usual course of * * * professional practice" and to issue a prescription for a legitimate medical purpose." *Stodola,* 74 FR at 20731; *Shyngle,* 74 FR at 6057–58 (citing *Moore,* 423 U.S. at 141–43). The CSA looks to State law to determine whether a bonafide doctor-patient relationship existed. *Stodola,* 74 FR at 20731; *Shyngle,* 74 FR at 6058; *Garces-Mejias,* 72 FR at 54935; *United Prescription Servs.,* 72 FR at 50407. It was Dr. Kennedy's uncontroverted opinion that his evaluation of chart entries convinced him that they were so defective that the Respondent did not establish a sufficient doctor-patient relationship to justify the prescribing of controlled substances, and that "this was not the practice of medicine in [his] opinion." Tr. at 160–61.

Under Florida law, grounds for disciplinary action or denial of State licensure include "prescribing * * * any controlled substance, other than in the course of the physician's professional practice," and prescribing such substances "inappropriately or in excessive or inappropriate quantities is not in the best interest of the patient and is not in the course of the physician's professional practice, without regard to his or her intent." Fla. Stat. § 458.331(q) (2009). Florida law further provides that grounds for such disciplinary action also include:

> Failing to keep legible, as defined by department rule in consultation with the board, medical records that identify the licensed physician * * * and that justify the course of treatment of the patient, including, but not limited to, patient histories; examination results; test results; records of drugs prescribed, dispensed, or administered; and reports of consultations and hospitalizations.

Id. § 458.331(m).

In exercising its rulemaking function,[65] the Florida Board of Medicine (Florida Board) promulgated a regulation addressing "Standards for Adequacy of Medical Records" applicable to all physicians. Fla. Admin. Code r. 64B8–9.003 (2009). That regulation provides, in pertinent part:

> (2) A licensed physician shall maintain patient medical records in English, in a legible manner and with sufficient detail to clearly demonstrate why the course of treatment was undertaken.
>
> (3) The medical record shall contain sufficient information to identify the patient, support the diagnosis, justify the treatment and document the course and results of treatment accurately, by including, at a minimum, patient histories; examination results; test results; records of drugs prescribed, dispensed or administered; reports of consultations and hospitalizations; and copies of records or reports or other documentation obtained from other health care practitioners at the request of the physician and relied upon by the physician in determining the appropriate treatment of the patient.
>
> (4) All entries made into the medical records shall be accurately dated and timed. Late entries are permitted, but must be clearly and accurately noted as late entries and dated and timed accurately when they are entered in to the record * * *.

Fla. Admin. Code r. 64B8–9.003 (2009).

With respect to defining the parameters of what constitutes "professional practice" in the context of pain management prescribing, Florida State law provides:

> Notwithstanding any other provision of law, a physician may prescribe or administer any controlled substance under Schedules II–V * * * to a person for the treatment of intractable pain,[66] provided the physician does so in accordance with that level of care, skill, and treatment recognized by a

[63] 21 U.S.C. 823(f).

[64] "Ultimate user" is defined as "a person who has lawfully obtained, and who possesses, a controlled substance for his own use or for the use of a member of his household or for an animal owned by him or by a member of his household." 21 U.S.C. 802(27).

[65] Rulemaking authority regarding the practice of medicine within the State of Florida has been delegated to the Florida Board of Medicine (Florida Board). Fla. Stat. § 458.309(1) (2009).

[66] Florida defines "intractable pain" to mean "pain for which, in the generally accepted course of medical practice, the cause cannot be removed and otherwise treated." Fla. Stat. § 458.326 (2009).

reasonably prudent physician under similar conditions and circumstances.

Fla. Stat. § 458.326 (2009). Moreover, the Florida Board has adopted,[67] albeit in modified version, the *Model Policy for the Use of Controlled Substances for the Treatment of Pain* (*Model Policy*), a document drafted by the Federation of State Medical Boards (FSMB) to provide professional guidelines for the treatment of pain with controlled substances. The standards adopted by Florida share the key tenants of the *Model Policy's* standards for pain management prescribing, including the emphasis on diligent efforts by physicians to prevent drug diversion, prescribing based on clear documentation of unrelieved pain and thorough medical records, and compliance with applicable Federal and State law.

Like the *Model Policy,* which was promulgated "to encourage the legitimate medical uses of controlled substances for the treatment of pain while stressing the need to safeguard against abuse and diversion," Florida's regulation providing "Standards for the Use of Controlled Substances for Treatment of Pain," Fla. Admin. Code r. 64B8–9.013 (2009) (Florida Standards), recognizes that "inappropriate prescribing of controlled substances * * * may lead to drug diversion and abuse by individuals who seek them for other than legitimate medical use." The language employed by the regulation under the preamble section titled "Pain Management Principles" makes clear that the standards "are not intended to define *complete or best practice,* but rather to communicate what the [Florida Board] considers to be *within the boundaries of professional practice*" (emphasis supplied), *id.* at 9.013(1)(g); thus, the plain text supports an inference that the standards provide the *minimum* requirements for establishing conduct that comports with the professional practice of controlled substance-based pain management within the State. Likewise, the level of integral range of acceptable practice that is built into the regulation underscores the importance of seeking an expert professional opinion in reaching a correct adjudication of whether a registrant has met the applicable Florida standard. It is clear that in assessing whether the controlled substance prescribing practices of a Florida practitioner fall within the acceptable range of what constitutes being within the bounds of being "issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice," [68] resort must be had to an expert.

The Florida Standards direct that "[p]hysicians should be diligent in preventing the diversion of drugs for illegitimate purposes," *id.* at 9.013(1)(d), and provide that the prescribing of controlled substances for pain will be considered

> to be for a legitimate medical purpose if based on accepted scientific knowledge of the treatment of pain or if based on sound clinical grounds. All such prescribing must be based on *clear documentation* of unrelieved pain and in compliance with applicable state or Federal law.

Id. at 9.013(1)(e) (emphasis supplied).

The Florida Standards further provide that the validity of prescribing will be judged "based on the physician's treatment of the patient and *on available documentation,* rather than on the quantity and chronicity of prescribing" (emphasis supplied). *Id.* at 9.013(1)(g). Furthermore, the Standards advise that physicians should not fear disciplinary action for "prescribing controlled substances * * * for a legitimate medical purpose and that is supported by *appropriate documentation* establishing a valid medical need and treatment plan" (emphasis supplied), or "for failing to adhere strictly to the provisions of these standards, *if good cause is shown for such deviation*" (emphasis supplied). *Id.* at 9.013(1)(b),(f).

Although, as discussed above, the Florida Board instituted general guidance applicable to all physicians regarding medical records, it also promulgated a separate set of documentation requirements in the Florida Standards applicable specifically to those physicians who prescribe controlled substances in the pain-management context. The Florida Standards, under the subheading "Medical Records," state that "[t]he physician is required to keep *accurate and complete records*" (emphasis supplied) including, though not limited to:

> 1. The medical history and physical examination, including history of drug abuse or dependence, as appropriate;
> 2. Diagnostic, therapeutic, and laboratory results;
> 3. Evaluations and consultations;
> 4. Treatment objectives;
> 5. Discussion of risks and benefits;
> 6. Treatments;
> 7. Medications (including date, type, dosage, and quantity prescribed);
> 8. Instructions and agreements; and
> 9. Periodic reviews.

Id. at 9.013(3)(f). The same section directs that "[r]ecords must remain current and be maintained in an acceptable manner and readily available for review. *Id.*

The Florida Standards similarly emphasize the need for proper documentation in the patient evaluation context by specifying:

> A complete [69] medical history and physical examination must be conducted and documented in the medical record. The medical record should document the nature and intensity of the pain, current and past treatments for pain, underlying or coexisting diseases or conditions, the effect of the pain on physical and psychological function, and history of substance abuse. The medical record also should document the presence of one or more recognized medical indications for the use of a controlled substance.

Id. at 9.013(3)(a).

Furthermore, the Florida Standards require a written treatment plan that "should state objectives that will be used to determine treatment success, such as pain relief and improved physical and psychosocial function, and should indicate if any further diagnostic evaluations or other treatments are planned." *Id.* at 9.013(3)(b). Subsequent to the initiation of treatment, "the physician should *adjust* drug therapy to the individual medical needs of each patient. Other treatment modalities or a rehabilitation program may be necessary depending on the etiology of the pain and the extent to which the pain is associated with physical and psychosocial impairment." (emphasis supplied). *Id.*

Another standard adopted by the Florida Board, under the subheading "Informed Consent and Agreement for Treatment," is the directive that

> [t]he physician should discuss the risks and benefits of the use of controlled substances with the patient, persons designated by the patient, or with the patient's surrogate or guardian if the patient is incompetent. The patient should receive prescriptions from one physician and one pharmacy where possible. If the patient is determined to be at high risk for medication abuse or have a history of substance abuse, the physician should employ the use of a written agreement between the physician and patient outlining patient responsibilities, including, but not limited to:
> 1. Urine/serum medication levels screening when requested;

[67] Pursuant to authority vested in the Florida Board by the Florida legislature to promulgate rules regarding State standards for pain management clinical practice specifically. Fla. Stat. § 458.309(5) (2009).

[68] 21 CFR 1306.04(a).

[69] The original *Model Policy* version of the guidelines does not contain a reference to the need for a *complete* medical history, instead only requiring a medical history generally. Thus, the Florida Board has adopted a higher standard than the measure that has been set in the *Model Policy* by the FSMB.

2. Number and frequency of all prescription refills; and

3. Reasons for which drug therapy may be discontinued (*i.e.,* violation of agreement.)

Id. at 9.003(3)(c).

The Florida Standards contain a further requirement to periodically review "the course of pain treatment and any new information about the etiology of the pain or the patient's state of health." *Id.* at 9.013(3)(d). The Florida Standards explain the importance of periodic review in the following manner:

> Continuation or modification of therapy depends on the physician's evaluation of the patient's progress. If treatment goals are not being achieved, despite medication *adjustments,* the physician should reevaluate the appropriateness of continued treatment. The physician should monitor patient compliance in medication usage and related treatment plans.

Id.

Under the subheading "Consultation," the Florida Board promulgated the instruction that

> [t]he physician should be willing to refer the patient as necessary for additional evaluation and treatment in order to achieve treatment objectives. Special attention should be given to those pain patients who are at risk for misusing their medications and those whose living arrangements pose a risk for medication misuse or diversion. The management of pain in patients with a history of substance abuse or with a comorbid psychiatric disorder requires extra care, monitoring, and documentation, and may require consultation with or referral to an expert in the management of such patients.

Id. at 9.003(3)(e).

It is abundantly clear from the plain language of the Florida Standards that the Florida Board places critical emphasis on physician implementation of adequate safeguards in their practice to minimize diversion and the need to document the objective signs and rationale employed in the course of pain treatment utilizing the prescription of controlled substances. Conscientious documentation is repeatedly emphasized as not just a ministerial act, but a key treatment tool and a vital indicator to evaluate whether the physician's prescribing practices are "within the usual course of professional practice." Here, the uncontroverted expert opinion of Dr. Kennedy, the only expert witness to testify at these proceedings, reflects that the documentation he reviewed in the Respondent's patient charts reflected care that was markedly below the standard of care set by the Florida Medical Board. Dr. Kennedy's expert assessment was consistent with the State statutory and regulatory guidance. In Kennedy's view, the Respondent's charts demonstrated minimalistic, incomplete, and otherwise medically inadequate documentation of his contacts with patients and the prescribing rationale for his issuance of controlled substance prescriptions to those patients for alleged pain management purposes. The boilerplate-style, "one high-dosage controlled substances treatment plan fits all" nature of nearly all of the patient medical records at issue, at least in the view of the uncontroverted expert, evidences a failure on the part of the Respondent to conduct his practice of medicine in a manner to minimize the potential of controlled substance abuse and diversion, and supports a conclusion that he failed to even substantially comply with the minimum obligations for professional practice imposed under the Florida Standards—and without "good cause [] shown for such deviation." *Id.* at 9.013(1)(f).

In his Argument, Proposed Findings of Fact and Proposed Conclusions of Law (Respondent's Brief), the Respondent's counsel has prepared and submitted a thoughtful and detailed analysis of the counsel's application of the relevant standards in Florida to the charts analyzed by Dr. Kennedy. Respt's Br. at 3–17. Unfortunately, counsel's analysis is the product of a lay evaluation of standards applicable to the nuanced and sophisticated science that is the practice of medicine. Where his opinion and that of the only accepted medical expert to provide an expert opinion conflict, his opinion cannot and will not be afforded controlling deference. Argument supplied by counsel (albeit a diligent and persuasive counsel) that the relevant standards were satisfactorily applied as evidenced by the protocols and procedures documented in the patient charts cannot supplant the unrefuted view of an accepted expert witness.

The Respondent, who was in a unique position to conclusively refute Dr. Kennedy's views and explain the format and nuances of the reviewed documentation, elected not to testify in this matter. At a DEA administrative hearing, it is permissible to draw an adverse inference from the silence of the Respondent, even in the face of a Fifth Amendment invocation. *Hoxie* v. *DEA,* 419 F.3d 477, 483 (6th Cir. 2005) (citing *United States* v. *Hale,* 422 U.S. 171, 176 (1975) ("silence gains more probative weight where it persists in the face of accusation, since it is assumed in such circumstances that the accused would be more likely than not to dispute an untrue accusation.")); *Joseph Baumstarck, M.D.,* 74 FR 17525, 17528, n.3 (2009) (citing *Ohio Adult Parole Auth.* v. *Woodward,* 523 U.S. 272, 286 (1998)). On the facts of this case, where the allegations are of a nature that a registrant would be more likely than not to dispute them if untrue, an adverse inference based on the Respondent's silence is appropriate. Where, as here, the Government, through its expert, has alleged that the Respondent's charts do not reflect genuine analysis, but rather (at least in its view and the opinion of its expert), a sort of sham-by-check-box form designed specifically to present a false impression of a compliant registrant, it is precisely the type of allegation that would naturally all but oblige a registrant to spring to offer a contradictory account. The Respondent's choice to remain silent in the face of such allegations, where he could have related his version of his practice as a registrant, adds at least some additional credence to the factual and analytical views of the Government's expert in this regard.

In the Social Security context, where an Administrative Law Judge has received expert medical opinions on the issue of the claimant's ability to work and they are not repudiated in any respect by substantial evidence, an adverse decision should be set aside as based on "suspicion and speculation." *Miracle* v. *Celebrezze,* 351 F.2d 361, 378 (6th Cir. 1965); *see also Hall* v. *Celebrezze,* 314 F.2d 686, 689–90 (6th Cir. 1963); *cf. Harris* v. *Heckler,* 756 F.2d 431, 436 (6th Cir. 1985) (improper to reject uncontroverted evidence supporting complaints of pain simply because of claimant's demeanor at hearing). When an administrative tribunal elects to disregard the uncontradicted opinion of an expert, it runs the risk of improperly declaring itself as an interpreter of medical knowledge. *Ross* v. *Gardner,* 365 F.2d 554 (6th Cir. 1966). While in this case it is ironically true, much like in the Social Security context, that the opinion of a treating physician should be afforded greater weight than the opinion of an expert whose opinion is limited to a review of the patient file, *see Magallenes* v. *Bowen,* 881 F.2d 747, 751 (9th Cir. 1989), the treating-source Respondent in this case offered no evidence, not even his own opinion, regarding the treatment rendered. Thus, in this adjudication, the record contains no dispute between experts to be resolved; instead, there is but one, unrefuted, uncontroverted, credible expert opinion. To ignore that expert opinion on this record and replace it with the opinion of this tribunal,

Respondent's counsel, or any other lay source would be a dangerous course and more importantly, a plainly erroneous one.

Accordingly, after carefully balancing the admitted evidence, the evidence establishes, by a preponderance of the evidence, that the prescriptions the Respondent issued in Florida were not issued within "the usual course of [the Respondent's] professional practice." 21 CFR 1306.04(a). Consideration of the evidence under the second and fourth factors support the COR revocation sought by the Government in this case.

To the extent that the Respondent's prescribing practices fell below the requisite standard in Florida, that conduct also impacts upon the Fifth statutory factor. Under Factor 5, the Deputy Administrator is authorized to consider "other conduct which may threaten the public health and safety." 21 U.S.C. 823(f)(5). Although this factor authorizes consideration of a somewhat broader range of conduct reaching beyond those activities typically associated with a registrant's practice, an adverse finding under this factor requires some showing that the relevant conduct actually constituted a threat to public safety. *See Holloway Distrib.,* 72 FR 42118, 42126 (2007).

The evidence establishes that the Respondent engaged in a course of practice wherein he prescribed unsafely high doses of controlled substances to patients irrespective of the patients' need for such medication and ignoring any and red flags that could or did indicate likely paths of diversion. The testimony of Dr. Kennedy, the DEA regulations, and the Florida Standards make clear that physicians prescribing controlled substances do so under an obligation to monitor the process to minimize the risk of diversion. The patient charts reflect that the Respondent, contrary to his obligations as a DEA registrant, did not follow up in the face of multiple red flags. The Respondent's disregard of his obligations as a DEA registrant and Federal and State laws related to controlled substances militate in favor of revocation.

By routinely prescribing unsafely high doses of controlled substances to opioid-naïve patients and ignoring his responsibilities to monitor the controlled substance prescriptions he was authorizing to minimize diversion, and by participating in an insufficiently documented and thoughtful process for the issuance of potentially dangerous controlled substances, the Respondent created a significant potential conduit for the unchecked diversion of controlled substances. *See Holloway Distrib.,* 72 FR at 42124 (a policy of "see no evil, hear no evil" is fundamentally inconsistent with the obligations of a DEA registrant). Agency precedent has long recognized that "[l]egally, there is absolutely no difference between the sale of an illicit drug on the street and the illicit dispensing of a licit drug by means of a physician's prescription." *EZRX, LLC,* 69 FR 63178, 63181 (1988); *Floyd A. Santner, M.D.,* 55 FR 37581 (1988).

Agency precedent has consistently held that where, as here, the Government has met its burden to establish a prima facie case that a registrant has committed acts demonstrating that continued registration is inconsistent with the public interest, acceptance of responsibility is a condition precedent to continued registration. *Jeri Hassman, M.D.,* 75 FR 8194, 8236 (2010); *Medicine Shoppe,* 73 FR at 387. The record contains no evidence that the Respondent has either acknowledged or accepted responsibility for the misconduct at issue in these proceedings.

Recommendation

Based on the foregoing, the evidence supports a finding that the Government has established that the Respondent has committed acts that are inconsistent with the public interest. A balancing of the statutory public interest factors supports the revocation of the Respondent's Certificate of Registration and a denial of his application to renew. The Respondent has not accepted responsibility for his actions, expressed remorse for his conduct at any level, or presented evidence that could reasonably support a finding that the Deputy Administrator should continue to entrust him with a Certificate of Registration.

Accordingly, the Respondent's Certificate of Registration should be *revoked* and any pending applications for renewal should be *denied.*

Dated: August 10, 2010.

John J. Mulrooney, II,
U.S. Administrative Law Judge.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 10–37]

Roni Dreszer, M.D.; Decision and Order

On August 10, 2010, Administrative Law Judge (ALJ) John J. Mulrooney, II, issued the attached recommended decision.[1] Thereafter, Respondent filed exceptions to the decision.

Having reviewed the entire record including the ALJ's recommended decision and Respondent's exceptions, I have decided to adopt the ALJ's rulings, findings of fact,[2] conclusions of law,[3] and recommended Order.

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[1] All citations to the ALJ's Decision (ALJ) are to the slip opinion as issued on August 10, 2010, and not to the attached decision which has been reformatted.

[2] The ALJ found that there is "no evidence that the Respondent 'prescribe[d] and dispense[d] *inordinate* amounts of controlled substances." ALJ at 26. While there is no evidence as to the amounts that Respondent directly dispensed, there is evidence, which is unrefuted, that Respondent prescribed inordinate amounts of controlled substances. In his report, an Expert witness explained that the usual starting dose of Xanax is .25 to .5 mg. once to twice per day and yet Respondent prescribed Xanax 2 mg. twice per day to patients "who had not had Xanax before or recently," and that he did so without documenting that he had considered any of the possible underlying causes of his patients' complaint that they had anxiety; moreover, Respondent did not refer the patients to a mental health professional. GX 5, at 9–10. As the Expert explained, "[t]he treatment was with a very high dose of the controlled substance Xanax. This was clearly not within the boundaries of professional practice." *Id.* at 10. There is also unrefuted evidence that Respondent's prescribing of drug cocktails of oxycodone and Xanax lacked a legitimate medical purpose. *Id.* at 13. In this manner, Respondent did prescribe inordinate amounts.

[3] I do not, however, adopt the ALJ's discussion of the standards applied by the Agency in assessing a practitioner's experience in dispensing controlled substances, which cites cases involving list chemical I distributors, a different category of registrant. *See* ALJ at 25–26. As the Agency has previously made clear, DEA can revoke based on a single act of intentional diversion and "evidence that a practitioner has treated thousands of patients" in circumstances that do not constitute diversion "does not negate a *prima facie* showing that the practitioner has committed acts inconsistent with the public interest." *Jayam Krishna-Iyer,* 74 FR 459, 463 (2009). *See also Dewey C. MacKay,* 75 FR 49956, 49977 (2010); *Medicine Shoppe-Jonesborough,* 73 FR 364, 386 & n.56 (noting that pharmacy "had 17,000 patients," but that "[n]o amount of legitimate dispensings can render * * * flagrant violations [acts which are] 'consistent with the public interest'"), *aff'd, Medicine Shoppe-Jonesborough* v. *DEA,* 300 Fed. Appx. 409 (6th Cir. 2008). As I further explained, "[w]hile such evidence may be [entitled to] some weight in assessing whether a practitioner has credibly shown that [he] has reformed his practices," it is entitled to no weight where a practitioner fails to acknowledge his wrongdoing. *Krishna-Iyer,* 74 FR at 463.

In any event, Respondent offered no evidence on the issue of his experience in dispensing controlled substances and the ALJ's ultimate conclusions that Respondent violated the CSA's prescription requirement because he dispensed controlled substance prescriptions that were not "within 'the usual course of [his] professional practice,'" ALJ at 39 (quoting 21 CFR 1306.04(a)), and that "the evidence under the [experience] * * * factor[] support[s]" the revocation of his registration, is consistent with Agency precedent. *Id.*

With respect to factor five, "[s]uch other conduct which may threaten public health and safety," 21 U.S.C. 823(f)(5), the ALJ opined that "an adverse finding under this factor requires some showing that the relevant conduct *actually constituted* a

Respondent first takes exception to the ALJ's acceptance of L. Douglas Kennedy, M.D., as an expert on the proper prescribing of controlled substances. Respondent contends that Dr. Kennedy should not have been permitted to opine on his prescribing practices because he does not hold a DEA registration in Florida, has not prescribed a controlled substance since 2004, does not currently have either a medical office or hospital privileges in Florida, and "has never practiced medicine regularly in Florida and has not practiced medicine in Florida at all in over 10 years." Resp. Exc. at 1.

Respondent's contention is unavailing as Dr. Kennedy was clearly qualified to render an expert opinion on the proper practice for prescribing controlled substances to treat pain and whether Respondent's controlled substance prescriptions were issued in the usual course of professional practice and for a legitimate medical purpose. *See* 21 CFR 1306.04(a). Dr. Kennedy currently holds a Florida medical license, is a diplomate of both the American Board of Pain Medicine and the American Board of Anesthesiology, and is currently on the faculty of the University of Miami's Miller School of Medicine. GX 117, at 1, 10. Previously, Dr. Kennedy was a Fellow with the Pain Therapy Unit of the Cleveland Clinic, served as the Director of Chronic Pain Management at the University of Kentucky Medical Center, and, for fourteen years, was the Medical Director of a multidisciplinary pain medicine and rehabilitation practice. *Id.* at 1–2.

Dr. Kennedy has published several articles and book chapters on pain management issues and has made several dozen presentations on pain management issues at professional meetings.[4] *Id.* at 3–7. In addition, he is a member of several professional organizations including the American Academy of Pain Medicine, the American Board of Pain Medicine, the American Pain Society, the International Association for the Study of Pain, the American Society of Addiction Medicine, the American Board of Anesthesiology, and the American Society of Anesthesiology. *Id.* at 10; Tr. 22. Finally, Dr. Kennedy explained that he was familiar with the Florida Board of Medicine's standards for prescribing controlled substances to treat pain and that he had reviewed them prior to preparing his report. Tr. 24–26; GX 101, at 6–7.

Thus, Dr. Kennedy was clearly qualified to provide expert testimony. I therefore agree with the ALJ that Dr. Kennedy's testimony was sufficiently reliable to constitute substantial evidence on the issue of whether Respondent acted within the usual course of professional practice and had a legitimate medical purpose in prescribing controlled substances to the patients whose files he reviewed and reject this exception. ALJ at 17.

Next, Respondent contends that Dr. Kennedy's opinion testimony is entitled to no weight because it was based on only sixteen patient charts, which Respondent maintains were not randomly selected and is too small a sample to draw sufficient conclusions about the validity of his prescribing practices. Resp. Exc. at 2. In support of this contention, Respondent relies on Dr. Kennedy's testimony that "'[i]t might not be fair'" to "'cherry-pick[]'" sixteen charts out of a physician's patients because those might be the "the only people out of 2,000" and that the problems found would "be 'an administrative issue for education with the Board of Medical License and not'" necessarily justify the revocation of Respondent's medical license (or DEA registration). *Id.* (quoting Tr. 612–13).

However, even acknowledging that one of the sixteen files reviewed by Dr. Kennedy with respect to Respondent was not randomly selected because it was that of an undercover officer, the ALJ found credible the Diversion Investigator's testimony that the files were not specially selected to enhance the strength of the Government's case. ALJ at 5 (citing Tr. 768). More importantly, the requirement of Federal law that a prescription "must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice," 21 CFR 1306.04(a), applies to each and every prescription issued by a practitioner. Thus, contrary to the Expert's understanding, in determining whether a practitioner has committed acts which render his "registration inconsistent with the public interest," 21 U.S.C. 824(a)(4), DEA is not required to randomly select the files which it will base its case on.

For example, where the Government has developed information that particular patients are drug dealers or engaged in self-abuse, it is not required to ignore the files pertaining to these patients and base its case on a random sample of files. Rather, it can lawfully select the files pertaining to those patients and base its case entirely on them. Moreover, where the Government has seized files, it can review them and choose to present at the hearing only those files which evidence a practitioner's most egregious acts. Of course, where, as here, the Government's case relies so heavily on a chart review, the practitioner can put on his own evidence and argue that the Government's evidence does not establish that he violated the prescription requirement or that his conduct was not so egregious as to warrant revocation. *See Paul Caragine,* 63 FR 51592 (1998). *See also Dewey C. MacKay,* 75 FR at 49977; *Krishna-Iyer,* 74 FR at 463 (holding that DEA can revoke based on a single act of diversion); *Medicine Shoppe-Jonesborough,* 73 FR at 386 & n.56.[5] Accordingly, there is no merit to Respondent's contention.

Finally, Respondent takes exception to the ALJ's findings that he violated Florida's standards for prescribing controlled substances. Resp. Exceptions at 4–5. More specifically, Respondent contends that he complied with the standards set forth under Florida regulations and that he "took a complete medical history and conducted a physical evaluation that was documented," that he maintained "medical records documenting the

threat to public safety." ALJ at 39 (emphasis added). Contrary to the ALJ's reasoning, Congress, by inserting the word "may" in factor five, clearly manifested its intent to grant the Agency authority to consider conduct which creates a probable or possible threat (and not only an actual) threat to public health and safety. *See Webster's Third New Int'l Dictionary* 1396 (1976) (defining "may" in relevant part as to "be in some degree likely to"); *see also The Random House Dictionary of the English Language* 1189 (1987) (defining "may" in relevant part as "used to express possibility"). While the ALJ misstated the applicable standard, his conclusion that Respondent repeatedly ignored "red flags" indicative of likely diversion and thus "created a significant potential conduit for the unchecked diversion of controlled substances," ALJ at 39, is clearly supported by substantial evidence and warrants an adverse finding under factor five.

The ALJ also opined that "[i]t is clear that in assessing whether the controlled substance prescribing practices of a Florida practitioner fall within the acceptable range of what constitutes being within the bounds of being 'issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice,' resort must be had to an expert." ALJ at 34 (quoting 21 CFR 1306.04(a)). While the ALJ properly noted the importance of expert testimony in this case, in which the Government primarily relied on a review of the medical charts, whether expert testimony is needed in any case necessarily depends on the nature of the allegations and the other evidence in the case. Where, for example, the Government produces evidence of undercover visits showing that a physician knowingly engaged in outright drug deals, expert testimony adds little to the proof necessary to establish a violation of Federal law.

[4] He also co-edited and contributed to the State of Kentucky's Guidelines for Prescribing Controlled Substances, 2nd Edition. GX 117, at 9.

[5] Consistent with DEA's longstanding precedent, *see* ALJ at 19, a respondent is also entitled to put on evidence as to his acceptance of responsibility and any remedial measures he has undertaken to prevent the re-occurrence of similar acts.

patient's intensity of pain, current and past treatments for pain, and the effect of pain on physical and psychological function." *Id.* at 4. He further argues that "[h]e set out a written treatment plan, discussed the risks and benefits of controlled substances and conducted periodic reviews" as also required by Florida's regulations. *Id.* at 4–5.

While it is true that Dr. Kennedy acknowledged that he was not familiar with the specific standard imposed by the State of Florida for excessive prescribing and that he had not reviewed any Florida Medical Board decisions addressing the issue of what is an adequate medical history, *see* ALJ at 17; as noted above, in his report Dr. Kennedy discussed at length the Florida Board of Medicine's *Standards for the Use of Controlled Substances for the Treatment of Pain,* Fla. Admin. Code 64B8–9.013. *See* GX 101, at 6–7.[6] Nor did Respondent produce any evidence that his recordkeeping and prescribing complied with the standards of the Florida Medical Board. Moreover, there is substantial evidence to support the conclusion that Respondent was not engaged in legitimate medical practice and was diverting drugs.

As Dr. Kennedy explained, most of the patients were from out-of-state, with some travelling up to 1200 miles,[7] even though Respondent had no specialized training in pain management, and yet, Respondent did not obtain reports from the prescription monitoring programs run by the States where his patients lived. *Id.* at 16–17. Moreover, Respondent did not obtain adequate medical histories and perform adequate physical examinations; he also never obtained medical records from other treating physicians (or even contacted them) for any of the patients whose files are in evidence. *Id.* at 14–17.

As Dr. Kennedy explained, while "[t]he chart was set up to give the appearance of a legitimate medical practice in an attempt to justify the initial and continued prescription and dispensing of high dose multiple controlled substances ('drug cocktails')," and that while "on the surface [the charts] were adequate for evaluating and treating a patient," on closer review, "the actual contents in the charts, clearly evidence[] just the opposite" as the charts "were very difficult * * * to read [with] many sections left blank or incompletely filled in." *Id.* at 17. Continuing, Dr. Kennedy explained that "[t]he notes were not within the standard of care; all were outside the boundaries of professional practice, lacking significant information and ignoring significant history that was present." *Id.* Moreover, Respondent's failure to obtain patients' medical records "was well outside the boundaries of medical practice and below the standard of medical care," especially for patients receiving "very high dose[s]" of controlled substances. *Id.*

The evidence further shows that this case is not simply a matter of inadequate record keeping. While Respondent apparently required his patients to obtain an MRI, in multiple instances the MRI was obtained before the patient was even evaluated by Respondent, and generally, no other imaging studies such as x-rays or CT scans were done.[8] *Id.* at 16. Moreover, Respondent rarely referred a patient to another physician or health care professional for a consultation.[9] As Dr. Kennedy explained, "alternative opinions should have been sought in order to better diagnose and treat; not to do so was outside the boundaries of professional practice and not within the standard of care." *Id.* Dr. Kennedy thus concluded that Respondent's "diagnoses were usually very vague and/or without medical merit" and were done in an "attempt[] to justify what controlled substances he prescribed." *Id.* at 17.

Dr. Kennedy further observed that while Respondent performed urine drug screens, he ignored the results even when they were inconsistent with other information provided by the patients such as when a patient tested positive for controlled substances which he had previously indicated that he was not currently taking. *Id.* at 14–15; ALJ at 15–16. Moreover, the drug screens were rarely performed other than at the patient's initial visit and lacked quality controls.[10] GX 101, at 15.

Also, although the charts indicate that Respondent discussed doing yoga and stretching, using an anti-inflammatory diet, and taking several over-the-counter supplements (fish oil and glucosamine chondroitin), Respondent's treatment plan primarily involved prescribing "drug cocktails" of high doses of controlled substances with the same regimen of drugs (typically two strengths of oxycodone immediate release and Xanax) prescribed in nearly every case. *Id.* at 5, 13, 15. Most significantly, Respondent never referred any of the sixteen patients for consultations with specialists related to their pain complaints, or for physical, occupational or mental health therapy. GX 101, at 13.

Dr. Kennedy further observed that while the typical starting dose of Xanax is 0.25 to 0.5 mg., once to twice per day, Respondent prescribed Xanax 2 mg., once or twice per day to fourteen of the sixteen patients, and he did so even with patients who had not been on the drug either "before or recently" and "no matter the age or clinical situation." *Id.* While Xanax is used as an anti-anxiety agent, Respondent's medical records did not support the prescribings because "[h]e did not list important factors that could cause anxiety * * * such as depression, life stressors, psychosocial situation, caffeine intake, sleep disturbance [and a] previous medical evaluation"; he also did not refer these patients for evaluation by a mental health professional. *Id.* And with respect to J.S., Dr. Kennedy concluded that Respondent's prescribing of this very high dose of Xanax "was clearly not within the boundaries of professional practice." *Id.*

Finally, Dr. Kennedy noted that beginning with a patient's first visit, Respondent prescribed very high initial doses of oxycodone. Dr. Kennedy explained that the usual starting dose for an opioid naïve patient in moderate to severe pain was five milligrams of oxycodone taken every four hours as needed for a total of thirty milligrams per day. *Id.* at 9. Yet at J.S.'s first visit, Respondent prescribed (in addition to 60 Xanax), 180 Roxicodone 30 mg. (with

[6] Even after *Gonzales* v. *Oregon,* 546 U.S. 243 (2006), multiple courts of appeals, including the Eleventh Circuit, "have applied a general-practice standard when determining whether the practitioner acted in the 'usual course of professional practice.'" *United States* v. *Smith,* 573 F.3d 639, 647–48 (8th Cir. 2009); *see also id.* at 648 (discussing *United States* v. *Moore,* 423 U.S. 122 (1975); "Thus informed by the Supreme Court and other controlling and persuasive precedent, we believe that it was not improper to measure the 'usual course of professional practice' under § 841(a)(1) and [21 CFR] 1306.04 with reference *to generally recognized and accepted medical practices* * * *."). Likewise, the Eleventh Circuit has held that "[t]he appropriate focus * * * rests upon whether the physician prescribes medicine 'in accordance with *a standard of medical practice generally recognized and accepted in the United States.'*" *United States* v. *Merrill,* 513 F.3d 1293, 1306 (11th Cir. 2008) (quoting *Moore,* 423 U.S. at 139).

[7] Of the sixteen patients, only five were from Florida. Of the remaining patients, five were from Kentucky, two were from Tennessee, and one was from each of the following States: North Carolina, Ohio, Massachusetts, and Georgia. GX 101, at 9.

[8] Dr. Kennedy explained that referring a patient to obtain an MRI prior to having some contact is unusual and medically inappropriate. Tr. 71–72.

[9] While Respondent referred one patient to his primary care physician for jaundice, and another to the Emergency Room to be evaluated for cellulitis, according to their respective medical records, both of these patients went to Respondent because of lower back pain. *See* GX 108, at 9; GX 109, at 1.

[10] Dr. Kennedy explained that the urine drug screens did not indicate the temperature and specific gravity of the specimen, whether the giving of the sample had been observed, or the type of drug screen used. GX 101, at 4; Tr. 100–03.

one tablet to be taken every four hours), as well as sixty Roxicodone 15 mg. (one tablet, twice a day, as needed for pain), an amount that is seven times the usual starting dose. *Id.* at 19. While J.S. had noted on his medication contract that three months earlier, he had been prescribed 210 oxycodone 30 mg., 90 oxycodone 15 mg., and 90 Xanax 2mg., which was "almost exactly what [Respondent] prescribed[,]" Respondent did not identify the name of the physician who had issued the prescriptions and did not attempt to confirm them. *Id.* at 11.

At each of J.S.'s subsequent visits, Respondent prescribed an additional thirty tablets of oxycodone 30 mg. (for a total of 210), along with sixty tablets of oxycodone 15 mg. and 60 tablets of Xanax 2 mg. *Id.* at 19. While Dr. Kennedy acknowledged that prescribing an additional strength of oxycodone could be legitimate if it was done to treat breakthrough or episodic pain on an as-needed basis, with respect to J.S., who received prescriptions for oxycodone 30 mg. and 15 mg., "there was no specific reason stated in the medical record" for prescribing both drugs. *Id.* at 12. And with respect to all of the patients whose files he reviewed, Dr. Kennedy explained that Respondent's prescribing of drug cocktails of "a very high dose opioid" (including two forms of oxycodone) and a "high dose * * * benzodiazepine" (Xanax) lacked "any legitimate medical purpose." *Id.* at 15.

As Dr. Kennedy concluded, Respondent "was not engaged in the practice of medicine," and "[t]he vast majority of [his] prescriptions for controlled substances was not for a legitimate medical purpose and w[as] beyond the boundaries of professional practice." *Id.* at 18. His "routine and excessive prescription of multiple controlled substances * * * and lack of arriving at a valid medical diagnosis and treatment most likely caused harm to the patients he saw as well as * * * to other people in their communities." *Id.* I thus reject this exception as well.

Finally, I also reject Respondent's exception to the ALJ's ultimate finding that Respondent has committed acts which render his registration inconsistent with the public interest. Resp. Exc. 5. Because the record establishes that Respondent has repeatedly violated Federal law by issuing controlled substance prescriptions which lacked a legitimate medical purpose and were issued outside of the usual course of professional practice, 21 CFR 1306.04, and Respondent has offered no evidence establishing that he has accepted responsibility for his misconduct and that he has reformed his practice, *see Steven M. Abbadessa,* 74 FR 10077, 10081 (2009), I adopt the ALJ's recommendation that Respondent's registration be revoked.

Order

Pursuant to the authority vested in me by 21 U.S.C. 823(f) and 824(a), as well as 21 CFR 0.100(b) and 0.104, I order that DEA Certificate of Registration, FD1201196, issued to Roni Dreszer, M.D., be, and it hereby is, revoked. I further order that any pending application of Roni Dreszer, M.D., to renew or modify his registration, be, and it hereby is, denied. This Order is effective immediately.

Dated: March 31, 2011.

Michele M. Leonhart,

Administrator.

Larry P. Cote., Esq., for the Government

Sean M. Ellsworth., Esq., for the Respondent

Recommended Rulings, Findings of Fact, Conclusions of Law, and Decision of the Administrative Law Judge

John J. Mulrooney, II, Administrative Law Judge. On February 25, 2010, the Deputy Administrator, Drug Enforcement Administration (DEA or Government), issued an Order to Show Cause and Immediate Suspension of Registration (OSC/ISO), immediately suspending the DEA Certificate of Registration (COR), Number FD1201196, of Roni Dreszer, M.D. (Respondent), as a practitioner, pursuant to 21 U.S.C. 824(d), alleging that such registration constitutes an imminent danger to the public health and safety. The OSC/ISO also sought revocation of the Respondent's registration, pursuant to 21 U.S.C. 824(a)(4), and denial of any pending applications for renewal or modification of such registration, pursuant to 21 U.S.C. 823(f), alleging that the Respondent's continued registration is inconsistent with the public interest, as that term is used in 21 U.S.C. 823(f). On March 22, 2010, the Respondent timely requested a hearing, which, pursuant to a change of venue granted at his request was conducted in Miami, Florida, on July 7, 2010 through July 9, 2010.[11] The immediate suspension of the Respondent's COR has remained in effect throughout these proceedings.

The issue ultimately to be adjudicated by the Deputy Administrator, with the assistance of this recommended decision, is whether the record as a whole establishes by substantial evidence that Respondent's registration with the DEA should be revoked as inconsistent with the public interest as that term is used in 21 U.S.C. 823(f) and 824(a)(4). The Respondent's DEA practitioner registration expires by its terms on June 30, 2011.

After carefully considering the testimony elicited at the hearing, the admitted exhibits, the arguments of counsel, and the record as a whole, I have set forth my recommended findings of fact and conclusions below.

The Evidence

The OSC/ISO issued by the Government alleges that the Respondent, through the medical practice he participated in at American Pain, LLC (American Pain), prescribed and dispensed inordinate amounts of controlled substances, primarily oxycodone,[12] under circumstances where he knew, or should have known, that the prescriptions were not dispensed for a legitimate medical purpose. ALJ Ex. 1. The OSC/ISO further charges that these prescriptions were issued outside the usual course of professional practice based on a variety of circumstances [13] surrounding the manner in which American Pain is operated and the manner in which its physicians, including Respondent, engaged in the practice of medicine. *Id.* Respondent is also alleged to have provided undercover law enforcement personnel with controlled substances, including, *inter alia,* oxycodone and alprazolam,[14] after cursory or no medical examinations, and therefore without a legitimate medical purpose. *Id.* The Government also alleges that Respondent's former patients have apprised law enforcement personnel that "they were able to obtain prescriptions for controlled substances from [the Respondent] for other than a legitimate medical purpose and with the intention of selling the controlled substances and/or personally abusing the drugs." *Id.*

At the hearing, the Government presented the testimony of three witnesses, DEA Miami Field Division (MFD) Group Supervisor (GS) Susan

[11] Pursuant to an order issued on April 15, 2010, with the consent of the Respondent, the hearing in this matter was consolidated with the cases of four other registrants who were working at the same clinic as the Respondent and who were also issued OSC/ISOs on February 25, 2010, alleging similar and related conduct.

[12] A schedule II controlled substance.

[13] The majority of which are supported by no evidence introduced by the Government during the course of these proceedings.

[14] A schedule IV controlled substance.

Langston, DEA Special Agent (SA) Michael Burt, and L. Douglas Kennedy, M.D., D.A.B.P.M., Affiliate Clinical Assistant Professor at the University of Miami, Miller School of Medicine.

GS Langston testified that the investigation of the American Pain Clinic had its origins on November 30, 2009, during a routine inspection that she and a subordinate diversion investigator conducted at Appurtenance Biotechnology, LLC, a pharmacy doing business under the name Boca Drugs (Boca Drugs), and located a few blocks away from one of the former locations of American Pain. Tr. at 713, 717–20. According to Langston, an examination of the prescriptions seized from Boca Drugs revealed that the majority of those prescriptions were for oxycodone and alprazolam authorized over the signature of physicians associated with American Pain.[15] *Id.* at 721. Under Langston's supervision, DEA diversion investigators catalogued the prescriptions seized at Boca Drugs (Boca Drugs Prescription Log). Govt. Ex. 118. However, inasmuch as the Boca Drugs Prescription Log fails to distinguish between the Respondent, and another registrant with the same last name, the document is of no utility in reaching a disposition of the present case.

GS Langston also testified that, on March 3, 2010, a criminal search warrant was executed on the American Pain Clinic simultaneously with the OSC/ISO that initiated the present case. Tr. at 735. According to Langston, the items seized from American Pain included a sign that had been posted in what she believes to have served as the urinalysis waiting room. *Id.* at 735–37. The seized sign set forth the following guidance:

ATTENTION PATIENTS

Due to increased fraudulent prescriptions, [i]t's best if you fill your medication in Florida or your regular pharmacy. Don't go to a pharmacy in Ohio when you live in Kentucky and had the scripts written in Florida. The police will confiscate your scripts and hold them while they investigate. This will take up to 6 months. So only fill your meds in Florida or a pharmacy that you have been using for at least 3 months or more.

Govt. Ex. 119 at 1. This sign is attached, apparently by some sort of tape, to the top portion of two other signs, posted at the same location, the first of which reads:

ATTENTION:

Patients

Please do *NOT* fill your prescriptions at any *WALGREENS PHARMACY*[16] or *OUTSIDE* the STATE OF FLORIDA.

Id. The final attachment to the composite sign bears the words "24 Hour Camera Surveillance." *Id.* A photograph of the composite sign was admitted into evidence.

Langston also testified that while she was present in the American Pain offices, she noticed that each physician's desk was equipped with a group of stamps, each of which depicted a controlled substance medication with a corresponding medication usage instruction (sig). Tr. at 738–39. A photograph of one set of prescription script stamps was admitted as an exhibit.[17] Govt. Ex. 119 at 2.

GS Langston also testified that a great number of medical charts were seized from the American Pain offices, and that she and her staff selected a number of these files to be analyzed by a medical expert procured by the Government. Tr. at 762. According to GS Langston, after the execution of the warrant, the charts from the entire office were placed into piles in alphabetical order, and not separated by physician. Langston testified that she and three of her diversion investigators reviewed the seized files with a view towards choosing approximately fifteen files for each doctor with the aspirational criteria that each would reflect at least three to four visits by that doctor with a patient. Each investigator was empowered to place a chart on the selected pile, and when the target number (or about that number) was reached for each physician, the selection effort relative to that physician was deemed accomplished. *Id.* at 765. Langston credibly testified that there was no effort to specially select files under some prosecution-enhancement or "cherry picking" purpose. *Id.* at 768.

Langston also explained DEA's Automated Record Consolidated Ordering System (ARCOS) and testified that she generated an ARCOS report relative to the Respondent's ordering of controlled substances from January 2009 through February 2010. Govt. Ex. 97.

In the same fashion, Langston explained the purposes of and circumstances behind the generation of state prescription monitoring reports (PMPs) relative to the Respondent maintained by West Virginia, Kentucky, and Ohio. Govt. Exs. 98–100. Review of the PMP report data reflects that during the time period of February 1, 2006 through February 11, 2010, pharmacies filled 167 controlled substance prescriptions issued over the Respondent's signature to fifty-four patients located in West Virginia, 110 similar prescriptions provided to fifty-seven Kentucky-based patients were filled between January 1, 2009 and April 4, 2010, and sixty-six such prescriptions pertaining to twenty-eight patients located in Ohio were filled between April 1, 2008 and April 19, 2010. *Id.*

No evidence was introduced at the hearing that would provide any reliable level of context regarding the raw data set forth in the databases received into evidence at the Government's request. Other than the observations noted above, no witness who testified at the hearing ever explained the significance of the data set forth in any of these databases to any issue that must or should be considered in deciding the present case. As discussed above, the fact that the Boca Drugs Prescription Log prepared by the agents does not distinguish between prescriptions authorized by the Respondent and another registrant of the same name deprives the document of virtually any relevance regarding the enforcement action against this Respondent.[18]

GS Langston provided evidence that was sufficiently detailed, consistent and plausible to be deemed credible in this recommended decision.

SA Michael Burt testified that he has been employed by DEA since March 2004 and has been stationed with the Miami Field Division (MFD) since September 2004. Tr. at 813–14. Burt testified that he is the lead case agent for DEA in the investigation of American Pain Clinic and has participated in the investigation since the latter part of 2008. According to Burt, American Pain, which was previously known by the name South Florida Pain, has conducted business at four different locations, and

[15] Although GS Langston testified that DEA immediately suspended the COR that had been issued to Boca Drugs, Tr. at 715, and that a voluntary surrender by that registrant followed a day later, *id.* at 776, no evidence has been presented that would lend that fact any particular significance related to any issue that must or should be found regarding the disposition of the present case.

[16] GS Langston testified that she was unaware of the location of the closest Walgreens to American Pain's offices. Tr. at 779. No evidence was presented that would tend to establish that any Walgreens or any other pharmacy has taken a position regarding its willingness to fill prescriptions authorized by American Pain.

[17] Although GS Langston testified that she did not actually take the photographs taken during the search warrant execution at American Pain, she did provide sufficient, competent evidence to support the admission of the photographs that were ultimately received into evidence. Tr. at 737, 739–41.

[18] Remarkably, although this unfortunate aspect of this document was brought to light during the course of the hearing, Tr. at 732, no effort on the part of the Government was made to provide additional details or explanation that might tend to differentiate between the respondents.

he surveilled the Boca Raton and Lake Worth locations both in person and by periodic live review of video captured via pole cameras [19] set up outside the clinic. *Id.* at 815–17. These pole cameras, which were in operation during a three week period from January to February 2010, were initially in operation on a 24-hour basis, but Burt testified that they were later activated only between the hours of 7 a.m. through 6 p.m. due to an observed lack of activity at the clinic outside of that time period. *Id.* at 820–21. The pole camera recordings were not offered into evidence at the hearing or made available to opposing counsel.

Based on these surveillance efforts, SA Burt testified concerning various activities he observed occurring outside the Boca and Lake Worth clinic locations, which were open to the public from 8 a.m. to 5 p.m. At the Boca location, Burt stated that on any given day, beginning at 7 a.m. in the morning, automobiles could be seen pulling into the parking lot and approximately twenty to thirty people were routinely lined up outside of the clinic waiting to gain admittance. Additionally, there was a steady stream of automobile and foot traffic in and out of the clinic throughout the day. *Id.* at 817, 821. Burt testified that in his estimation, approximately 80–90 percent of the automobiles had out-of-state tags, predominantly from Kentucky, Ohio, West Virginia and Tennessee. *Id.* at 817–18. Burt also observed security personnel with "staff" written on their shirts [20] riding around the exterior of the building in golf carts and who, in Burt's assessment, appeared to be directing patients into the American Pain facility. Burt indicated his surveillance of the Lake Worth location yielded similar observations. *Id.* at 818.

Based on his review of some (but not all) [21] of the audio and video tapes made by agents and informers sent into the clinic by the Government at various times, SA Burt also testified about his understanding of the process by which patients obtained controlled substance prescriptions at American Pain. According to Burt, after entering the clinic, a patient would meet with the receptionist, who would determine if the patient had an MRI. If not, the receptionist would issue that individual an MRI prescription in exchange for a $50 cash payment, and the patient "would be directed to a place to obtain an MRI." *Id.* at 822. Burt testified that one such MRI location was Faye Imaging, which was a mobile MRI trailer located behind a gentlemen's club several miles away from American Pain. *Id.* at 822–23. The cost for the MRI was $250, and the patient could pay an additional fee "to have the MRI expedited and faxed over to American Pain." *Id.* at 823–24. Once the MRI was procured and faxed to American Pain, the patient would return to the clinic and be seen by a doctor. According to Burt, the clinic accepted what he referred to as "*predominantly* cash only" [22] for these office visits, and the six doctors at the clinic saw "anywhere from 200 upward to 375 patients a day" [23] in this manner.[24] *Id.* at 882–83 (emphasis supplied).

SA Burt also testified regarding his review of some [25] of the video and audio recordings made by an undercover agent (UC) named Luis Lopez capturing activity inside of American Pain.[26] In those recordings, Burt observed who he believed to be an American Pain employee inside the facility standing up in a waiting room full of patients and directing them "not to have their prescriptions filled out of state, not to go out into the parking lot and snort their pills," and directing the patients to have their prescriptions filled "in house" (meaning at American Pain), at "a pharmacy they have in Orlando, Florida," or at "a pharmacy they have down the street," which, in Burt's view, was a reference to Boca Drugs. *Id.* at 825–26. Burt further testified that the purported employee on the recording told the patients to "obey all the traffic laws; do not give the police a reason to pull you over." *Id.* Although Burt testified as to the contents of these recordings, the physical recordings were not offered into evidence by the Government or made available to opposing counsel.

SA Burt also testified that he received information from Dr. Eddie Sollie, a former physician employed during the time period American Pain was doing business as South Florida Pain, who terminated his employment at the Oakland Park clinic location in November or December 2008 after working there for approximately two and a half to three months. *Id.* at 827, 898. During the course of an interview where Burt was present, Dr. Sollie related various "concerns about how the practice was being handled or managed." *Id.* at 827–28. These concerns included medical records being, in his opinion, annotated inadequately by the doctors, and what he perceived as a lack of supervision during patient urinalysis testing, where patients would "go[] to the bathrooms together, bringing items with them to the bathrooms that could possibly disguise the urinalysis." According to Burt, Sollie explained that he perceived that patients were substituting urine produced by other persons that contained the metabolites for controlled substances that the patients claimed to be legitimately taking, with a view towards falsely providing evidence to the American Pain doctors showing that they were actually taking prescribed medications and not diverting them. *Id.* at 828–29. During cross-examination, Burt explained that Dr. Sollie told him he had raised these concerns with Christopher George, the owner of American Pain, and that Burt had no evidence that the deficient practices that Sollie had objected to continued through 2010. *Id.* at 900, 906. Burt also acknowledged that he was aware Dr. Sollie had been involved in litigation with Mr. George and that their relationship was strained. *Id.* at 1009. Dr. Sollie was not called as a witness by either party.

SA Burt also provided testimony concerning three confidential sources (only one of whom was seen by the Respondent) and their contacts with doctors at American Pain. Relative to the Respondent, based on the investigative assistance he provided to the Palm Beach County, FL, Sheriff's Office (PBSO), Burt testified regarding the circumstances surrounding a confidential source's (CS3) visit to obtain controlled substances from

[19] SA Burt described the pole cameras as "covert cameras that are installed to observe the activity in the clinic." Tr. at 816. Burt testified that he was able to use a laptop to access the live video feed from the cameras after inputting a username and password. The camera video was also recorded to DVR. *Id.* at 821.

[20] Tr. at 910.

[21] SA Burt conceded that although he is the designated lead case agent for DEA, he did not review all the audio and video tapes made in the case or even review the transcripts. Tr. at 1002–05.

[22] Later on cross-examination, SA Burt admitted that the clinic also accepted payment via credit card. Tr. at 916.

[23] Inasmuch as the Government provided no information from which any specific number of patients seen by any given clinic doctor on any day could be derived, or any expert testimony regarding a reasonable number of pain patients that could or should be seen per day, the value of providing the raw number of patients walking through the door at the clinic is negligible.

[24] Burt further testified that the doctors were paid $75.00 per patient visit, *id.* at 884, but because he indicated that he could not disclose his basis of knowledge for this information, this portion of his testimony can be afforded no weight. *See Richardson* v. *Perales,* 402 U.S. 389, 402 (1971); *J.A.M. Builders* v. *Herman,* 233 F.3d 1350, 1354 (11th Cir. 2000); *Keller* v. *Sullivan,* 928 F.2d 227, 230 (7th Cir. 1991); *Calhoun* v. *Bailar,* 626 F.2d 145, 149 (9th Cir. 1980).

[25] Tr. at 1002–05.

[26] The fact that these recordings were made during the course of seven different office visits by an undercover agent to both the Boca Raton and Lake Worth locations was established on cross-examination. Tr. at 900, 985.

American Pain in October 2009.[27] Burt stated that he was approached by an unnamed PBSO officer who advised that he had a confidential source "that could go into American Pain and purchase oxycodone from one of the doctors." *Id.* at 870. Burt met CS3 at a predesignated location, at which time the source was searched for contraband and provided with a recording device prior to entering American Pain to visit the Respondent, whom he had a scheduled appointment with and had previously been seen by at the clinic. *Id.* at 871, 877, 1050. At a subsequent debriefing, Burt testified that "the source told [him] that he went into the office with [the Respondent], put on the blood pressure cuff himself, took his own blood pressure, was given no physical exam by the doctor, and left with a prescription of oxycodone." *Id.* at 878. Burt testified that he was not able to simultaneously listen to the audio capturing the details of this office visit, and further admitted that has not reviewed the associated audio recording; instead, Burt's testimony was based on his review of a PBSO detective's written report and Burt's participation in the debriefing of CS3. Burt's testimony revealed that the investigative assistance of CS3 was secured as part of his cooperation with PBSO in relation to a pending criminal charge. *Id.* at 1047. Burt declined to disclose the name of CS3 when queried on cross-examination. *Id.* at 1045. The audio recording made by CS3 was not introduced by the Government into evidence or provided to opposing counsel.[28] SA Burt was extremely vague and sketchy regarding the details of his encounter with CS3 relative to the Respondent. *Id.* at 870–82. In fact, without a refreshment of his recollection, Burt was not even sure that CS3 met with the Respondent, and not another American Pain physician with the same last name. *Id.* at 871–77. This portion of his testimony was received over the vociferous objections of Respondent, based on lack of relevance, unfair prejudice, and the inability for meaningful cross-examination based on a lack of access to either the recorded audio or even a witness who has heard the audio (or even knew the details of the visit), in conjunction with the absence of evidence of the name that would be on the patient chart reflecting the office visit. Tr. at 877–82. Under the circumstances present here, including the tentative nature of his testimony as well as the manner in which it was produced, which, categorically denied the Respondent of any meaningful opportunity for the cross-examination required by the A.P.A.,[29] this aspect of Burt's testimony may be accorded no weight. To proceed otherwise would deny the Respondent the ability guaranteed by the APA "to conduct such cross-examination as may be required for a full and true disclosure of the facts." 5 U.S.C. 556(d); *see Richardson* v. *Perales,* 402 U.S. 389, 402 (1971); *J.A.M. Builders* v. *Herman,* 233 F.3d 1350, 1354 (11th Cir. 2000); *Keller* v. *Sullivan,* 928 F.2d 227, 230 (7th Cir. 1991); *Calhoun* v. *Bailar,* 626 F.2d 145, 149 (9th Cir. 1980); see Tr. at 882.

SA Burt also testified regarding the drug overdose deaths of TY and SM after obtaining controlled substances from American Pain.[30] Burt's record testimony indicates that DEA Task Force Officer[31] (TFO) Barry Adams informed him that a Kentucky resident named TY overdosed in Kentucky from oxycodone intoxication induced by medication procured at American Pain. Burt testified that this information was furnished pursuant to a working law enforcement relationship between the Kentucky State Police, Kentucky FBI, Kentucky DEA and Miami DEA aimed at addressing "the brunt of the pill problem" centered within the state of Kentucky relative to illegal use and resale of prescription pain medications. *Id.* at 833–35. However, in his testimony, Burt was unable to recall the name of the doctor from whom TY obtained his pills, and, thus, no admissible evidence was presented by the Government with respect to TY's death.[32] Likewise, the record evidence concerning SM did not implicate prescribing activity by the Respondent.

Perhaps among the more striking aspects of SA Burt's performance on the witness stand is the anticipated testimony which he did not provide. When viewed in its entirety, SA Burt's record testimony was stunningly sparse when compared with his proposed testimony as noticed in the Government's prehearing statement.[33] That certain information may be unavailable for reasons related to other litigation forums or other equally valid reasons are of no moment with respect to the evaluation that must be made at this administrative forum. Equally important, such considerations do not alter the burdens imposed upon the respective parties. Simply put, the admitted evidence must succeed or fail on its own merits, irrespective of extraneous considerations.

Even apart from the marked contrast between the Burt testimony as proffered and as realized, his testimony was marred by periodic memory failures on significant issues and an inability to supply details to an extent that it could arguably have diminished the weight that could be fairly attached to those aspects of his own investigation that he did manage to recollect. During his testimony, SA Burt acknowledged his own marked lack of preparation and unfamiliarity with the investigation and confessed simply that "[t]here's no excuse . * * *" *Id.* at 1003–05.

Even acknowledging its obvious suboptimal aspects, SA Burt's testimony had no apparent nefarious motivation or indicia of intentional deceit. Burt came across as an earnest and believable witness, who, regarding the aspects of the case that he did recall, was able to impart substantial information about the investigation and activities involving American Pain and its doctors. While frequently lacking in detail, his testimony was not internally inconsistent or facially implausible, and although the legal weight I have assigned to certain portions of Burt's testimony varies given the issues described, I find his testimony to be credible overall.

The Government presented the bulk of its case through the report and testimony of its expert, L. Douglas Kennedy, M.D., D.A.B.P.M., Affiliate Clinical Assistant Professor at the University of Miami, Miller School of Medicine.[34] Dr. Kennedy, who testified that he is board certified by the American Board of Pain Medicine and the American Board of Anesthesiology,[35] was offered and accepted as an expert in the field of pain medicine. *Id.* at 39.

Dr. Kennedy testified that after a review of a group of selected patient files from those seized at the Respondent's practice that were to him provided by the Government, he

[27] Tr. at 1046.

[28] Astonishingly, although SA Burt was offered by the Government as the proponent of all of the information relative to CS3, he conceded that he never listened to the audio tape created as a result of the wire worn by the informant. Tr. at 1051. According to Burt, the sum total of his awareness about the details regarding CS3 was gleaned from his presence at the post-encounter debriefing. *Id.*

[29] 5 U.S.C. 556(d).

[30] Although similar testimony concerning the overdose death of a third individual, OB, was noticed in the Government's prehearing statement, it was not offered by the Government at the hearing. ALJ Ex. 6 at 8.

[31] According to SA Burt, a "task force officer" is a local police officer or sheriff's deputy that is assigned to work on a DEA task force, rather than a sworn DEA criminal investigator. Tr. at 1031.

[32] *See* Tr. at 836–53 (addressing exclusion of Govt. Ex. 27 and associated testimony).

[33] ALJ Ex. 6.

[34] Dr. Kennedy's CV was admitted into evidence. Govt. Ex. 117.

[35] Tr. at 17.

concluded that the Respondent's physical examinations, treatment plans, and patient histories were below the standard fixed by the Florida Medical Board and that that controlled substances was not for a legitimate medical purpose. *Id.* at 585–88.

Dr. Kennedy took professional issue with several aspects of the Respondent's patient care as reflected in the charts regarding the prescribing of controlled substances. It is apparent from his testimony that Dr. Kennedy's analysis is restricted to those matters which can be gleaned from an examination of the written word in that subset of the Respondent's patient charts provided by the Government for his review, and that limitation perforce circumscribes the breadth of his input. That being said, Dr. Kennedy highlighted numerous features in the Respondent's chart documentation that he found wanting, or at least remarkable.

Dr. Kennedy explained that there are basic elements to practicing pain medicine. The acquisition of a thorough history and physical examination is important. *Id.* at 41–42. He also stressed the vital importance of obtaining past medical records to evaluate what treatments, therapies, medications, and dosages have been utilized in the past so that correct current treatment decisions can be made. *Id.* at 45–46. Reliance upon the patient's memory of these elements without the prior medical records, in Dr. Kennedy's view is not reliable or acceptable. *Id.* at 46–47. Dr. Kennedy acknowledged that physicians customarily accept patients at their word, but on the subject of verifying a patient's subjective complaint and medication history, Dr. Kennedy explained that

> [s]ometimes you have to help people understand why they're suffering or what their problems are. A person with an addiction or drug abuse problem is no worse a human being than me. I'm not any better than them. But it's your job as a doctor to sit down and find out what the truth is as well as you reasonably can under the circumstances.

Id. at 357.

Dr. Kennedy prepared a report in connection with the Government's case against the Respondent, which is dated April 30, 2010, and was admitted into evidence. Govt. Ex. 101; Tr. at 585. The report describes a general analysis of sixteen charts that the Respondent maintained on as many patients, that were (selected by and) provided to Dr. Kennedy by the Government from among patient files seized pursuant to a criminal search warrant executed at the Respondent's practice on March 3, 2010 (Patient Charts Analysis). Although this report purports to describe practices common to all sixteen files reviewed by Dr. Kennedy, much of the analysis is directed toward a chart prepared in connection with JS,[36] one of the Respondent's patients.

Dr. Kennedy's report makes it unambiguously clear that, in his opinion, all sixteen of the Respondent's charts that he reviewed suffered from the same shortcomings.[37] The Patient Charts Analysis states that the Respondent's patient charts that Dr. Kennedy reviewed "are essentially the same with regard to review issues; as stated in the report of [JS] referenced and discussed in this report in detail, [and that] there were no significant differences that affected [his] conclusions and summary." Govt. Ex. 101 at 2.

In Dr. Kennedy's opinion, the patient charts he reviewed that were prepared by the Respondent reflected care that fell below the applicable standard on multiple levels. In his report, Dr. Kennedy noted that the treatment notes in the charts: (1) Contained no typewritten clinical notes and were "very brief, difficult to read (often impossible) and not within the standard of care due to their brevity and quality";[38] (2) reflected prescriptions, right from the initial patient visit, that "were almost entirely for controlled substances, most often one or two immediate release oxycodone pills * * * with Xanax," and which were, in Dr. Kennedy's view, inappropriate and more powerful than justified by the objective signs documented in the written notes;[39] (3) showed that "the same or very similar 'drug cocktails' were prescribed [among all patients in the reviewed files] in the same or very similar doses, [directions] * * * with a 30-day supply," and were affixed to the prescription scripts with a few prepared stamps utilized by all American Pain physicians that reflected "drug, dose, sig (directions) and quantity dispensed";[40] (4) contained medication contracts that were "not always signed" and "listed criteria that was not followed by the doctors at American Pain;"[41] (5) failed to document the efficacy of the prescribed medication; (6) did not set forth a "diagnostic plan except to obtain an occasional MRI, the results of which made no difference in the 'treatment' ";[42] (7) reflected "no therapeutic plan, except to use controlled substances to 'treat' the subjective complaint of 'pain' which was inadequately described";[43] (8) reflected "no real therapeutic goals * * * for improvement of quality of life (activities of daily living, work, sleep, mood)";[44] (9) did not reflect "consultations with other physicians or specialists outside the American Pain group [which] could have and in some cases should have included orthopedics, neurology, neurosurgery, psychiatry, addiction medicine and psychology";[45] (10) reflected "a gross lack of past medical records in all charts reviewed and in some cases none at all";[46] and, (11) demonstrated controlled substance patient monitoring practices that were "not within the standard of care and was outside the boundaries of professional practice."[47]

[36] At the request of the Government, a protective order was issued that is designed to minimize the risk of the dissemination of identifying information related to patients and their relatives associated with this case. Accordingly, initials have been substituted for the names of individuals within the protection of the protective order throughout the body of this decision. ALJ Ex. 15.

[37] The Government's tactical decision to essentially unload a pile of charts that are explained only by the representations and generalizations in a report, with no attempt whatsoever to have its expert witness explain the applicable aspects of most charts to this tribunal or any future reviewing body is clearly at odds with the directive provided by the Deputy Administrator in *Gregg & Son Distributors* that "it is the Government's obligation as part of its burden of proof and not the ALJ's responsibility to sift through the records and highlight that information which is probative of the issues in the proceeding." 74 FR 17517 n.1.

[38] Govt. Ex. 101 at 5.

[39] Govt. Ex. 101 at 5. In Dr. Kennedy's opinion, the Respondent "prescribed, at the first visit, very high initial doses of controlled substance combinations despite not being within standard of care for histories, physical examinations and/or absent past medical records." *Id.* at 8.

[40] Govt. Ex. 101 at 5.

[41] Govt. Ex. 101 at 4. As an example of the failure to adhere to the terms of the medication contract, Dr. Kennedy cites a contract term that provides notice that the physician may stop prescribing opioids or change treatment if pain or activity improvement is not demonstrated, and points out that pain and activity levels are routinely not documented in treatment notes. *Id.* at 4. Similarly, Dr. Kennedy references a medication contract warning that termination of services may result from failure to make regular follow-up appointments with primary care physicians, and notes that the American Pain charts contain no notes from primary care physicians or medical records generated by them. *Id.* at 4–5.

[42] Govt. Ex. 101 at 8. In Dr. Kennedy's opinion, Respondent "in effect, acted as a 'barrier' for [JS] to receive appropriate medical evaluation and treatment. In other words, the very potent, high doses of opioids (oxycodone) and benzodiazepine (Xanax) may have masked [JS's] underlying disease process(s), making them more difficult to diagnose, and allowing the disease(s) to unnecessarily worsen. Without an accurate diagnosis, all [the Respondent] was doing was, again, masking or covering up the symptoms. *Id.* at 13.

[43] Govt. Ex. 101 at 8.

[44] Govt. Ex. 101 at 8.

[45] Govt. Ex. 101 at 8.

[46] Govt. Ex. 101 at 17. JS's chart did not contain any past medical records, save for a Lumbar report from an MRI performed the day before JS's first clinic visit to see the Respondent. *Id.* at 11.

[47] Govt. Ex. 101 at 15.

Dr. Kennedy found the Respondent's controlled substance patient monitoring to be deficient in numerous respects. From the reviewed patient charts, Dr. Kennedy gleaned that an initial, in-office urine drug screen was frequently executed during the patients' initial visit to the office but repeated only occasionally. Govt. Ex. 101 at 15. It was Dr. Kennedy's observation that even a drug screen anomaly did not alter the seemingly inexorable continuation of controlled substance prescribing from the Respondent. *Id.* Dr. Kennedy also noted that the Respondent did not utilize out-of-office toxicology tests, or obtain out-of-state prescription monitoring program or outside pharmacy drug profiles. Furthermore, the charts contained only rare evidence of contact with primary care physicians, treating physicians, pharmacists, or other health care providers. *Id.* at 15–16.

The identified shortcomings of controlled substance patient monitoring systems was of particular significance where Dr. Kennedy identified specific evidence that he identified as "red flags" of possible or likely diversion. Red flags noted by Dr. Kennedy in the reviewed charts included the relatively young age of the Respondent's chronic pain patients,[48] incomplete history information provided by the patients, periodically significant gaps between office visits,[49] referrals from friends, relatives, or advertising, but not other physicians,[50] and the fact that a relatively high number of patients were traveling significant distances to American Pain for pain treatment, although no physician employed at that facility had any specialized training in pain management.[51]

Dr. Kennedy also found it remarkable that each American Pain patient file provided notice to its patients that American Pain did not accept any form of health care insurance. Govt. Ex. 101 at 3, 17. Dr. Kennedy's report set forth his opinion that this practice was designed to "effectively keep [the physicians at American Pain] 'off the radar' from monitoring by any private health care insurance company as well as all state and federal agencies (Medicaid and Medicare respectively). *Id.* at 17. Significantly, however, when asked, Dr. Kennedy acknowledged that he conducts his own current medical practice on a cash-only basis. Tr. at 151.

Regarding the discomfiture that Dr. Kennedy expressed regarding non-physician referrals in his report, during his testimony at the hearing, he clarified that it was not unusual for a physician to treat patients that have been referred by relatives and friends. Tr. at 154. Further, Kennedy conceded while in the course of his own medical practice he has treated patients referred by family and friends, and that in his report he was focusing on what he perceived as a lack of any referrals by physicians in the files he reviewed, or what he perceived as "trends" or "patterns." Tr. at 154–55. Given Dr. Kennedy's acknowledgement that such referrals are not unusual, coupled with the absence of any record-evidence way to measure the relative percentage of physician referrals in the Respondent's practice, the observations regarding referral sources are of limited value here.[52]

A review of the sixteen patient files that informed the analysis, findings and conclusions offered in Dr. Kennedy's written report and testimony does reflect the presence of at least some of the red flag issues he identified therein, but there was not the unanimity among the files that he repeatedly urges. For instance, in terms of evidence related to therapeutic plans, it is notable that Respondent's patient files contain at least some indications of recommended treatment modalities in addition to the Respondent's exclusive use of controlled substances for pain management. There are notations in the charts reflecting a patient was to see a "PCP," or primary care physician, regarding jaundice, Govt. Ex. 108 at 9; in another patient file, a note listed under referrals reads "ER for eval of Cellulite + Possible IV ATBx." Govt. Ex. 109 at 1.

An examination of the reviewed patient charts does reveal the presence of other red flags that should have inspired additional diligence or inquiry on the part of the Respondent. RR's patient file, for example, contains a form indicating a positive UDS for oxycodone and benzodiazepine from 11/20/08, yet on the same date, the medication contract signed by RR is blank in that portion of the form designated for the patient to reveal any medications he or she is currently taking. Govt. Ex. 105 at 15, 31; *see also* Govt. Exs. 107 at 8–9, 21; 109 at 46, 54–55; 114 at 8–9, 20 (similar issues). Patient RS's file indicates a positive test for oxycodone on 9/10/09, yet on her medication contract sharing the same date, she crosses out her handwritten listings of Percocet and Xanax, and notes "*Sorry am not currently taking*." Govt. Ex. 110 at 10, 26. DS's patient file indicates a positive UDS for oxycodone and benzodiazepine only on January 14, 2010; however, the patient indicates elsewhere on a medical form filled out on the same date, in response to a question concerning whether she has taken any illegal or illicit drugs in the last 30 days, that she "smoked some marijuana because of [her] cancer." This disclosure notwithstanding, the lack of an indication of a positive "THC" result on the aforementioned UDS form is not addressed by the Respondent anywhere in the patient file. Govt. Ex. 112 at 10, 19. Patient JR's 7/17/09 UDS indicates a negative test for all listed substances, yet on two different forms dated 7/13/09 she indicates she is currently taking hydrocodone or Lortab, a discrepancy which raises questions about the validity of the testing procedures and/or the patient's candor. Govt. Exs. 106 at 12–13, 30; *see also* Govt. Ex. 113 at 11–12, 29[53] (similar issue). Patient CA's[54] UDS form, on the other hand, lists a positive test result for oxycodone only on 11/3/09, yet the patient states she is also currently taking Xanax elsewhere on the medical forms from the same date. Govt. Ex. 103 at 10–11, 24; *see also* Govt. Ex. 116 at 17–18, 42 (same issue). A prescribed controlled substance that is not reflected in a drug screen should have raised a sufficient suspicion of diversion to merit further inquiry by the registrant reflected in the patient file. At a minimum, these observations support the conclusion there was a general lack of vigilance on the part of the Respondent regarding his obligations as a registrant to minimize the risk of controlled substance diversion.

In addition to the lack of adequately completed forms in some patient files noted by Dr. Kennedy, other patient files appear to be missing key documentation altogether. For instance,

[48] Govt. Ex. 101 at 17.

[49] Govt. Ex. 101 at 15.

[50] Govt. Ex. 101 at 10, 17.

[51] Govt. Ex. 101 at 17.

[52] Dr. Kennedy did not testify that a referral that emanated from a source other than a physician could or should be a basis for a diversion red flag on a given case. His opinion was limited to culling some manner of a trend or pattern. In view of the fact that the record contains no development of the numbers of files with non-physician referrals versus the total number of files, or even an acceptable metric upon which the issue could be evaluated, there is very little useful analysis that can come from Dr. Kennedy's observation regarding the files he reviewed.

[53] Although the disclosed date the medications were last prescribed could provide a plausible explanation for the discrepancy, this misses the point. These types of inconsistencies raise potential red flags that require a prudent registrant to make additional inquiry and document, at a minimum, how the issue has been resolved to the satisfaction of the registrant before controlled substance prescriptions are issued.

[54] It is notable that patient "CA" is referred to using three different last names in the patient file records covering the period of time from 11/3/09 to 2/4/10, only one of which is present on her driver's license. *See* Govt. Ex. 103 at 1–2, 4, 8. This discrepancy is not addressed in any manner in the documentation.

patient RR's file contains a South Florida Pain Management Clinic physical examination form that was not filled out, and no physical examination form is present in the file reflecting such an exam was conducted by the Respondent. *See* Govt. Ex. 105 at 9–10.

Dr. Kennedy concluded his report regarding the Respondent's prescribing practices with the following summary:

> [The Respondent] was not engaged in the practice of medicine, rather he was engaged in an efficient, "[a]ssembly [l]ine" business. His "patients" were revenue streams, not true patients. This business allowed him to collect cas[h] for office visits as well as being a "[d]ispensing [p]hysician" for controlled substances. He prescribed controlled substances so that "patients" would return to his office on a regular basis, allowing him to generate further revenue. [The Respondent's] routine and excessive prescription of multiple controlled substances (oxycodone and Xanax) and lack of arriving at a valid medical diagnosis and treatment most likely caused harm to the "patients" he saw. Drug diversion most likely caused a "mushroom" effect of increased drug abuse, drug addiction, drug overdoses, serious bodily injury and death in those communities spread over several different states. [The Respondent's] continued ability to prescribe controlled substances will only perpetuate the suffering and be a threat to the public.

Govt. Ex. 101 at 18.

On cross examination, Dr. Kennedy agreed that he assumed, for the purposes of his analysis, that where the Respondent's charts reflected an entry or a procedure, that the event actually occurred. Tr. at 654. Kennedy also acknowledged that every one of the patient files he reviewed contained at least a complaint of chronic pain symptoms by the patient and MRI results that could support such a diagnosis. *Id.* at 655–57.

The Government's presentation of Dr. Kennedy's testimony at the hearing was substantially consistent with the conclusions included in the Patient Charts Analysis, but Dr. Kennedy's presentation was clearly not without its blemishes. Although he testified that he was familiar with prescribing practices in Florida, and that he utilized the medical standards applicable to Florida practice,[55] he was unable to identify the documentation standard in the Florida Administrative code with any degree of particularity, and he also acknowledged that he was not aware of what the standard is in Florida Medical Board administrative decisions regarding the overprescribing of medication or what constitutes an adequate medical history. *Id.* at 149–51, 233, 304. While, overall, Kennedy presented testimony that appeared candid and knowledgeable, there were areas in his written report that rang of hyperbole and over-embellishment. The reasoning behind some of the seemingly critical observations in the written report, such as the "cash basis" of the Respondent's practice and the absence of doctor referrals among the reviewed patient files, did not well survive the crucible of cross examination at the hearing. However, overall, Dr. Kennedy's testimony was sufficiently detailed, plausible, and internally consistent to be considered credible, and, consistent with his qualifications, he spoke persuasively and with authority on some relevant issues within his expertise, and notwithstanding the Respondent's objections relative to his Florida-related experience, he is currently an assistant professor teaching at a Florida Medical School. It may well be that the greatest and most significant aspect of Dr. Kennedy's opinion is that on the current record, it stands unrefuted. Thus, his opinion is the only expert opinion available for reliance in this action.[56] Accordingly, Dr. Kennedy's expert opinion that the Respondent's controlled substance prescribing practices, at least as evidenced through his examination of the patient charts he reviewed, fell below the standards applicable in Florida, and that the controlled substance prescriptions contained in those files were not issued for a legitimate medical purpose is unrefuted on this record and (although by no means overwhelming) is sufficiently reliable to be accepted and relied upon in this recommended decision.

The Analysis

Pursuant to 21 U.S.C. 824(a)(4), the Deputy Administrator[57] may revoke a registrant's DEA Certificate of Registration if persuaded that the registrant "has committed such acts that would render * * * registration under section 823 * * * inconsistent with the public interest * * *." The following factors have been provided by Congress in determining "the public interest":

> (1) The recommendation of the appropriate State licensing board or professional disciplinary authority.
>
> (2) The applicant's experience in dispensing, or conducting research with respect to controlled substances.
>
> (3) The applicant's conviction record under Federal or State laws relating to the manufacture, distribution, or dispensing of controlled substances.
>
> (4) Compliance with applicable State, Federal or local laws relating to controlled substances.
>
> (5) Such other conduct which may threaten the public health and safety.

21 U.S.C. 823(f).

"[T]hese factors are considered in the disjunctive." *Robert A. Leslie, M.D.,* 68 FR 15227, 15230 (2003). Any one or a combination of factors may be relied upon, and when exercising authority as an impartial adjudicator, the Deputy Administrator may properly give each factor whatever weight she deems appropriate in determining whether an application for a registration should be denied. *JLB, Inc., d/b/a Boyd Drugs,* 53 FR 43945 (1988); *England Pharmacy,* 52 FR 1674 (1987); *see also David H. Gillis, M.D.,* 58 FR 37507, 37508 (1993); *Joy's Ideas,* 70 FR 33195, 33197 (2005); *Henry J. Schwarz, Jr., M.D.,* 54 FR 16422 (1989). Moreover, the Deputy Administrator is "not required to make findings as to all of the factors * * *." *Hoxie* v. *DEA,* 419 F.3d 477, 482 (6th Cir. 2005); *see also Morall* v. *DEA,* 412 F.3d 165, 173–74 (D.C. Cir. 2005). The Deputy Administrator is not required to discuss consideration of each factor in equal detail, or even every factor in any given level of detail. *Trawick* v. *DEA,* 861 F.2d 72, 76 (4th Cir. 1988) (the Administrator's obligation to explain the decision rationale may be satisfied even if only minimal consideration is given to the relevant factors and remand is required only when it is unclear whether the relevant factors were considered at all). The balancing of the public interest factors "is not a contest in which score is kept; the Agency is not required to mechanically count up the factors and determine how many favor the Government and how many favor the registrant. Rather, it is an inquiry which focuses on protecting the public interest * * *." *Jayam Krishna-Iyer, M.D.,* 74 FR 459, 462 (2009).

In an action to revoke a registrant's DEA COR, the DEA has the burden of proving that the requirements for revocation are satisfied. 21 CFR 1301.44(e). Once DEA has made its *prima facie* case for revocation of the registrant's DEA Certificate of Registration, the burden of production then shifts to the Respondent to show that, given the totality of the facts and circumstances in the record, revoking the registrant's registration would not be appropriate. *Morall,* 412 F.3d at 174; *Humphreys* v. *DEA,* 96 F.3d 658, 661 (3d Cir. 1996); *Shatz* v. *U.S. Dept. of Justice,* 873 F.2d 1089, 1091 (8th Cir. 1989); *Thomas E. Johnston,* 45 FR 72, 311 (1980). Further, "to rebut the Government's *prima facie* case, [the Respondent] is required not only to

[55] Tr. at 628.

[56] The Respondent did not testify on her own behalf.

[57] This authority has been delegated pursuant to 28 CFR 0.100(b) and 0.104.

accept responsibility for [the established] misconduct, but also to demonstrate what corrective measures [have been] undertaken to prevent the reoccurrence of similar acts." *Jeri Hassman, M.D.,* 75 FR 8194, 8236 (2010).

Where the Government has sustained its burden and established that a registrant has committed acts inconsistent with the public interest, that registrant must present sufficient mitigating evidence to assure the Deputy Administrator that he or she can be entrusted with the responsibility commensurate with such a registration. *Steven M. Abbadessa, D.O.,* 74 FR 10077 (2009); *Medicine Shoppe-Jonesborough,* 73 FR 364, 387 (2008); *Samuel S. Jackson, D.D.S.,* 72 FR 23848, 23853 (2007). Normal hardships to the practitioner, and even the surrounding community, that are attendant upon the lack of registration are not a relevant consideration. *Abbadessa,* 74 FR at 10078; *see also Gregory D. Owens, D.D.S.,* 74 FR 36751, 36757 (2009).

The Agency's conclusion that past performance is the best predictor of future performance has been sustained on review in the courts, *Alra Labs.* v. *DEA,* 54 F.3d 450, 452 (7th Cir. 1995), as has the Agency's consistent policy of strongly weighing whether a registrant who has committed acts inconsistent with the public interest has accepted responsibility and demonstrated that he or she will not engage in future misconduct. *Hoxie,* 419 F.3d at 483; *George C. Aycock, M.D.,* 74 FR 17529, 17543 (2009); *Abbadessa,* 74 FR at 10078; *Krishna-Iyer,* 74 FR at 463; *Medicine Shoppe,* 73 FR at 387.

While the burden of proof at this administrative hearing is a preponderance-of-the-evidence standard, *see Steadman* v. *SEC,* 450 U.S. 91, 100–01 (1981), the Deputy Administrator's factual findings will be sustained on review to the extent they are supported by "substantial evidence." *Hoxie,* 419 F.3d at 481. While "the possibility of drawing two inconsistent conclusions from the evidence" does not limit the Deputy Administrator's ability to find facts on either side of the contested issues in the case, *Shatz,* 873 F.2d at 1092; *Trawick,* 861 F.2d at 77, all "important aspect[s] of the problem," such as a respondent's defense or explanation that runs counter to the Government's evidence, must be considered. *Wedgewood Vill. Pharmacy* v. *DEA,* 509 F.3d 541, 549 (D.C. Cir. 2007); *Humphreys,* 96 F.3d at 663. The ultimate disposition of the case must be in accordance with the weight of the evidence, not simply supported by enough evidence to justify, if the trial were to a jury, a refusal to direct a verdict when the conclusion sought to be drawn from it is one of fact for the jury. *Steadman,* 450 U.S. at 99 (internal quotation marks omitted).

Regarding the exercise of discretionary authority, the courts have recognized that gross deviations from past agency precedent must be adequately supported, *Morall,* 412 F.3d at 183, but mere unevenness in application does not, standing alone, render a particular discretionary action unwarranted. *Chein* v. *DEA,* 533 F.3d 828, 835 (D.C. Cir. 2008) (citing *Butz* v. *Glover Livestock Comm. Co., Inc.,* 411 U.S. 182, 188 (1973)), *cert. denied,* __ U.S. __, 129 S.Ct. 1033 (2009). It is well-settled that since the Administrative Law Judge has had the opportunity to observe the demeanor and conduct of hearing witnesses, the factual findings set forth in this recommended decision are entitled to significant deference, *Universal Camera Corp.* v. *NLRB,* 340 U.S. 474, 496 (1951), and that this recommended decision constitutes an important part of the record that must be considered in the Deputy Administrator's decision, *Morall,* 412 F.3d at 179. However, any recommendations set forth herein regarding the exercise of discretion are by no means binding on the Deputy Administrator and do not limit the exercise of that discretion. 5 U.S.C. 557(b); *River Forest Pharmacy, Inc.* v. *DEA,* 501 F.2d 1202, 1206 (7th Cir. 1974); *Attorney General's Manual on the Administrative Procedure Act* 8 (1947).

Factors 1 and 3: The Recommendation of the Appropriate State Licensing Board or Professional Disciplinary Authority and Conviction Record Under Federal or State Laws Relating to the Manufacture, Distribution, or Dispensing of Controlled Substances

In this case, it is undisputed that the Respondent holds a valid and current state license to practice medicine. The record contains no evidence of a recommendation regarding the Respondent's medical privileges by any cognizant state licensing board or professional disciplinary authority. However, that a state has not acted against a registrant's medical license is not dispositive in this administrative determination as to whether continuation of a registration is consistent with the public interest. *Patrick W. Stodola, M.D.,* 74 FR 20727, 20730 (2009); *Jayam Krishna-Iyer,* 74 FR at 461. It is well-established Agency precedent that a "state license is a necessary, but not a sufficient condition for registration." *Leslie,* 68 FR at 15230; *John H. Kennedy, M.D.,* 71 FR 35705, 35708 (2006). Even the reinstatement of a state medical license does not affect the DEA's independent responsibility to determine whether a registration is in the public interest. *Mortimer B. Levin, D.O.,* 55 FR 9209, 8210 (1990). The ultimate responsibility to determine whether a registration is consistent with the public interest has been delegated exclusively to the DEA, not to entities within state government. *Edmund Chein, M.D.,* 72 FR 6580, 6590 (2007), *aff'd, Chein* v. *DEA,* 533 F.3d 828 (D.C. Cir. 2008), *cert. denied,* __ U.S. __, 129 S.Ct. 1033 (2009). Congress vested authority to enforce the CSA in the Attorney General and not state officials. *Stodola,* 74 FR at 20375. Thus, on these facts, the fact that the record contains no evidence of a recommendation by a state licensing board does not weigh for or against a determination as to whether continuation of the Respondent's DEA certification is consistent with the public interest.

Similarly, regarding Factor 3, while testimony was received at the hearing that indicated that a criminal search warrant was executed regarding the Respondent and American Pain, the record contains no evidence that the Respondent has ever been convicted of any crime or even arrested in connection with any open criminal investigation. Thus, consideration of the record evidence under the first and third factors does not militate in favor of revocation.

Factors 2, 4 and 5: The Respondent's Experience in Dispensing Controlled Substances, Compliance With Applicable State, Federal or Local Laws Relating to Controlled Substances, and Such Other Conduct Which May Threaten the Public Health and Safety

In this case, the gravamen of the allegations in the OSC/ISO, as well as the factual concentration of much of the evidence presented, share as a principal focus the manner in which the Respondent has managed that part of his practice relative to prescribing and dispensing controlled substances and acts allegedly committed in connection with his practice at American Pain. Thus, it is analytically logical to consider public interest factors two, four and five together. That being said, factors two, four and five involve analysis of common and distinct considerations.

Regarding Factor 2, the qualitative manner and the quantitative volume in which a registrant has engaged in the dispensing of controlled substances, and how long he has been in the business of doing so are factors to be evaluated in reaching a determination as to whether

he should be entrusted with a DEA certificate. In some cases, viewing a registrant's actions against a backdrop of how he has performed activity within the scope of the certificate can provide a contextual lens to assist in a fair adjudication of whether continued registration is in the public interest.

There are two principal considerations embedded within a consideration of this public interest factor. In considering a similar factor under the List I chemical context, the Agency has recognized that the level of experience held by those who will be charged with recognizing and taking steps to minimize diversion factors greatly in determining whether entrusting a COR will be in the public interest. *See Volusia Wholesale,* 69 FR 69409, 69410 (2004); *Xtreme Enters., Inc.,* 67 FR 76195, 76197–98 (2004); *Prachi Enters.,* 69 FR 69407, 69409 (2004); *J&S Distribs.,* 69 FR 62089, 62090 (2004); *K.V.M. Enters.,* 67 FR 70968, 70969 (2002). The Agency has also recognized that evidence that a registrant may have conducted a significant level of sustained activity within the scope of the registration for a sustained period is a relevant and correct consideration, which must be accorded due weight. However, this factor can be outweighed by acts held to be inconsistent with the public interest. Experience which occurred prior and subsequent to proven allegations of malfeasance may be relevant. Evidence that precedes proven misconduct may add support to the contention that, even acknowledging the gravity of a particular registrant's transgressions, they are sufficiently isolated and/or attenuated that adverse action against its registration is not compelled by public interest concerns. Likewise, evidence presented by the Government that the proven allegations are consistent with a consistent past pattern of poor behavior can enhance the Government's case.

In this case, the Respondent introduced no evidence regarding his level of knowledge and experience, or even the quality or length of his experience as a physician-registrant, but the Government has elected to do so.

Regarding the Government's presentation, Agency precedent has long held that in DEA administrative proceedings that "the parameters of the hearing are determined by the prehearing statements." *CBS Wholesale Distribs.,* 74 FR 36746, 36750 (2009) (citing *Darrel Risner, D.M.D.,* 61 FR 728, 730 (1996); *see also Roy E. Berkowitz, M.D.,* 74 FR 36758, 36759–60 (2009) ("pleadings in administrative proceedings are not judged by the standards applied to an indictment at common law" and "the rules governing DEA hearings do not require the formality of amending a show cause order to comply with the evidence"). That being said, however, the marked difference between the amount of evidence that the Government noticed in its OSC/ISO and the amount that it introduced at the hearing is striking. For example, contrary to its allegations, there was no evidence that the Respondent "prescribe[d] and dispense[d] *inordinate* amounts of controlled substances," that the "*majority*" of the Respondent's patients were "from states other than Florida," and there was no evidence that American Pain patients were issued "*pre-signed* prescriptions to obtain MRI[s]," nor was there evidence that individuals positioned outside the American Pain building were there to "monitor the activity of patients in the parking lot *to prevent patients from selling their recently obtained controlled substances.*" Likewise, no evidence was introduced at the hearing that could support the allegations that "employees of American Pain [] *frequently* ma[d]e announcements to patients in the clinic advising them on how to avoid being stopped by law enforcement upon departing the pain clinic" and "*frequently* ma[d]e announcements [] advising [patients], among other things, not to attempt to fill their prescriptions at out-of state pharmacies and warning them against trying to fill their prescriptions at particular local retail pharmacies." ALJ Ex. 1 (emphasis supplied).

In like fashion, the Government's prehearing statement proffered that SA Burt would testify to several of the items described but not established in the OSC/ISO. Among the list of allegations that were not supported by any evidence introduced at the hearing, were representations that SA Burt would testify concerning the following:

> Law enforcement in Florida and [other states that correspond to license plates seen in the American Pain parking lot] frequently arrest people for illegal possession and/or illegal distribution of controlled substances who have obtained the controlled substances from American Pain;
>
> American Pain hired individuals to "roam" the parking lot of the clinic to dissuade people from selling their recently obtained controlled substances on the property;
>
> [The reason American Pain placed] signs within American Pain warning individuals not to have their prescriptions filled at Walgreens pharmacies [is] because Walgreens refuses to dispense the prescriptions;
>
> Walgreens has flagged all American Pain doctors and will not fill any of their prescriptions;
>
> [Physical exams at American Pain are] usually no more than a blood pressure check and some bending and stretching;
>
> Dismissed patients would be routed to other doctors within the clinic;
>
> [There was] co-mingling of [American Pain] physician's drugs;
>
> [American Pain maintained] no inventories of drugs dispensed;
>
> [Details surrounding] the death of [American Pain] patient OB [where] [t]he cause of death was determined to be drug intoxication—opiate and benzodiazepine;
>
> [Information] from a confidential source [who indicated] that she traveled to American Pain in order to obtain controlled substances that were later sold in Kentucky for $25 per pill[,] [that] [the American Pain physician she encountered] did not spend any significant time conducting a physical examination of [her] [,] [that she would simply ask questions regarding [her] well being and would then "stamp" a prescription for [controlled substances][,] * * * that on one visit [during a power failure a] security guard working for the clinic instructed everyone to be patient and that the doctors would be with them shortly to "get your fix."

ALJ Ex. 6 at 3–9.

To be clear, it is not that the evidence was introduced and discredited; no evidence to support these (and other) allegations was introduced at all. To the extent the Government had this evidence, it left it home. While the stunning disparity between the allegations proffered and those that were supported with any evidence does not raise due process concerns, it is worthy of noting, without deciding the issue, that Agency precedent has acknowledged the Supreme Court's recognition of the applicability of the *res judicata* doctrine in DEA administrative proceedings. *Christopher Henry Lister, P.A.,* 75 FR 28068, 28069 (2010) (citing *Univ. of Tenn.* v. *Elliot,* 478 U.S. 788, 797–98 (1986) ("When an administrative agency is acting in a judicial capacity and resolves disputed issues of fact properly before it which the parties have had an adequate opportunity to litigate, the courts have not hesitated to apply *res judicata*[.]")

The evidence the Government did present raises issues regarding not only Factor 2 (experience dispensing [58] controlled substances), but also Factors 4 (compliance with federal and state law relating to controlled substances) and 5 (other conduct which may threaten public health and safety). Succinctly put, the Government's evidence related to the manner in which the Respondent practiced, and whether his practice complied with the law and/or was a threat to the public.

[58] The statutory definition of the term "dispense" includes the prescribing and administering of controlled substances. 21 U.S.C. 802(10).

While true that GS Langston convincingly testified about the course of her investigation and laid an adequate foundation for numerous database results, the Government provided no foundational context for any relevant uses for those database results. Even apart from the unfortunate reality that one of the databases contained data that could not be directly tied to this Respondent as opposed to another with the same last name, without some insight into what types of results from these databases should be expected when compared to similarly-situated registrants engaged in acceptable prescribing practices, the raw data is without use. In short, there was no evidence elicited wherein the percentage of the Respondent's in-state to out-of state patients could be assessed, and no reasonable measuring stick based on sound principles upon which to evaluate such data. Likewise, there was no reliable yardstick upon which to measure the amount of controlled substances reflected in the databases compared to what a reasonable regulator would expect to see regarding a compliant registrant. To the extent Langston possessed this information (and she well may have) it was not elicited from her. The same could be said of the allegation set forth in the Government's Prehearing Statement that alleges that from a given period the Respondent "was the 20th largest practitioner purchaser of oxycodone in the United States." [59] No evidence to support that allegation (or its relevance) was ever brought forth at the hearing. To the extent that fact may have been true or relevant, it was never developed. What's more, the Florida Administrative Code specifically eschews pain medication prescribing analysis rooted only in evaluation of medication quantity. Fla. Admin. Code r. 64B8–9.013(g). Lastly, there was no indication that despite Langston's obvious qualifications to do so, that she or anyone else ever conducted an audit of the controlled-substance-inventory-related recordkeeping practices at American Pain.

SA Burt testified that, during a temporally limited period of time, he observed some of the images captured by a pole camera positioned outside American Pain, and that he observed what in his view was a high percentage of vehicles in the parking lot with out-of-state license tags. This testimony arguably provides some support for the Government's contention that out-of-state patients (or at least patients being dropped off by cars with out-of-state tags) were being seen at the clinic, but his testimony did not provide much else in terms of relevant information. In any event, recent Agency precedent holds that details such as "where [a registrant's] patients were coming from," without additional factual development, can support a "strong suspicion that [a] respondent was not engaged in a legitimate medical practice" but that "under the substantial evidence test, the evidence must 'do more than create a suspicion of the existence of the fact to be established.'" *Alvin Darby, M.D.,* 75 FR 26993, 26999, n.31 (2010) (citing *NLRB* v. *Columbian Enameling & Stamping Co.,* 306 U.S. 292, 300 (1939).

Likewise, without additional details or at least some context, Burt's testimony that individuals with "staff" written on their shirts appeared to be directing patients into the clinic reveals virtually nothing about the Respondent's prescribing practices. Tr. at 818, 910. Furthermore, that Burt observed an individual on a videotape, who he believed to be an American Pain employee, on a single occasion, instruct patients not to "snort [their] pills" in the parking lot,[60] or advising them to comply with vehicle and traffic laws,[61] does not shed illumination on the Respondent's prescribing practices. There was no evidence that the Respondent knew that these isolated incidents occurred, nor was there contextual evidence from which the relevance to these proceedings could be gleaned. Even if this tribunal was inclined to engage in the unsupported assignment of motives to the actions of these employees, under these circumstances, such an exercise could not constitute substantial evidence that could be sustained at any level of appeal.

Burt's testimony regarding his conversations with Dr. Sollie, who was formerly employed by American Pain, was also not received in a manner that could meaningfully assist in the decision process. According to Burt, Sollie told him that some (unnamed) physicians at American Pain were inadequately documenting their patient charts in some manner that was apparently never explained to Burt,[62] and that some patients were intentionally evading the American Pain urinalysis process. Sollie did not specifically name the Respondent or any physician as being connected with his allegations of misconduct. Tr. at 853. Thus, this tribunal is at something of a loss as to how the information, as presented, would tend to establish a fact relevant to whether the continuation of the Respondent's authorization to handle controlled substances is in the public interest.

The Government's evidence targeted not only the Respondent's experience practicing under Factor 2, but also his compliance with applicable state and federal laws relating to controlled substances under Factor 4. To effectuate the dual goals of conquering drug abuse and controlling both legitimate and illegitimate traffic in controlled substances, "Congress devised a closed regulatory system making it unlawful to manufacture, distribute, dispense, or possess any controlled substance except in a manner authorized by the CSA." *Gonzales* v. *Raich,* 545 U.S. 1, 13 (2005). Consistent with the maintenance of that closed regulatory system, subject to limited exceptions not relevant here, a controlled substance may only be dispensed upon a prescription issued by a practitioner, and such a prescription is unlawful unless it is "issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice." 21 U.S.C. 829; 21 CFR 1306.04(a). Furthermore, "an order purporting to be a prescription issued not in the usual course of professional treatment * * * is not a prescription within the meaning and intent of [21 U.S.C. 829] and the person knowingly * * * issuing it, shall be subject to the penalties provided for violations of the provisions of law related to controlled substances." *Id.*

A registered practitioner is authorized to dispense,[63] which the CSA defines as "to deliver a controlled substance to an ultimate user [64] * * * by, or pursuant to the lawful order of a practitioner." 21 U.S.C. 802(10); *see also Rose Mary Jacinta Lewis,* 72 FR 4035, 4040 (2007). The prescription requirement is designed to ensure that controlled substances are used under the supervision of a doctor, as a bulwark against the risk of addiction and recreational abuse. *Aycock,* 74 FR at 17541 (citing *Gonzales* v. *Oregon,* 546 U.S. 243, 274 (2006); *United States* v. *Moore,* 423 U.S. 122, 135, 142–43 (1975) (noting that evidence established that a physician exceeded the bounds of professional practice when he gave inadequate examinations or none at all, ignored the results of the tests he did

[59] ALJ Ex. 6 at 11–12.

[60] Tr. at 825.

[61] Tr. at 826.

[62] Tr. at 898.

[63] 21 U.S.C. 823(f).

[64] "Ultimate user" is defined as "a person who has lawfully obtained, and who possesses, a controlled substance for his own use or for the use of a member of his household or for an animal owned by him or by a member of his household." 21 U.S.C. 802(27).

make, and took no precautions against misuse and diversion)). The prescription requirement likewise stands as a proscription against doctors "peddling to patients who crave the drugs for those prohibited uses." *Id.* The courts have sustained criminal convictions based on the issuing of illegitimate prescriptions where physicians conducted no physical examinations or sham physical examinations. *United States* v. *Alerre,* 430 F.3d 681, 690–91 (4th Cir. 2005), *cert. denied,* 574 U.S. 1113 (2006); *United States* v. *Norris,* 780 F.2d 1207, 1209 (5th Cir. 1986).

While true that the CSA authorizes the "regulat[ion] of medical practice so far as it bars doctors from using their prescription-writing powers as a means to engage in illicit drug dealing and trafficking as conventionally understood," *Gonzales,* 546 U.S. at 266–67, an evaluation of cognizant state standards is essential. *Joseph Gaudio, M.D.,* 74 FR 10083, 10090 (2009); *Kamir Garces-Mejias, M.D.,* 72 FR 54931, 54935 (2007); *United Prescription Servs., Inc.,* 72 FR 50397, 50407 (2007). In this adjudication, the evaluation of the Respondent's prescribing practices must be consistent with the CSA's recognition of state regulation of the medical profession and its bar on physicians from peddling to patients who crave drugs for prohibited uses. The analysis must be "tethered securely" to state law and federal regulations in application of the public interest factors, and may not be based on a mere disagreement between experts as to the most efficacious way to prescribe controlled substances to treat chronic pain sufferers. *Volkman* v. *DEA,* 567 F.3d 215, 223 (6th Cir. 2009) (citing *Gonzales,* 546 U.S. at 272, 274).

Under the CSA, it is fundamental that a practitioner must establish a bonafide doctor-patient relationship in order to act "in the usual course of * * * professional practice" and to issue a prescription for a legitimate medical purpose." *Stodola,* 74 FR at 20731; *Shyngle,* 74 FR at 6057–58 (citing *Moore,* 423 U.S. at 141–43). The CSA looks to state law to determine whether a bonafide doctor-patient relationship existed. *Stodola,* 74 FR at 20731; *Shyngle,* 74 FR at 6058; *Garces-Mejias,* 72 FR at 54935; *United Prescription Servs.,* 72 FR at 50407. It was Dr. Kennedy's uncontroverted opinion that his evaluation of chart entries convinced him that they were so defective that the Respondent did not establish a sufficient doctor-patient relationship to justify the prescribing of controlled substances, and that "this was not the practice of medicine in [his] opinion." Tr. at 160–61.

Under Florida law, grounds for disciplinary action or denial of state licensure include "prescribing * * * any controlled substance, other than in the course of the physician's professional practice," and prescribing such substances "inappropriately or in excessive or inappropriate quantities is not in the best interest of the patient and is not in the course of the physician's professional practice, without regard to his or her intent." Fla. Stat. § 458.331(q) (2009). Florida law further provides that grounds for such disciplinary action also include:

> Failing to keep legible, as defined by department rule in consultation with the board, medical records that identify the licensed physician * * * and that justify the course of treatment of the patient, including, but not limited to, patient histories; examination results; test results; records of drugs prescribed, dispensed, or administered; and reports of consultations and hospitalizations.

Id. § 458.331(m).

In exercising its rulemaking function,[65] the Florida Board of Medicine (Florida Board) promulgated a regulation addressing "Standards for Adequacy of Medical Records" applicable to all physicians. Fla. Admin. Code r. 64B8–9.003 (2009). That regulation provides, in pertinent part:

> (2) A licensed physician shall maintain patient medical records in English, in a legible manner and with sufficient detail to clearly demonstrate why the course of treatment was undertaken.
>
> (3) The medical record shall contain sufficient information to identify the patient, support the diagnosis, justify the treatment and document the course and results of treatment accurately, by including, at a minimum, patient histories; examination results; test results; records of drugs prescribed, dispensed or administered; reports of consultations and hospitalizations; and copies of records or reports or other documentation obtained from other health care practitioners at the request of the physician and relied upon by the physician in determining the appropriate treatment of the patient.
>
> (4) All entries made into the medical records shall be accurately dated and timed. Late entries are permitted, but must be clearly and accurately noted as late entries and dated and timed accurately when they are entered in to the record * * *.

Fla. Admin. Code r. 64B8–9.003 (2009).

With respect to defining the parameters of what constitutes "professional practice" in the context of pain management prescribing, Florida state law provides:

> Notwithstanding any other provision of law, a physician may prescribe or administer any controlled substance under Schedules II–V * * * to a person for the treatment of intractable pain,[66] provided the physician does so in accordance with that level of care, skill, and treatment recognized by a reasonably prudent physician under similar conditions and circumstances.

Fla. Stat. § 458.326 (2009). Moreover, the Florida Board has adopted,[67] albeit in modified version, the *Model Policy for the Use of Controlled Substances for the Treatment of Pain* (*Model Policy*), a document drafted by the Federation of State Medical Boards (FSMB) to provide professional guidelines for the treatment of pain with controlled substances. The standards adopted by Florida share the key tenants of the *Model Policy's* standards for pain management prescribing, including the emphasis on diligent efforts by physicians to prevent drug diversion, prescribing based on clear documentation of unrelieved pain and thorough medical records, and compliance with applicable Federal and State law.

Like the *Model Policy,* which was promulgated "to encourage the legitimate medical uses of controlled substances for the treatment of pain while stressing the need to safeguard against abuse and diversion," Florida's regulation providing "Standards for the Use of Controlled Substances for Treatment of Pain," Fla. Admin. Code r. 64B8–9.013 (2009) (Florida Standards), recognizes that "inappropriate prescribing of controlled substances * * * may lead to drug diversion and abuse by individuals who seek them for other than legitimate medical use." The language employed by the regulation under the preamble section titled "Pain Management Principles" makes clear that the standards "are not intended to define *complete or best practice,* but rather to communicate what the [Florida Board] considers to be *within the boundaries of professional practice*" (emphasis supplied), *id.* at 9.013(1)(g); thus, the plain text supports an inference that the standards provide the minimum requirements for establishing conduct that comports with the professional practice of controlled substance-based pain management

[65] Rulemaking authority regarding the practice of medicine within the State of Florida has been delegated to the Florida Board of Medicine (Florida Board). Fla. Stat. § 458.309(1) (2009).

[66] Florida defines "intractable pain" to mean "pain for which, in the generally accepted course of medical practice, the cause cannot be removed and otherwise treated." Fla. Stat. § 458.326 (2009).

[67] Pursuant to authority vested in the Florida Board by the Florida legislature to promulgate rules regarding State standards for pain management clinical practice specifically. Fla. Stat. § 458.309(5) (2009).

within the state. Likewise, the level of integral range of acceptable practice that is built into the regulation underscores the importance of seeking an expert professional opinion in reaching a correct adjudication of whether a registrant has met the applicable Florida standard. It is clear that in assessing whether the controlled substance prescribing practices of a Florida practitioner fall within the acceptable range of what constitutes being within the bounds of being "issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice," [68] resort must be had to an expert.

The Florida Standards direct that "[p]hysicians should be diligent in preventing the diversion of drugs for illegitimate purposes," *id.* at 9.013(1)(d), and provide that the prescribing of controlled substances for pain will be considered

> to be for a legitimate medical purpose if based on accepted scientific knowledge of the treatment of pain or if based on sound clinical grounds. All such prescribing must be based on *clear documentation* of unrelieved pain and in compliance with applicable state or federal law.

Id. at 9.013(1)(e) (emphasis supplied).

The Florida Standards further provide that the validity of prescribing will be judged "based on the physician's treatment of the patient and *on available documentation,* rather than on the quantity and chronicity of prescribing" (emphasis supplied). *Id.* at 9.013(1)(g). Furthermore, the Standards advise that physicians should not fear disciplinary action for "prescribing controlled substances * * * for a legitimate medical purpose and that is supported by *appropriate documentation* establishing a valid medical need and treatment plan" (emphasis supplied), or "for failing to adhere strictly to the provisions of these standards, *if good cause is shown for such deviation*" (emphasis supplied). *Id.* at 9.013(1)(b),(f).

Although, as discussed above, the Florida Board instituted general guidance applicable to all physicians regarding medical records, it also promulgated a separate set of documentation requirements in the Florida Standards applicable specifically to those physicians who prescribe controlled substances in the pain-management context. The Florida Standards, under the subheading "Medical Records," state that "[t]he physician is required to keep *accurate and complete records*" (emphasis supplied) including, though not limited to:

1. The medical history and physical examination, including history of drug abuse or dependence, as appropriate;
2. Diagnostic, therapeutic, and laboratory results;
3. Evaluations and consultations;
4. Treatment objectives;
5. Discussion of risks and benefits;
6. Treatments;
7. Medications (including date, type, dosage, and quantity prescribed);
8. Instructions and agreements; and
9. Periodic reviews.

Id. at 9.013(3)(f). The same section directs that "[r]ecords must remain current and be maintained in an acceptable manner and readily available for review. *Id.*

The Florida Standards similarly emphasize the need for proper documentation in the patient evaluation context by specifying:

> A complete [69] medical history and physical examination must be conducted and documented in the medical record. The medical record should document the nature and intensity of the pain, current and past treatments for pain, underlying or coexisting diseases or conditions, the effect of the pain on physical and psychological function, and history of substance abuse. The medical record also should document the presence of one or more recognized medical indications for the use of a controlled substance.

Id. at 9.013(3)(a).

Furthermore, the Florida Standards require a written treatment plan that "should state objectives that will be used to determine treatment success, such as pain relief and improved physical and psychosocial function, and should indicate if any further diagnostic evaluations or other treatments are planned." *Id.* at 9.013(3)(b). Subsequent to the initiation of treatment, "the physician should *adjust* drug therapy to the individual medical needs of each patient. Other treatment modalities or a rehabilitation program may be necessary depending on the etiology of the pain and the extent to which the pain is associated with physical and psychosocial impairment." (emphasis supplied). *Id.*

Another standard adopted by the Florida Board, under the subheading "Informed Consent and Agreement for Treatment," is the directive that

> [t]he physician should discuss the risks and benefits of the use of controlled substances with the patient, persons designated by the patient, or with the patient's surrogate or guardian if the patient is incompetent. The patient should receive prescriptions from one physician and one pharmacy where possible. If the patient is determined to be at high risk for medication abuse or have a history of substance abuse, the physician should employ the use of a written agreement between the physician and patient outlining patient responsibilities, including, but not limited to:
>
> 1. Urine/serum medication levels screening when requested;
> 2. Number and frequency of all prescription refills; and
> 3. Reasons for which drug therapy may be discontinued (i.e., violation of agreement).

Id. at 9.003(3)(c).

The Florida Standards contain a further requirement to periodically review "the course of pain treatment and any new information about the etiology of the pain or the patient's state of health." *Id.* at 9.013(3)(d). The Florida Standards explain the importance of periodic review in the following manner:

> Continuation or modification of therapy depends on the physician's evaluation of the patient's progress. If treatment goals are not being achieved, despite medication *adjustments,* the physician should reevaluate the appropriateness of continued treatment. The physician should monitor patient compliance in medication usage and related treatment plans.

Id.

Under the subheading "Consultation," the Florida Board promulgated the instruction that

> [t]he physician should be willing to refer the patient as necessary for additional evaluation and treatment in order to achieve treatment objectives. Special attention should be given to those pain patients who are at risk for misusing their medications and those whose living arrangements pose a risk for medication misuse or diversion. The management of pain in patients with a history of substance abuse or with a comorbid psychiatric disorder requires extra care, monitoring, and documentation, and may require consultation with or referral to an expert in the management of such patients.

Id. at 9.003(3)(e).

It is abundantly clear from the plain language of the Florida Standards that the Florida Board places critical emphasis on physician implementation of adequate safeguards in their practice to minimize diversion and the need to document the objective signs and rationale employed in the course of pain treatment utilizing the prescription of controlled substances. Conscientious documentation is repeatedly emphasized as not just a ministerial act, but a key treatment tool and a vital indicator to evaluate whether the

[68] 21 CFR 1306.04(a).

[69] The original *Model Policy* version of the guidelines does not contain a reference to the need for a complete medical history, instead only requiring a medical history generally. Thus, the Florida Board has adopted a higher standard than the measure that has been set in the *Model Policy* by the FSMB.

physician's prescribing practices are "within the usual course of professional practice." Here, the uncontroverted expert opinion of Dr. Kennedy, the only expert opinion presented [70] in these proceedings, reflects that the documentation he reviewed in the Respondent's patient charts reflected care that was markedly below the standard of care set by the Florida Medical Board. Dr. Kennedy's expert assessment was consistent with the state statutory and regulatory guidance. In Kennedy's view, the Respondent's charts demonstrated minimalistic, incomplete, and otherwise medically inadequate documentation of his contacts with his patients, and the prescribing rationale for his issuance of controlled substance prescriptions to those patients for alleged pain management purposes. The boilerplate-style, "one high-dosage controlled substances treatment plan fits all" nature of nearly all of the patient medical records at issue, at least in the view of the uncontroverted expert, evidences a failure on the part of the Respondent to conduct his practice of medicine in a manner to minimize the potential of controlled substance abuse and diversion, and supports a conclusion that he failed to even substantially comply with the minimum obligations for professional practice imposed under the Florida Standards, and without "good cause [] shown for such deviation." *Id.* at 9.013(1)(f).

In his Post-Hearing Brief (Respondent's Brief), the Respondent's counsel has prepared and submitted a thoughtful and detailed review of one of the patient charts that was analyzed by Dr. Kennedy in his report. Respt's Br. at 22–26. While counsel argues that the patient chart entries were, at least by his interpretation of his client's obligations, satisfactory, the expert's opinion at the hearing remained unchanged. Even acknowledging, as this recommended decision does, that Dr. Kennedy's presentation was not without its deficiencies, its shortcomings do render it so fundamentally defective as to completely undermine his credibility and viability as within the scope of what a litigant may depend upon.[71] As recognized in the Respondent's Brief, "the [G]overnment, like any party in a contested hearing, is free to hire an expert to advocate its position." Respt's Br. at 12. Unfortunately, counsel's analysis of the patient chart prepared by the Respondent is the product of a lay evaluation of standards applicable to the nuanced and sophisticated science that is the practice of medicine. Where his opinion and that of the only accepted medical expert to provide an expert opinion conflict, his opinion cannot and will not be afforded controlling deference. Argument supplied by counsel (albeit a diligent and persuasive counsel) that the relevant standards were satisfactorily applied as evidenced by the protocols and procedures documented in the patient charts cannot supplant the unrefuted view of an accepted expert witness.

The Respondent, who was in a unique position to conclusively refute Dr. Kennedy's views and explain the format and nuances of the reviewed documentation, elected not to testify in this matter. At a DEA administrative hearing, it is permissible to draw an adverse inference from the silence of the Respondent, even in the face of a Fifth Amendment invocation. *Hoxie* v. *DEA,* 419 F.3d 477, 483 (6th Cir. 2005) (citing *United States* v. *Hale,* 422 U.S. 171, 176 (1975) ("silence gains more probative weight where it persists in the face of accusation, since it is assumed in such circumstances that the accused would be more likely than not to dispute an untrue accusation.")); *Joseph Baumstarck, M.D.,* 74 FR 17525, 17528, n.3 (2009) (citing *Ohio Adult Parole Auth.* v. *Woodward,* 523 U.S. 272, 286 (1998)). On the facts of this case, where the allegations are of a nature that a registrant would be more likely than not to dispute them if untrue, an adverse inference based on the Respondent's silence is appropriate. Where, as here, the Government, through its expert, has alleged that the Respondent's charts do not reflect genuine analysis, but rather (at least in its view and the opinion of its expert), a sort of sham-by-check-box form designed specifically to present a false impression of a compliant registrant, it is precisely the type of allegation that would naturally all but oblige a registrant to spring to offer a contradictory account. The Respondent's choice to remain silent in the face of such allegations, where he could have related his version of his practice as a registrant, adds at least some additional credence to the factual and analytical views of the Government's expert in this regard.

In the Social Security context, where an Administrative Law Judge has received Expert medical opinions on the issue of the claimant's ability to work and they are not repudiated in any respect by substantial evidence, an adverse decision should be set aside as based on "suspicion and speculation." *Miracle* v. *Celebrezze,* 351 F.2d 361, 378 (6th Cir. 1965); *see also Hall* v. *Celebrezze,* 314 F.2d 686, 689–90 (6th Cir. 1963); *cf. Harris* v. *Heckler,* 756 F.2d 431, 436 (6th Cir. 1985) (improper to reject uncontroverted evidence supporting complaints of pain simply because of claimant's demeanor at hearing). When an administrative tribunal elects to disregard the uncontradicted opinion of an expert, it runs the risk of improperly declaring itself as an interpreter of medical knowledge. *Ross* v. *Gardner,* 365 F.2d 554 (6th Cir. 1966). While in this case it is ironically true, much like in the Social Security context, that the opinion of a treating physician should be afforded greater weight than the opinion of an expert whose opinion is limited to a review of the patient file, *see Magallenes* v. *Bowen,* 881 F.2d 747, 751 (9th Cir. 1989), the treating-source Respondent in this case offered no evidence, not even his own opinion, regarding the treatment rendered. Thus, in this adjudication, the record contains no dispute between experts to be resolved; instead, there is but one, unrefuted, uncontroverted, credible expert opinion. To ignore that expert opinion on this record and replace it with the opinion of this tribunal, Respondent's counsel, or any other lay source would be a dangerous course and more importantly, a plainly erroneous one.

Accordingly, after carefully balancing the admitted evidence, the evidence establishes, by a preponderance, that the prescriptions the Respondent issued in Florida were not issued within "the usual course of [the Respondent's] professional practice." 21 CFR 1306.04(a). Consideration of the evidence under the second and fourth factors support the COR revocation sought by the Government in this case.

To the extent that the Respondent's prescribing practices fell below the requisite standard in Florida, that conduct also impacts upon the Fifth statutory factor. Under Factor 5, the

[70] Respondent, in his brief, correctly points out that (for reasons not readily apparent) the Government elicited no testimony from Dr. Kennedy regarding any patient treated by the Respondent. Respt's Br. at 10–11.

[71] Likewise, contrary to the position taken by the Respondent in his brief (Respt's Br. at 7), Dr. Kennedy's opinions are not invalidated by the size of the representative sample of files he reviewed or the manner in which they were selected. Firstly, SA Langston provided credible testimony regarding the selection process, which although admittedly not a paradigm of scientific sampling methodology, was likewise not designed to achieve a particular result. Secondly, contrary to the assertion in the Respondent's brief (Respt's Br. at 15), there is no baseline magic number of files or registrant actions that must be examined to support an expert opinion and ultimately an Agency determination as to whether a registrant has committed acts inconsistent with the public interest sufficient to merit adverse action relative to a DEA COR. *See Krishna-Iyer,* 74 FR at 464.

Deputy Administrator is authorized to consider "other conduct which may threaten the public health and safety." 21 U.S.C. 823(f)(5). Although this factor authorizes consideration of a somewhat broader range of conduct reaching beyond those activities typically associated with a registrant's practice, an adverse finding under this factor requires some showing that the relevant conduct actually constituted a threat to public safety. *See Holloway Distrib.,* 72 FR 42118, 42126 (2007).

The evidence establishes that the Respondent engaged in a course of practice wherein he prescribed controlled substances to patients irrespective of the patients' need for such medication and ignoring any and red flags that could or did indicate likely paths of diversion. The testimony of Dr. Kennedy, the DEA regulations, and the Florida Standards make clear that physicians prescribing controlled substances do so under an obligation to monitor the process to minimize the risk of diversion. The patient charts reflect that the Respondent, contrary to his obligations as a DEA registrant, did not follow up in the face of multiple red flags. The Respondent's disregard of his obligations as a DEA registrant and Federal and state laws related to controlled substances militate in favor of revocation.

By ignoring his responsibilities to monitor the controlled substance prescriptions he was authorizing to minimize diversion, and by participating in an insufficiently documented and thoughtful process for the issuance of potentially dangerous controlled substances, the Respondent created a significant potential conduit for the unchecked diversion of controlled substances. *See Holloway Distrib.,* 72 FR at 42124 (a policy of "see no evil, hear no evil" is fundamentally inconsistent with the obligations of a DEA registrant). Agency precedent has long recognized that "[l]egally, there is absolutely no difference between the sale of an illicit drug on the street and the illicit dispensing of a licit drug by means of a physician's prescription." *EZRX, LLC,* 69 FR 63178, 63181 (1988); *Floyd A. Santner, M.D.,* 55 FR 37581 (1988).

Agency precedent has consistently held that where, as here, the Government has met its burden to establish a prima facie case that a registrant has committed acts demonstrating that continued registration is inconsistent with the public interest, acceptance of responsibility is a condition precedent to continued registration. *Jeri Hassman, M.D.,* 75 FR 8194, 8236 (2010); *Medicine Shoppe,* 73 FR at 387. The record contains no evidence that the Respondent has either acknowledged or accepted responsibility for the misconduct at issue in these proceedings.

Recommendation

Based on the foregoing, the evidence supports a finding that the Government has established that the Respondent has committed acts that are inconsistent with the public interest. A balancing of the statutory public interest factors supports the revocation of the Respondent's Certificate of Registration and a denial of his application to renew. The Respondent has not accepted responsibility for his actions, expressed remorse for his conduct at any level, or presented evidence that could reasonably support a finding that the Deputy Administrator should continue to entrust him with a Certificate of Registration. Accordingly, the Respondent's Certificate of Registration should be revoked and any pending applications for renewal should be denied.

Dated: August 10, 2010.

John J. Mulrooney, II,
U.S. Administrative Law Judge.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 10–34]

Cynthia M. Cadet, M.D.; Decision and Order

On August 10, 2010, Administrative Law Judge (ALJ) John J. Mulrooney, II, issued the attached recommended decision.[1] The Respondent did not file exceptions to the decision.

Having reviewed the entire record including the ALJ's recommended decision, I have decided to adopt the ALJ's rulings, findings of fact,[2] conclusions of law,[3] and recommended Order.

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[1] All citations to the ALJ's Decision (ALJ) are to the slip opinion as issued on August 10, 2010, and not to the attached decision which has been reformatted.

[2] The ALJ found that there is "no evidence that the Respondent 'prescribe[d] and dispense[d] *inordinate* amounts of controlled substances." ALJ at 27. While there is no evidence as to the amounts Respondent may have dispensed directly, there is such evidence, which is unrefuted, with respect to her prescriptions. The Government's Expert specifically found that Respondent "prescribed very high initial and subsequent doses of oxycodone and Xanax to [R.A.] *excessively* and inappropriately without adequate medical justification." GX 55, at 9 (emphasis added). The Government's Expert further noted that "[t]he typical Xanax (alprazolam) starting dose is 0.25 to 0.5 mg. once to twice per day," yet Respondent prescribed "high dose[s] of Xanax" 2 mg. "once to three times per day to 12 of the 13 'patients' whose files [he] reviewed" without "consider[ing] many important factors that cause anxiety" and any "previous medical evaluation"; she also not refer these patients "to a mental health professional for evaluation." *Id.* at 10. The Expert thus concluded that "[t]he treatment was with a very high dose of the controlled substance Xanax" and "was clearly not within the boundaries of professional practice." *Id.* Finally, the Expert provided unrefuted evidence that Respondent prescribed "drug cocktails" of oxycodone and Xanax, which "were clearly not for any legitimate medical purpose." *Id.* at 13. I thus reject the ALJ's finding to the extent that it states that there was no evidence that Respondent prescribed inordinate amounts.

[3] I do not, however, adopt the ALJ's discussion of the standards applied by the Agency in assessing a practitioner's experience in dispensing controlled substances, which cites cases involving list chemical I distributors, a different category of registrant. *See* ALJ Dec. at 26–27. As the Agency has previously made clear, DEA can revoke based on a single act of intentional diversion and "evidence that a practitioner has treated thousands of patients" in circumstances that do not constitute diversion "does not negate a *prima facie* showing that the practitioner has committed acts inconsistent with the public interest." *Jayam Krishna-Iyer,* 74 FR 459, 463 (2009). *See also Dewey C. MacKay,* 75 FR49956, 49977 (2010); *Medicine Shoppe-Jonesborough,* 73 FR 364, 386 & n.56 (noting that pharmacy "had 17,000 patients," but that "[n]o amount of legitimate dispensings can render * * * flagrant violations [acts which are] 'consistent with the public interest' "), *aff'd, Medicine Shoppe-Jonesborough* v. *DEA,* 300 Fed. Appx. 409 (6th Cir. 2008). As I further explained, "[w]hile such evidence may be [entitled to] some weight in assessing whether a practitioner has credibly shown that [he] has reformed his practices," it is entitled to no weight where a practitioner fails to acknowledge her wrongdoing. *Krishna-Iyer,* 74 FR at 463.

In any event, Respondent offered no evidence on the issue of his experience in dispensing controlled substances and the ALJ's ultimate conclusion that Respondent violated the CSA's prescription requirement because she dispensed controlled substance prescriptions that were not "within 'the usual course of [her] professional practice,' " ALJ at 39 (quoting 21 CFR 1306.04(a)), and that "the evidence under the [experience] * * * factor[] support[s]" the revocation of her registration, is consistent with Agency precedent. *Id.* at 40.

With respect to factor five, "[s]uch other conduct which may threaten public health and safety," 21 U.S.C. 823(f)(5), the ALJ opined that "an adverse finding under this factor requires some showing that the relevant conduct *actually constituted* a threat to public safety." ALJ at 40 (emphasis added). Contrary to the ALJ's reasoning, Congress, by inserting the word "may" in factor five, clearly manifested its intent to grant the Agency authority to consider conduct which creates a probable or possible threat (and not only an actual) threat to public health and safety. *See Webster's Third New Int'l Dictionary* 1396 (1976) (defining "may" in relevant part as to "be in some degree likely to"); *see also The Random House Dictionary of the English Language* 1189 (1987) (defining "may" in relevant part as "used to express possibility"). While the ALJ misstated the applicable standard, his conclusion that Respondent repeatedly ignored "red flags" indicative of likely diversion and thus "created a significant potential conduit for the unchecked diversion of controlled substances" is clearly supported by substantial evidence and warrants an adverse finding under factor five. *Id.* at 41.

Order

Pursuant to the authority vested in me by 21 U.S.C. 823(f) and 824(a), as well as 21 CFR 0.100(b) and 0.104, I order that DEA Certificate of Registration, BC8112637, issued to Cynthia M. Cadet, M.D., be, and it hereby is revoked. I further order that any pending application of Cynthia M. Cadet, M.D., to renew or modify his registration, be, and it hereby is, denied.

This Order is effective immediately.

Dated: March 31, 2011.

Michele M. Leonhart,

Administrator.

Larry P. Cote, Esq., for the Government.

Glenn B. Kritzer, Esq., for the Respondent.

Recommended Rulings, Findings of Fact, Conclusions of Law, and Decision of the Administrative Law Judge

John J. Mulrooney, II, Administrative Law Judge. On February 25, 2010, the Deputy Administrator, Drug Enforcement Administration (DEA or Government), issued an Order to Show Cause and Immediate Suspension of Registration (OSC/ISO), immediately suspending the DEA Certificate of Registration (COR), Number BC8112637, of Cynthia M. Cadet, M.D. (Respondent), as a practitioner, pursuant to 21 U.S.C. 824(d), alleging that such registration constitutes an imminent danger to the public health and safety. The OSC/ISO also sought revocation of the Respondent's registration, pursuant to 21 U.S.C. 824(a)(4), and denial of any pending applications for renewal or modification of such registration, pursuant to 21 U.S.C. 823(f), alleging that the Respondent's continued registration is inconsistent with the public interest, as that term is used in 21 U.S.C. 823(f). On March 22, 2010, the Respondent timely requested a hearing, which, pursuant to a change of venue granted at her request, was conducted in Miami, Florida, on July 7, 2010 through July 9, 2010.[4] The immediate suspension of the Respondent's COR has remained in effect throughout these proceedings.

The issue ultimately to be adjudicated by the Deputy Administrator, with the assistance of this recommended decision, is whether the record as a whole establishes by substantial evidence that Respondent's registration with the DEA should be revoked as inconsistent with the public interest as that term is used in 21 U.S.C. §§ 823(f) and 824(a)(4). The Respondent's DEA practitioner registration expires by its terms on August 31, 2011.

After carefully considering the testimony elicited at the hearing, the admitted exhibits, the arguments of counsel, and the record as a whole, I have set forth my recommended findings of fact and conclusions below.

The Evidence

The OSC/ISO issued by the Government alleges that the Respondent, through the medical practice she had been participating in at American Pain, LLC (American Pain), has prescribed and dispensed inordinate amounts of controlled substances, primarily oxycodone,[5] under circumstances where she knew, or should have known, that the prescriptions were not dispensed for a legitimate medical purpose. ALJ Ex. 1. The OSC/ISO further charges that these prescriptions were issued outside the usual course of professional practice based on a variety of circumstances[6] surrounding the manner in which American Pain had been operated and the manner in which its physicians, including Respondent, engaged in the practice of medicine. *Id.* The Government also alleges that Respondent's former patients have apprised law enforcement personnel that "they were able to obtain prescriptions for controlled substances from [the Respondent] for other than a legitimate medical purpose and with little or no medical examination." *Id.* Lastly, as an additional ground for the OSC/ISO, the Government cites the death of one of Respondent's patients from an overdose of oxycodone and alprazolam[7] one day after obtaining prescriptions for those same controlled substances from a visit to the Respondent at American Pain, and notes that the investigation determined the deceased patient "frequently made trips from his home in Kentucky to Florida pain clinics with others for the purpose of acquiring controlled substances for other than a legitimate medical purpose." *Id.*

At the hearing, the Government presented the testimony of three witnesses, DEA Miami Field Division (MFD) Group Supervisor (GS) Susan Langston, DEA Special Agent (SA) Michael Burt, and L. Douglas Kennedy, M.D., D.A.B.P.M., Affiliate Clinical Assistant Professor at the University of Miami, Miller School of Medicine.

GS Langston testified that the investigation of the American Pain Clinic had its origins on November 30, 2009, during a routine inspection that she and a subordinate diversion investigator conducted at Appurtenance Biotechnology, LLC, a pharmacy doing business under the name Boca Drugs (Boca Drugs), and located a few blocks away from one of the former locations of American Pain. Tr. at 713, 717–20. According to Langston, an examination of the prescriptions seized from Boca Drugs revealed that the majority of those prescriptions were for oxycodone and alprazolam authorized over the signature of physicians associated with American Pain.[8] *Id.* at 721. Under Langston's supervision, DEA diversion investigators catalogued the prescriptions seized at Boca Drugs (Boca Drugs Prescription Log). Govt. Ex. 118. A review of the data relative to the Respondent on the Boca Drug Prescription Log reveals that from November 2, 2009 through November 25, 2009, 151 controlled substance prescriptions issued over the Respondent's signature, to seventy-eight patients, only seven of whom resided in Florida. The remainder of the patients had listed addresses in Kentucky, Tennessee, Ohio, Georgia, West Virginia, Indiana, and Missouri. The log also reflected that the Respondent wrote one non-controlled substance prescription to a patient for cyclobenzaprine, a muscle relaxant.

GS Langston also testified that, on March 3, 2010, a criminal search warrant was executed on the American Pain Clinic simultaneously with the OSC/ISO that initiated the present case.

The ALJ also opined that "[i]t is clear that in assessing whether the controlled substance prescribing practices of a Florida practitioner fall within the acceptable range of what constitutes being within the bounds of being 'issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice,' resort must be had to an expert." ALJ at 34 (quoting 21 CFR 1306.04(a)). While the ALJ properly noted the importance of expert testimony in this case, in which the Government primarily relied on a review of the medical charts, whether expert testimony is needed is necessarily dependent on the nature of the allegations and the other evidence in the case. Where, for example, the Government produces evidence of undercover visits showing that a physician knowingly engaged in outright drug deals, expert testimony adds little to the proof necessary to establish a violation of Federal law.

[4] Pursuant to an order issued on April 15, 2010, the hearing in this matter was consolidated with the cases of four other registrants who were working at the same clinic as the Respondent and who were also issued OSC/ISOs on February 25, 2010, alleging similar and related conduct.

[5] A schedule II controlled substance.

[6] The majority of which are supported by no evidence introduced by the Government during the course of these proceedings.

[7] A schedule IV controlled substance.

[8] Although GS Langston testified that DEA immediately suspended the COR that had been issued to Boca Drugs, Tr. at 715, and that a voluntary surrender by that registrant followed a day later, *id.* at 776, no evidence has been presented that would lend that fact any particular significance related to any issue that must or should be found regarding the disposition of the present case.

Tr. at 735. According to Langston, the items seized from American Pain included a sign that had been posted in what she believes to have served as the urinalysis waiting room. *Id.* at 735–37. The seized sign set forth the following guidance:

> Attention Patients
>
> Due to increased fraudulent prescriptions, [i]t's best if you fill your medication in Florida or your regular pharmacy. Don't go to a pharmacy in Ohio when you live in Kentucky and had the scripts written in Florida. The police will confiscate your scripts and hold them while they investigate. This will take up to 6 months. So only fill your meds in Florida or a pharmacy that you have been using for at least 3 months or more.

Govt. Ex. 119 at 1. This sign is attached, apparently by some sort of tape, to the top portion of two other signs, posted at the same location, the first of which reads:

> ATTENTION:
>
> *Patients*
>
> Please do *NOT* fill your prescriptions at any *WALGREENS PHARMACY*[9] or *OUTSIDE* the STATE OF FLORIDA.

Id. The final attachment to the composite sign bears the words "24 Hour Camera Surveillance."

Id. A photograph of the composite sign was admitted into evidence.

Langston also testified that while she was present in the American Pain offices, she noticed that each physician's desk was equipped with a group of stamps, each of which depicted a controlled substance medication with a corresponding medication usage instruction (sig). Tr. at 738–39. A photograph of one set of prescription script stamps was admitted as an exhibit.[10] Govt. Ex. 119 at 2.

GS Langston also testified that a great number of medical charts were seized from the American Pain offices, and that she and her staff selected a number of these files to be analyzed by a medical expert procured by the Government. Tr. at 762. According to GS Langston, after the execution of the warrant, the charts from the entire office were placed into piles in alphabetical order, and not separated by physician. Langston testified that she and three of her diversion investigators reviewed the seized files with a view towards choosing approximately fifteen files for each doctor with the aspirational criteria that each would reflect at least three to four visits by that doctor with a patient. Each investigator was empowered to place a chart on the selected pile, and when the target number (or about that number) was reached for each physician, the selection effort relative to that physician was deemed accomplished. *Id.* at 765. Langston credibly testified that there was no effort to specially select files under some prosecution-enhancement or "cherry picking" purpose. *Id.* at 768.

Langston also explained DEA's Automated Record Consolidated Ordering System (ARCOS)[11] and testified that she generated an ARCOS report relative to the Respondent's ordering of controlled substances from January 2009 through February 2010. Govt. Ex. 50.

In the same fashion, Langston explained the purposes of and circumstances behind the generation of State prescription monitoring reports (PMPs) relative to the Respondent maintained by West Virginia, Kentucky, and Ohio. Govt. Exs. 51–53. Review of the PMP report data reflects that during the time period of February 1, 2006 through February 11, 2010, pharmacies filled 166 controlled substance prescriptions issued over the Respondent's signature to fifty patients located in West Virginia, 124 similar prescriptions provided to fifty-one Kentucky-based patients were filled between January 1, 2009 and April 4, 2010, and fifty-five such prescriptions pertaining to twenty-eight patients located in Ohio were filled between April 1, 2008 and April 19, 2010. *Id.*

No evidence was introduced at the hearing that would provide any reliable level of context regarding the raw data set forth in the databases received into evidence at the Government's request. Other than the observations noted above, no witness who testified at the hearing ever explained the significance of the data set forth in any of these databases to any issue that must or should be considered in deciding the present case.

GS Langston provided evidence that was sufficiently detailed, consistent and plausible to be deemed credible in this recommended decision.

SA Michael Burt testified that he has been employed by DEA since March 2004 and has been stationed with the Miami Field Division (MFD) since September 2004. Tr. at 813–14. Burt testified that he is the lead case agent for DEA in the investigation of American Pain Clinic and has participated in the investigation since the latter part of 2008. According to Burt, American Pain, which was previously known by the name South Florida Pain, has conducted business at four different locations, and he surveilled the Boca Raton and Lake Worth locations both in person and by periodic live review of video captured via pole cameras[12] set up outside the clinic. *Id.* at 815–17. These pole cameras, which were in operation during a three week period from January to February 2010, were initially in operation on a 24 hour basis, but Burt testified that they were later activated only between the hours of 7:00 a.m. through 6:00 p.m. due to an observed lack of activity at the clinic outside of that time period. *Id.* at 820–21. The pole camera recordings were not offered into evidence at the hearing or made available to opposing counsel.

Based on these surveillance efforts, SA Burt testified concerning various activities he observed occurring outside the Boca and Lake Worth clinic locations, which were open to the public from 8 a.m. to 5 p.m. At the Boca location, Burt stated that on any given day, beginning at 7 a.m. in the morning, automobiles could be seen pulling into the parking lot and approximately twenty to thirty people were routinely lined up outside of the clinic waiting to gain admittance. Additionally, there was a steady stream of automobile and foot traffic in and out of the clinic throughout the day. *Id.* at 817, 821. Burt testified that in his estimation, approximately 80–90 percent of the automobiles had out-of-State tags, predominantly from Kentucky, Ohio, West Virginia and Tennessee. *Id.* at 817–18. Burt also observed security personnel with "staff" written on their shirts[13] riding around the exterior of the building in golf carts and who, in Burt's assessment, appeared to be directing patients into the American Pain facility. Burt indicated his surveillance of the

[9] Langston testified that she was unaware of the location of the closest Walgreens to American Pain's offices. Tr. at 779. No evidence was presented that would tend to establish that any Walgreens or any other pharmacy has taken a position regarding its willingness to fill prescriptions authorized by American Pain.

[10] Although GS Langston testified that she did not actually take the photographs taken during the search warrant execution at American Pain, she did provide sufficient, competent evidence to support the admission of the photographs that were ultimately received into evidence. Tr. at 737, 739–41.

[11] GS Langston explained that through the ARCOS system, "[d]rug manufacturers and distributors are required to report the sale of certain controlled substances to DEA," and the system "shows the history of a drug from the point of manufacture through the distribution chain to the retail dispensing level." Tr. at 685–86.

[12] SA Burt described the pole cameras as "covert cameras that are installed to observe the activity in the clinic." Tr. at 816. Burt testified that he was able to use a laptop to access the live video feed from the cameras after inputting a username and password. The camera video was also recorded to DVR. *Id.* at 821.

[13] Tr. at 910.

Lake Worth location yielded similar observations. *Id.* at 818.

Based on his review of some (but not all) [14] of the audio and video tapes made by agents and informers sent into the clinic by the Government at various times, SA Burt also testified about his understanding of the process by which patients obtained controlled substance prescriptions at American Pain. According to Burt, after entering the clinic, a patient would meet with the receptionist, who would determine if the patient had an MRI. If not, the receptionist would issue that individual an MRI prescription in exchange for a $50 cash payment, and the patient "would be directed to a place to obtain an MRI." *Id.* at 822. Burt testified that one such MRI location was Faye Imaging, which was a mobile MRI trailer located behind a gentlemen's club several miles away from American Pain. *Id.* at 822–23. The cost for the MRI was $250, and the patient could pay an additional fee "to have the MRI expedited and faxed over to American Pain." *Id.* at 823–24. Once the MRI was procured and faxed to American Pain, the patient would return to the clinic and be seen by a doctor. According to Burt, the clinic accepted what he referred to as "*predominantly* cash only" [15] for these office visits, and the six doctors at the clinic saw "anywhere from 200 upward to 375 patients a day" [16] in this manner.[17] *Id.* at 882–83 (emphasis supplied).

SA Burt also testified regarding his review of some [18] of the video and audio recordings made by an undercover agent (UC) who assumed the name Luis Lopez capturing activity inside of American Pain.[19] In those recordings, Burt observed who he believed to be an American Pain employee inside the facility standing up in a waiting room full of patients and directing them "not to have their prescriptions filled out of State, not to go out into the parking lot and snort their pills," and directing the patients to have their prescriptions filled "in house" (meaning at American Pain), at "a pharmacy they have in Orlando, Florida," or at "a pharmacy they have down the street," which, in Burt's view, was a reference to Boca Drugs. *Id.* at 825–26. Burt further testified that the purported employee on the recording told the patients to "obey all the traffic laws; do not give the police a reason to pull you over." *Id.* Although Burt testified as to the contents of these recordings, the physical recordings were not offered into evidence by the Government or made available to opposing counsel.

SA Burt also testified that he received information from Dr. Eddie Sollie, a former physician employed during the time period American Pain was doing business as South Florida Pain, who terminated his employment at the Oakland Park clinic location in November or December 2008 after working there for approximately two and a half to three months.[20] *Id.* at 827, 898. During the course of an interview where Burt was present, Dr. Sollie related various "concerns about how the practice was being handled or managed." *Id.* at 827–28. These concerns included medical records being, in his opinion, annotated inadequately by the doctors, and what he perceived as a lack of supervision during patient urinalysis testing, where patients would "go[] to the bathrooms together, bringing items with them to the bathrooms that could possibly disguise the urinalysis." According to Burt, Sollie explained that he perceived that patients were substituting urine produced by other persons that contained the metabolites for controlled substances that the patients claimed to be legitimately taking, with a view towards falsely providing evidence to the American Pain doctors showing that they were actually taking prescribed medications and not diverting them. *Id.* at 828–29. During cross-examination, Burt explained that Dr. Sollie told him he had raised these concerns with Christopher George, the owner of American Pain, and that Burt had no evidence that the deficient practices that Sollie had objected to continued through 2010. *Id.* at 900, 906. Burt also acknowledged that he was aware Dr. Sollie had been involved in litigation with Mr. George and that their relationship was strained. *Id.* at 1009. Dr. Sollie was not called as a witness by either party.

The Government also presented evidence through the testimony of SA Burt regarding the drug overdose deaths of TY and SM after obtaining controlled substances from American Pain.[21] Burt's record testimony indicates that DEA Task Force Officer [22] (TFO) Barry Adams informed him that a Kentucky resident named TY overdosed in Kentucky from oxycodone intoxication induced by medication procured at American Pain. Burt testified that this information was furnished pursuant to a working law enforcement relationship between the Kentucky State Police, Kentucky FBI, Kentucky DEA and Miami DEA aimed at addressing "the brunt of the pill problem" centered within the State of Kentucky relative to illegal use and resale of prescription pain medications. *Id.* at 833–35. However, in his testimony, Burt was unable to recall the name of the doctor from whom TY obtained his pills, and, thus, no admissible evidence was presented by the Government with respect to TY's death.[23]

SA Burt also testified that TFO Adams notified him about the overdose death of SM, whose body was found at his Kentucky home. *Id.* at 854; Govt. Ex. 54 at 1. SM's death occurred on January 1, 2009, the day after his first and only appointment with the Respondent. Govt. Ex. 69. Pursuant to Burt's request, Adams provided him with a packet of various documents pertaining to SM's death, including a narrative police report, medical examiner's report and toxicology report, which were admitted into evidence. Govt. Ex. 54. Respondent, through counsel, introduced a more complete version of the report, obtained directly from the Rockcastle County Sherriff's Office (RCSO), which was also admitted into evidence (RCSO Investigation).[24] Resp. Ex. 1.

[14] SA Burt conceded that although he is the designated lead case agent for DEA, he did not review all the audio and video tapes made in the case or even review the transcripts. Tr. at 1002–05.

[15] Later on cross-examination, SA Burt admitted that the clinic also accepted payment via credit card. Tr. at 916.

[16] Inasmuch as the Government provided no information from which any specific number of patients seen by any given clinic doctor on any day could be derived, or any expert testimony regarding a reasonable number of pain patients that could or should be seen per day, the value of providing the raw number of patients walking through the door at the clinic is negligible.

[17] Burt further testified that the doctors were paid $75.00 per patient visit, *id.* at 884, but because he indicated that he could not disclose his basis of knowledge for this information, this portion of his testimony can be afforded no weight. *See Richardson* v. *Perales,* 402 U.S. 389, 402 (1971); *J.A.M. Builders* v. *Herman,* 233 F.3d 1350, 1354 (11th Cir. 2000); *Keller* v. *Sullivan,* 928 F.2d 227, 230 (7th Cir. 1991); *Calhoun* v. *Bailar,* 626 F.2d 145, 149 (9th Cir. 1980).

[18] Tr. at 1002–05.

[19] The fact that these recordings were made during the course of seven different office visits by an undercover agent to both the Boca Raton and Lake Worth locations was established on cross-examination. Tr. at 900, 985.

[20] On cross-examination, Burt admitted the Respondent never worked at the South Florida Pain Clinic in Oakland Park, the facility where Sollie had previously been employed. *Id.* at 1027.

[21] Although similar testimony concerning the overdose death of a third individual, OB, was noticed in the Government's prehearing statement, it was not offered by the Government at the hearing. ALJ Ex. 6 at 8.

[22] According to SA Burt, a "task force officer" is a local police officer or sheriff's deputy that is assigned to work on a DEA task force, rather than a sworn DEA criminal investigator. Tr. at 1031.

[23] *See* Tr. at 836–53 (addressing exclusion of Govt. Ex. 27 and associated testimony).

[24] Although SA Burt testified that he requested "the complete report" and "all the documents" relating to SM's death from TFO Adams, *id.* at 860,

Continued

The certificate of death contained in the RCSO Investigation reflects the coroner's finding of "acute Oxycodone and Alprazolam intoxication" as SM's cause of death. Govt. Ex. 54 at 2; Respt. Ex. 1 at 7–8. The RCSO Investigation includes a narrative report, which states that the responding police officer reporting the incident procured various statements and paperwork from the decedent's parents indicating he "had been going to a pain clinic in Ft. Lauderdale, FL [t]o receive pain medication," copied said documents, and placed them in his case file. *Id.* at 1. Record evidence of these copied materials, absent from the Government's exhibit submission or Burt's testimonial presentation, includes an American Pain business card listing "1/28" under the heading "next appointment," and several prescription data printouts reflecting that on December 31, 2008, a prescription for oxycodone issued to SM by the Respondent was filled at Speedy Scripts Pharmacy in Fort Lauderdale. Respt. Ex. 1 at 21. The Respondent's patient chart pertaining to SM reflects that on the date of their first and only encounter, she issued prescriptions for oxycodone (15 mg), Roxicodone (30 mg), and Xanax (2 mg). Govt. Ex. 69 at 16. This is consistent with patient receipts provided to RCSO personnel by SM's mother. Respt. Ex. 1 at 17–22.

Also absent from the Government's version of the RCSO Investigation is that several prescription vials were found on SM's body at the time of his death. One empty prescription vial indicates that it had once contained forty-five hydrocodone pills filled on December 2, 2008 (twenty-eight days prior to his death and twenty-seven days prior to his first and only appointment with the Respondent), another empty hydrocodone vial indicates that it was filled on November 21, 2008 (forty-one days prior to his death and forty days prior to his first and only appointment with the Respondent), and a third vial of tizanidine (a non-controlled substance) was filled on November 19, 2008 (forty-three days prior to his death and forty-two days prior to his first and only appointment with the Respondent). Also found on the Respondent was a vial with what appeared to be marijuana seeds, baggies and a scale of a type that is commonly used in connection with drug paraphernalia. Respt. Ex. 1 at 4.

Statements of interviews contained in the RCSO Investigation reflect that SM's friends and family were aware that he had a pain-killer addiction that had its origins in the treatment of pain symptoms from an automobile accident and that he abused marijuana. *Id.* at 5, 25, 26. Witness statements also reflect that SM was emotionally upset by a recent break up with a girlfriend. *Id.* at 4, 23–29.

Although the coroner unambiguously concluded that "[a]cute Oxycodone and Alprazolam intoxication" was the cause of death,[25] the autopsy also reflected evidence that SM had ingested other controlled substances, including marijuana and oxymorphone. *Id.* at 8; Govt. Ex. 54 at 4–7; Tr. at 1033–38.

When viewed in its entirety, SA Burt's record testimony was stunningly sparse when compared with his proposed testimony as noticed in the Government's prehearing statement.[26] Indeed, perhaps among the more striking aspects of SA Burt's performance on the witness stand is the anticipated testimony which he did not provide. That certain information may be unavailable for reasons related to other litigation forums or other equally valid reasons are of no moment with respect to the evaluation that must be made at this administrative forum. Equally important, such considerations do not alter the burdens imposed upon the respective parties. Simply put, the admitted evidence must succeed or fail on its own merits, irrespective of extraneous considerations.

Even apart from the marked contrast between the Burt testimony as proffered and as realized, his testimony was marred by periodic memory failures on significant issues and an inability to supply details to an extent that it could arguably have diminished the weight that could be fairly attached to those aspects of his own investigation that he did manage to recollect. During his testimony, SA Burt acknowledged his own marked lack of preparation and unfamiliarity with the investigation and confessed simply that "[t]here's no excuse * * *." *Id.* at 1003–05.

Even acknowledging its obvious suboptimal aspects, SA Burt's testimony had no apparent nefarious motivation or indicia of intentional deceit. Burt came across as an earnest and believable witness, who, regarding the aspects of the case that he did recall, was able to impart substantial information about the investigation and activities involving American Pain and its doctors. While frequently lacking in detail, his testimony was not internally inconsistent or facially implausible, and although the legal weight I have assigned to certain portions of Burt's testimony varies given the issues described, I find his testimony to be credible overall.

The Government presented the bulk of its case through the report and testimony of its expert, L. Douglas Kennedy, M.D., D.A.B.P.M., Affiliate Clinical Assistant Professor at the University of Miami, Miller School of Medicine.[27] Dr. Kennedy, who testified that he is board certified by the American Board of Pain Medicine and the American Board of Anesthesiology,[28] was offered and accepted as an expert in the field of pain medicine. Tr. at 39.

Dr. Kennedy testified that after a review of a group of selected patient files from those seized at the Respondent's practice that were to him provided by the Government, he concluded that the charts lacked the individualized treatment plans and the variety of diagnostic tools required to meet the minimally acceptable standards of practice in the State of Florida, that Respondent's prescribing practices and the documentation present in those patient files fell below the standards fixed by the Florida State Medical Board, and that the controlled substance prescriptions contained in those files were not issued for a legitimate medical purpose.[29] *Id.* at 384–90.

At the hearing, Dr. Kennedy explained that he took professional

it was clear that the Government's version omitted a discomforting number of pages that should have been included. Respt. Ex. 1; Tr. at 1041–43. The Government's version included a toxicology report that was not present in the Respondent's version. Govt. Ex. 54 at 4–7.

[25] Respt. Ex. 1 at 7; Govt. Ex. 54 at 2.

[26] ALJ Ex. 6.

[27] Dr. Kennedy's CV was admitted into evidence. Govt. Ex. 117.

[28] Tr. at 17.

[29] At the consolidated hearing in this matter, the Government elicited testimony from Dr. Kennedy regarding additional aspects of practice that he found deficient regarding the prescribing practices of other respondents. For example, Dr. Kennedy opined that the prescribing of 30 mg of oxycodone to an opioid naïve patient would, in his opinion, be dangerous and improper. Similarly, Dr. Kennedy provided his opinion that the practice of ordering of an MRI prior to a physician meeting with a patient would be improper. However, regarding the charts that Dr. Kennedy reviewed relative to this Respondent, the government adduced no testimonial evidence regarding issues such as opioid naïveté or the timing of MRI scripts, and it would be unfair, improper and illogical for an Administrative Law Judge to extrapolate the testimony elicited relative to the patients of other physician(s) to this Respondent. *See Gregg & Son Distribs.*, 74 FR 17517 n.1 (2009) (data should be provided while record is open, and "[t]o make clear, it is the Government's obligation as part of its burden of proof and not the ALJ's responsibility to sift through the records and highlight that information which is probative of the issues in the proceeding") citing *Southwood Pharms., Inc.*, 72 FR 36487, 36503 n.25 (2007). The absence of testimonial support by Dr. Kennedy on these issues relative to this Respondent does not adversely affect the weight to be attached to the conclusions set forth in the reports he prepared in connection with this Respondent which were received into evidence. Govt. Exs. 28, 131.

issue with several aspects of the Respondent's patient care as reflected in the charts regarding the prescribing of controlled substances. It is apparent from his testimony that Dr. Kennedy's analysis is restricted to those matters which can be gleaned from an examination of the written word in that subset of the Respondent's patient charts provided by the Government for his review, and that limitation perforce circumscribes the breadth of his testimony. That being said, Dr. Kennedy highlighted numerous features in the Respondent's chart documentation that he found wanting, or at least remarkable.

Dr. Kennedy explained that there are basic elements to practicing pain medicine. The acquisition of a thorough history and physical examination is important. *Id.* at 41–42. He also stressed the vital importance of obtaining past medical records to evaluate what treatments, therapies, medications, and dosages have been utilized in the past so that correct current treatment decisions can be made. *Id.* at 45–46. Reliance upon the patient's memory of these elements without the prior medical records, in Dr. Kennedy's view is not reliable or acceptable. *Id.* at 46–47. Dr. Kennedy acknowledged that physicians customarily accept patients at their word, but on the subject of verifying a patient's subjective complaint and medication history, Dr. Kennedy explained that

> [s]ometimes you have to help people understand why they're suffering or what their problems are. A person with an addiction or drug abuse problem is no worse a human being than me. I'm not any better than them. But it's your job as a doctor to sit down and find out what the truth is as well as you reasonably can under the circumstances.

Id. at 357.

In his testimony, Dr. Kennedy related that, in his expert opinion, although the information in the charts required a prudent physician to seek out prior medical records and/or input from prior medical providers, none of the Respondent's charts reflected any attempt to do so. *Id.* at 525, 527–28.

Kennedy also explained the importance of establishing a differential or working diagnosis on the first visit and modifying and reviewing that diagnosis as more information and results become available. *Id.* at 52. Similarly, a diagnostic plan is a systematic methodology of eliminating possible causes of symptoms to allow the treating physician to accurately determine what is causing them so that a successful treatment plan can be developed. *Id.* at 52–53. In other words, the diagnostic plan allows the treating doctor to eliminate or confirm items on the differential diagnosis. *Id.* at 54. In Kennedy's view, the Respondent's charts did not reflect an adequate, deliberative differential diagnosis process. *Id.* at 477–78. The ultimate diagnosis conclusion, at least in Kennedy's view, appears assumed by the Respondent without supporting analysis. *Id.* at 478.

In Kennedy's view, the treatment plans in the Respondent's chart were also infirm in that they were not sufficiently individualized. *Id.* at 386. Although, on cross examination, Kennedy conceded that at least one file recommended such things as yoga, stretching, vitamins and smoking cessation,[30] his testimony supported the conclusion that every examined chart treated the patient primarily with controlled substances. *Id.* at 386, 472. Kennedy observed that comparing the patient charts,

> basically it's the same. [The patients are] given high-dose oxycodone and two different strengths. The Roxicodone 15 milligrams is twice a day. The Roxicodone 30 looks like it's been given six times a day in one case and eight times a day in another. Xanax is given at 2 miligrams.

Id. at 482.

Although Dr. Kennedy conceded that it is the judgment of the examining physician that is generally relied upon in determining the necessity and appropriateness of diagnostic testing,[31] he also testified that the Respondent's practice of routinely ordering magnetic resonance imaging (MRI) procedures before a physician meets with the patients was inappropriate because an MRI is not always required and not always appropriate. *Id.* at 71–73, 153–54. In Kennedy's opinion, a physician has an obligation to meet with the patient before including this procedure as part of the utilized diagnostic tools. *Id.* Kennedy noted that the Respondent's files reflected evidence that MRIs were the predominant diagnostic tool and were ordered prior to the patient's first interaction with her at a clinic visit. *Id.* at 385.

While acknowledging that some standardization and utilization of forms is not, standing alone, improper,[32] Dr. Kennedy took issue with what he perceived as flaws in the forms utilized by the Respondent to document patient care. According to Dr. Kennedy, many of the forms used by the Respondent omitted too much. *Id.* at 472–73, 486. The error was not so much that every blank space was not filled in, but that "important areas" such as the pain scale were left blank. Tr. at 486.

Dr. Kennedy prepared two reports in connection with the Government's case against the Respondent, which are dated April 28 and April 30, 2010, respectively, and both of which were admitted into evidence. Govt. Exs. 55, 132; Tr. at 381–82. One of the reports describes a general analysis of thirteen charts that the Respondent maintained on as many patients, that were (selected by and) provided to Dr. Kennedy by the Government from among patient files seized pursuant to a criminal search warrant executed at the Respondent's practice on March 3, 2010 (Patient Charts Analysis). Govt. Ex. 55. Although this report purports to describe practices common to all thirteen files reviewed by Dr. Kennedy, much of the analysis is directed toward a chart prepared in connection with RA,[33] one of the Respondent's patients. A second report (Supplemental Chart Analysis) prepared by Dr. Kennedy focuses on the chart of SM, the Kentucky-resident patient of the Respondent described in the RCSO Investigation who died from an overdose of the same variety of medications prescribed by the Respondent on the day after his first appointment with her. Govt. Ex. 132; Resp. Ex. 1; Tr. at 854–57. The Supplemental Chart Analysis notes that patient SM was seen by the Respondent at American Pain on December 31, 2008 and indicates the presence of a note found in patient SM's file stating "Deceased 12/31/08/1–1–09 O.D." *Id.* at 2.

Many of the observations and conclusions contained within the two reports are remarkably similar. Dr. Kennedy's report makes it unambiguously clear that, at least in his opinion, all fourteen of the Respondent's charts that he reviewed suffered from the same shortcomings. The Patient Charts Analysis states that the Respondent's patient charts reviewed by Dr. Kennedy "are essentially the same with regard to review issues; as stated in the report of [RA] referenced and discussed in this report in detail, [and that] there were no significant differences that affected [his] conclusions and summary." Govt. Ex. 55 at 2. A like-worded proviso accompanies Dr. Kennedy's analysis of

[30] Tr. at 542–44.

[31] Tr. at 59.

[32] Tr. at 74.

[33] At the request of the Government, a protective order was issued that is designed to minimize the risk of the dissemination of identifying information related to patients and their relatives associated with this case. Accordingly, initials have been substituted for the names of individuals within the protection of the protective order throughout the body of this decision. ALJ Ex. 15.

SM's patient chart in the Supplemental Chart Analysis. Govt. Ex. 132 at 1. When, on cross examination, Kennedy was directed to differences in exact wording, patient statements regarding chief complaints and dosage variations between patients,[34] he explained that notwithstanding some variation between some details, his concern was that among all the files, at least in his view, "the process is the same." Tr. at 477.

It is interesting to note that the SM patient chart contains no indication that the Respondent made any efforts to contact any prior doctors, pharmacists or family members. Likewise, there is no indication that any effort was made to query Kentucky PMP databases. A check to any of these sources could have informed the Respondent that another physician had recently prescribed oxycodone and other medications to SM, that SM was, at least in the opinion of his family and friends, addicted to pain medicine and was abusing marijuana, and that SM was emotionally labile due to the recent estrangement he had with his girlfriend. Unfortunately, because the Respondent made no efforts to reach out for any of that information, she merely talked to SM, prescribed controlled substances, and SM perished by an overdose of the same variety of medication she prescribed.

In Dr. Kennedy's opinion, the patient charts he reviewed that were prepared by the Respondent reflected care that fell below the applicable standard on multiple levels. In his report, Dr. Kennedy noted that the treatment notes in the charts: (1) Contained no typewritten clinical notes and were "very brief, difficult to read (often impossible) and not within the standard of care due to their brevity and quality; [35]" (2) reflected prescriptions, right from the initial patient visit, that "were almost entirely for controlled substances, most often one or two immediate release oxycodone pills with Xanax," and which were, in Dr. Kennedy's view, inappropriate and more powerful than justified by the objective signs documented in the written notes; [36] (3) showed that "the same or very similar 'drug cocktails' were prescribed [among all patients in the reviewed files] in the same or very similar doses, [directions] * * * with a 30-day supply," and were affixed to the prescription scripts with a few prepared stamps utilized by all American Pain physicians that reflected "drug, dose, sig (directions) and quantity dispensed; [37]" (4) contained medication contracts that were "not always signed" and "listed criteria that was not followed by the doctors at American Pain; [38] (5) failed to document the efficacy of the prescribed medication; (6) did not set forth a "diagnostic plan, except to obtain an occasional MRI, the results of which made no difference in the 'treatment;' "[39] (7) reflected "no therapeutic plan, except to use controlled substances to 'treat' the subjective complaint of 'pain' which was inadequately described; [40] (8) did not reflect "real therapeutic goals * * * for improvement of quality of life (activities of daily living, work, sleep, mood);"[41] (9) did not reflect "consultations with other physicians or specialists outside the American Pain group [which] could have and in some cases should have included orthopedics, neurology, neurosurgery, psychiatry, addiction medicine and psychology;"[42] (10) reflected "a gross lack of past medical records in all charts reviewed and in some cases none at all; [43]" and, (11) demonstrated controlled substance patient monitoring practices that were "not within the standard of care and outside the boundaries of professional practice." [44]

Dr. Kennedy found the Respondent's controlled substance patient monitoring to be deficient in numerous respects. From the reviewed patient charts, Dr. Kennedy gleaned that an initial, in-office urine drug screen was frequently executed during the patients' initial visit to the office but repeated only occasionally. Govt. Ex. 55 at 14. It was Dr. Kennedy's observation that even a drug screen anomaly did not alter the seemingly inexorable continuation of controlled substance prescribing from the Respondent. *Id.* Dr. Kennedy also noted that the Respondent did not utilize out-of-office toxicology tests, or obtain out-of-State prescription monitoring program or outside pharmacy drug profiles. Furthermore, the charts contained only rare evidence of contact with primary care physicians, treating physicians, pharmacists, or other health care providers. *Id.*

The identified shortcomings of controlled substance patient monitoring systems was of particular significance where Dr. Kennedy identified specific evidence that he identified as "red flags" of possible or likely diversion. In addition to providing incomplete and/or inconsistent information on his patient questionnaires, SM's file reflected a positive urine screen test for the presence of benzodiazepines, opiates, and oxycodone, significant potential depression, and the failure to disclose information about his Kentucky-based primary care and orthopedics treating physicians, and his physical therapist. Govt. Exs. 69, 132 at 6. Other red flags noted by Dr. Kennedy in the reviewed charts included the relatively young age of the Respondent's chronic pain patients,[45] incomplete history information provided by the patients, periodically significant gaps between office visits,[46] referrals from friends, relatives, or advertising, but not other physicians,[47] and the fact that a relatively high number of patients were traveling significant distances to American Pain for pain treatment, although no physician employed at that facility had any specialized training in pain management.[48]

During the course of his testimony, Dr. Kennedy highlighted evidence in the chart of patient RA reflecting that although he disclosed to the Respondent that he was currently taking oxycodone and Xanax, and had last been prescribed a dosage that should have still been sufficient to supply him with medication on the day of his first office

[34] Tr. at 470–74.

[35] Govt. Ex. 55 at 4.

[36] Govt. Ex. 55 at 4. In Dr. Kennedy's opinion, the Respondent "prescribed, at the first visit, very high initial doses of controlled substance combinations despite not being within the standard of care for histories, physical examinations and/or absent past medical records [with] no apparent consideration given to patient safety with initial or subsequent prescription of controlled substance[s]." *Id.* at 7.

[37] Govt. Ex. 55 at 4.

[38] As an example of the failure to adhere to the terms of the medication contract, Dr. Kennedy cites a contract term that provides notice that the physician may stop prescribing opioids or change treatment if pain or activity improvement is not demonstrated, and points out that pain and activity levels are routinely not documented in treatment notes. Govt. Ex. 55 at 4. Similarly, Dr. Kennedy references a medication contract warning that termination of services may result from failure to make regular follow-up appointments with primary care physicians, and notes that the American Pain charts contain no notes from primary care physicians or medical records generated by them. *Id.*

[39] Govt. Ex. 55 at 7. In Dr. Kennedy's opinion, Respondent

in effect, acted as a 'barrier' for [RA] to receive appropriate medical evaluation and treatment. In other words, the very potent, high doses of opioids (oxycodone) and benzodiazepine (Xanax) could cover up [RA's] underlying disease process(s), making it more difficult to diagnose, and allowing the disease(s) to unnecessarily worsen. Without an accurate diagnosis, all [the Respondent] was doing was, again, masking or covering up the symptoms.

Id. at 10.

[40] Govt. Ex. 55 at 7.

[41] Govt. Ex. 55 at 8.

[42] Govt. Ex. 55 at 7.

[43] Govt. Ex. 55 at 15. The only past medical record contained in RA's chart was a report from an MRI conducted five months prior to the patient's initial clinic visit with the Respondent. *Id.* at 8.

[44] Govt. Ex. 55 at 14.

[45] Govt. Ex. 55 at 15.

[46] Govt. Ex. 55 at 13.

[47] Govt. Ex. 55 at 8, 15.

[48] Govt. Ex. 55 at 16.

visit, the urinalysis conducted on that day reflected negative results. Tr. at 548–56; Govt. Ex. 57 at 5, 7, 10, 26. Notwithstanding this obvious anomaly, the Respondent issued prescriptions for Roxicodone in 15 and 30 mg doses and Xanax in a 2 mg dose. Govt. Ex. 57 at 19. Furthermore, based on the disclosed prior prescription amount and date, the issuance of these new prescriptions was at an earlier time than the prior prescriptions should have run out. *Id.* at 552–55. RA's chart reflects no inquiry, analysis, or even notation of these clear red flags. *Id.* at 554–55. Failing to inquire about these issues, according to Dr. Kennedy, fell below the standard of care that the Respondent should have exercised. *Id.* at 555.

Similarly, Dr. Kennedy explained that regarding RR's patient chart, the paperwork generated at the time of the first visit with the Respondent reflected that he had been prescribed controlled substance medications that should have, but did not, yield positive urinalysis results. *Id.* at 556–60, 573–76; Govt. Ex. 63 at 8, 14, 17, 34. Additionally, the patient examination form filled out by the Respondent based on her interview with RR reflected a chief complaint that included radicular symptoms extending to both legs, but the patient-completed questionnaire reflected that he did not have those symptoms. Tr. at 560–62; Govt. Ex. 63 at 8, 17. The chart did not contain additional inquiry regarding why the controlled substances were apparently not being taken by the patient or why the patient may not have had the symptoms the controlled substances were being prescribed to ameliorate. Dr. Kennedy testified that these discrepancies should have, but did not result in additional due diligence on the part of the physician. Tr. at 560–62.

Although Dr. Kennedy agreed during cross examination that a possible explanation for a negative urinalysis could be that the medication was not taken within a few days of the urinalysis, *Id.* at 567, this inquiry misses the point. The question is not whether there could be a benign explanation from the patient, it is whether an explanation of any type was sought by the registrant. Here, the Respondent faced an obvious red flag of potential diversion and made no effort to resolve the conflict as best as can be divined from the patient file she kept. Dr. Kennedy reasonably characterized this type of discrepancy as "an inconsistency that should have been developed or should have been explored." *Id.* at 571. Dr. Kennedy offered the following explanation regarding the nature of the due diligence that such inconsistencies should engender on the part of a physician:

> The duty was to talk with the—the first thing you do is talk with the person, the individual, the patient, and find out if they have an explanation for that; was it a misunderstanding? Did they mean what they wrote down? And find out exactly what's going on and get their side, get their story, because your job is to advocate for them, and also, to help them from doing any harm to themselves.

Id. at 573.

In his report, Dr. Kennedy also found it remarkable that each American Pain patient file provided notice to its patients that American Pain did not accept any form of health care insurance. Govt. Ex. 55 at 3–4, 16. Dr. Kennedy's report set forth his opinion that this practice was designed to "effectively keep [the physicians at American Pain] 'off the radar' from monitoring by any private health care insurance company as well as all State and Federal agencies (Medicaid and Medicare respectively). Govt. Ex. 55 at 16. Significantly, however, when asked, Dr. Kennedy acknowledged that he conducts his own current medical practice on a cash-only basis. Tr. at 151.

Regarding the discomfiture that Dr. Kennedy expressed regarding non-physician referrals in his report, during his testimony at the hearing, he clarified that it was not unusual for a physician to treat patients that have been referred by relatives and friends. *Id.* at 154. Further, Kennedy conceded while in the course of his own medical practice he has treated patients referred by family and friends, and that in his report he was focusing on what he perceived as a lack of any referrals by physicians in the files he reviewed, or what he perceived as "trends" or "patterns." *Id.* at 154–55. Given Dr. Kennedy's acknowledgement that such referrals are not unusual, coupled with the absence of any way to measure the relative percentage of physician referrals in the Respondent's practice based on the record evidence, the observations regarding referral sources are of limited value here.[49]

Dr. Kennedy concluded his report regarding the Respondent's prescribing practices with the following summary:

> [The Respondent] was not engaged in the practice of medicine, rather [s]he was engaged in an efficient, "[a]ssembly [l]ine" business. H[er] "patients" were revenue streams, not true patients. This business allowed h[er] to collect cas[h] for office visits as well as being a "[d]ispensing [p]hysician" for controlled substances. [Sh]e prescribed controlled substances so that "patients" would return to h[er] office on a regular basis, allowing h[er] to generate further revenue. [The Respondent's] routine and excessive prescription of multiple controlled substances (oxycodone and Xanax) and lack of arriving at a valid medical diagnosis and treatment most likely caused harm to the "patients" [s]he saw. Drug diversion most likely caused a "mushroom" effect of increased drug abuse, drug addiction, drug overdoses, serious bodily injury and death in those communities spread over several different states. [The Respondent's] continued ability to prescribe controlled substances will only perpetuate the suffering and be a threat to the public.

Govt. Ex. 55 at 16.

On cross examination at the hearing, Dr. Kennedy's attention was directed to what would seem, at least to a lay person, to present as including a significant level of detail set forth in the charts he reviewed relative to the Respondent's patient documentation, including both subjective complaints of discomfort and objective signs of medical anomalies. Tr. at 497–98, 532–42. Undaunted, Dr. Kennedy (the sole expert to testify at the hearing), remained committed to his position that the manner in which the documentation was completed was fundamentally insufficient and too omission-plagued for a physician to adequately proceed to treat the patients with controlled substances. *Id.* at 473–74, 489, 522, 525. Dr. Kennedy, more than once, characterized the Respondent's patient charts as demonstrating "gross errors of omission." *Id.* at 522, 525.

The Supplemental Chart Analysis focused exclusively on SM's chart, which contained information assembled on the date of his first and only visit to the Respondent's practice, which occurred on the day before he was pronounced dead of an overdose of the controlled substances prescribed to him by the Respondent. Govt. Exs. 69 at 10, 132, 54; Respt. Ex. 1. Among the deficiencies noted by Dr. Kennedy regarding SM's chart was an absence of any efforts to communicate with SM's prior physician or obtain prior medical records, and SM's failure to list any medications on the applicable portion of the medication contract. Govt. Ex. 132. Kennedy also opined that SM's failure to provide any contact information regarding his prior physician, who, like SM was located in Kentucky, should have presented a red flag to the

[49] Dr. Kennedy did not testify that a referral that emanated from a source other than a physician could or should be a basis for a diversion red flag on a given case. His opinion was limited to culling some manner of a trend or pattern. In view of the fact that the record contains no development of the numbers of files with non-physician referrals versus the total number of files, or even an acceptable metric upon which the issue could be evaluated, there is very little useful analysis that can come from Dr. Kennedy's observation regarding the files he reviewed.

Respondent. *Id.* at 6. In his report, Kennedy characterized the Respondent's patient evaluation and treatment regarding SM as "very clearly not within the standard of medical care." *Id.* at 7.

A review of the fourteen patient files [50] that informed the analysis, findings and conclusions offered in Dr. Kennedy's written report and testimony does reflect the presence of at least some of the red flag issues he identified therein, but there was not the unanimity among the files that he repeatedly urges. Contrary to Kennedy's representations that the patients were all referred by friends, family, and advertising, patient JA's file contains a representation by the patient that he was referred to the clinic by a doctor. Govt. Ex. 56 at 28. The significance of this anomaly is, however, diminished considerably by the fact that the doctor's name is never furnished by JA or presented anywhere in the chart.

Regarding Dr. Kennedy's objections to what he perceives as a virtually uniform pattern in the Respondent's therapeutic plans, the record is not without exception. For example, Respondent included notations in one patient's records referring him to see an oncologist based on potential liver cancer concerns. Govt. Ex. 68 at 9.

An examination of the reviewed patient charts does reveal the presence of other red flags that should have inspired additional diligence or inquiry on the part of the Respondent. GA's patient file contains a notation about the patient getting Roxicodone, Xanax, and Percocet "off the street," a patient comfort assessment guide where GA states that his current treatments or medicine include "street drugs," a medication contract that is signed but does not list any current medications at all, along with an initial positive urinalysis screen for opiates and oxycodone, yet the Respondent decided to prescribe all three substances to GA during his initial and subsequent visits. Govt. Ex. 58 at 8–9, 11, 35; *see also* Govt. Exs. 64 at 2; 66 at 6; 67 at 22 (similar notations involving other patients acquiring controlled substances "off the street").

Patient JA's file also contains an indication that he had previously received pain medications "off the street," along with a police incident report referring to the armed robbery of two "Roxycotin" (sic) prescriptions valued at $600 from the patient on 12/31/09 (the same date on which the Respondent provided them to him), and which further contains a statement that "[t]he victim completed a written statement affidavit, but refused to pursue criminal charges at this time." [51] Govt. Ex. 56 at 2–3, 7.

JA's patient file also contains a form indicating a positive UDS for oxycodone and benzodiazepine from 10/7/09, yet on the same date, the patient comfort assessment guide and medication contract signed by JA are both blank in the section where a patient is supposed to list any medications he or she is currently taking. Govt. Ex. 56 at 13–14, 30; *see also* Govt. Exs. 59 at 9–10, 24; 61 at 7–8, 19; 66 at 11–12, 29 (similar issues). Patient RA's 11/2/09 UDS indicates a negative test for all listed substances, yet on two different forms in his file which appear to be from the same date, he indicates he is currently taking oxycodone and Xanax. Govt. Ex. 57 at 10–11, 26; *see also* Govt. Exs. 63 at 14–15, 34; 67 at 9–10, 22 (similar issues). Patient RS's UDS form, on the other hand, lists a positive test result for oxycodone and benzodiazepine on 10/5/09, yet the patient states she is currently taking only oxycodone on a medication contract signed on the same date. Govt. Ex. 65 at 7, 18.

The Government's presentation of Dr. Kennedy's testimony at the hearing was substantially consistent with the conclusions included in the Patient Charts Analysis, but Dr. Kennedy's presentation was clearly not without its blemishes. Although he testified that he was familiar with prescribing practices in Florida, and that he utilized the medical standards applicable to Florida practice,[52] he was unable to identify the documentation standard in the Florida Administrative code with any degree of particularity, he also acknowledged that he was not aware of what the standard is in Florida Medical Board administrative decisions regarding the overprescribing of medication or what constitutes an adequate medical history. Tr. at 149–51, 233, 304. While, overall, Kennedy presented testimony that appeared candid and knowledgeable, there were areas in his written report that rang of hyperbole and over-embellishment. The reasoning behind some of the seemingly critical observations in the written report, such as the "cash basis" of the Respondent's practice and the absence of doctor referrals among the reviewed patient files, did not well survive the crucible of cross examination at the hearing. However, overall, Dr. Kennedy's testimony was sufficiently detailed, plausible, and internally consistent to be considered credible, and, consistent with his qualifications, he spoke persuasively and with authority on some relevant issues within his expertise, and notwithstanding the Respondent's objections relative to his Florida-related experience, he is currently an assistant professor teaching at a Florida Medical School. It may well be that the greatest and most significant aspect of Dr. Kennedy's opinion is that on the current record, it stands unrefuted. Thus, his opinion is the only expert opinion available for reliance in this action.[53] Accordingly, Dr. Kennedy's expert opinion that the Respondent's controlled substance prescribing practices, at least as evidenced through his examination of the patient charts he reviewed, fell below the standards applicable in Florida, and that the controlled substance prescriptions contained in those files were not issued for a legitimate medical purpose is unrefuted on this record and (although by no means overwhelming) is sufficiently reliable to be accepted and relied upon in this recommended decision.

The Analysis

Pursuant to 21 U.S.C. 824(a)(4), the Deputy Administrator [54] may revoke a registrant's DEA Certificate of Registration if persuaded that the registrant "has committed such acts that would render * * * registration under section 823 * * * inconsistent with the public interest * * *." The following factors have been provided by Congress in determining "the public interest":

(1) The recommendation of the appropriate State licensing board or professional disciplinary authority.

(2) The applicant's experience in dispensing, or conducting research with respect to controlled substances.

(3) The applicant's conviction record under Federal or State laws relating to the manufacture, distribution, or dispensing of controlled substances.

(4) Compliance with applicable State, Federal or local laws relating to controlled substances.

[50] The Government's tactical decision to essentially unload a pile of charts that are explained only by the representations and generalizations in a report, with no attempt whatsoever to have its expert witness explain the applicable aspects of most charts to this tribunal or any future reviewing body is clearly at odds with the directive provided by the Deputy Administrator in *Gregg & Son Distributors* that "it is the Government's obligation as part of its burden of proof and not the ALJ's responsibility to sift through the records and highlight that information which is probative of the issues in the proceeding" 74 FR 17517 n.1.

[51] Notably, however, there is no indication in the patient file that the patient sought or received replacement prescriptions from the Respondent.

[52] Tr. at 628.

[53] The Respondent did not testify on her own behalf.

[54] This authority has been delegated pursuant to 28 CFR 0.100(b) and 0.104.

(5) Such other conduct which may threaten the public health and safety. 21 U.S.C. 823(f).

"[T]hese factors are considered in the disjunctive." *Robert A. Leslie, M.D.,* 68 FR 15227, 15230 (2003). Any one or a combination of factors may be relied upon, and when exercising authority as an impartial adjudicator, the Deputy Administrator may properly give each factor whatever weight she deems appropriate in determining whether an application for a registration should be denied. *JLB, Inc., d/b/a Boyd Drugs,* 53 FR 43945 (1988); *England Pharmacy,* 52 FR 1674 (1987); *see also David H. Gillis, M.D.,* 58 FR 37507, 37508 (1993); *Joy's Ideas,* 70 FR 33195, 33197 (2005); *Henry J. Schwarz, Jr., M.D.,* 54 FR 16422 (1989). Moreover, the Deputy Administrator is "not required to make findings as to all of the factors * * *." *Hoxie* v. *DEA,* 419 F.3d 477, 482 (6th Cir. 2005); *see also Morall* v. *DEA,* 412 F.3d 165, 173–74 (DC Cir. 2005). The Deputy Administrator is not required to discuss consideration of each factor in equal detail, or even every factor in any given level of detail. *Trawick* v. *DEA,* 861 F.2d 72, 76 (4th Cir. 1988) (the Administrator's obligation to explain the decision rationale may be satisfied even if only minimal consideration is given to the relevant factors and remand is required only when it is unclear whether the relevant factors were considered at all). The balancing of the public interest factors "is not a contest in which score is kept; the Agency is not required to mechanically count up the factors and determine how many favor the Government and how many favor the registrant. Rather, it is an inquiry which focuses on protecting the public interest * * *." *Jayam Krishna-Iyer, M.D.,* 74 FR 459, 462 (2009).

In an action to revoke a registrant's DEA COR, the DEA has the burden of proving that the requirements for revocation are satisfied. 21 CFR 1301.44(e). Once DEA has made its *prima facie* case for revocation of the registrant's DEA Certificate of Registration, the burden of production then shifts to the Respondent to show that, given the totality of the facts and circumstances in the record, revoking the registrant's registration would not be appropriate. *Morall,* 412 F.3d at 174; *Humphreys* v. *DEA,* 96 F.3d 658, 661 (3d Cir. 1996); *Shatz* v. *U.S. Dept. of Justice,* 873 F.2d 1089, 1091 (8th Cir. 1989); *Thomas E. Johnston,* 45 FR 72, 311 (1980). Further, "to rebut the Government's *prima facie* case, [the Respondent] is required not only to accept responsibility for [the established] misconduct, but also to demonstrate what corrective measures [have been] undertaken to prevent the reoccurrence of similar acts." *Jeri Hassman, M.D.,* 75 FR 8194, 8236 (2010).

Where the Government has sustained its burden and established that a registrant has committed acts inconsistent with the public interest, that registrant must present sufficient mitigating evidence to assure the Deputy Administrator that he or she can be entrusted with the responsibility commensurate with such a registration. *Steven M. Abbadessa, D.O.,* 74 FR 10077 (2009); *Medicine Shoppe-Jonesborough,* 73 FR 364, 387 (2008); *Samuel S. Jackson, D.D.S.,* 72 FR 23848, 23853 (2007). Normal hardships to the practitioner, and even the surrounding community, that are attendant upon the lack of registration are not a relevant consideration. *Abbadessa,* 74 FR at 10078; *see also Gregory D. Owens, D.D.S.,* 74 FR 36751, 36757 (2009).

The Agency's conclusion that past performance is the best predictor of future performance has been sustained on review in the courts, *Alra Labs.* v. *DEA,* 54 F.3d 450, 452 (7th Cir. 1995), as has the Agency's consistent policy of strongly weighing whether a registrant who has committed acts inconsistent with the public interest has accepted responsibility and demonstrated that he or she will not engage in future misconduct. *Hoxie,* 419 F.3d at 483; *George C. Aycock, M.D.,* 74 FR 17529, 17543 (2009); *Abbadessa,* 74 FR at 10078; *Krishna-Iyer,* 74 FR at 463; *Medicine Shoppe,* 73 FR at 387.

While the burden of proof at this administrative hearing is a preponderance-of-the-evidence standard, *see Steadman* v. *SEC,* 450 U.S. 91, 100–01 (1981), the Deputy Administrator's factual findings will be sustained on review to the extent they are supported by "substantial evidence." *Hoxie,* 419 F.3d at 481. While "the possibility of drawing two inconsistent conclusions from the evidence" does not limit the Deputy Administrator's ability to find facts on either side of the contested issues in the case, *Shatz,* 873 F.2d at 1092; *Trawick,* 861 F.2d at 77, all "important aspect[s] of the problem," such as a respondent's defense or explanation that runs counter to the Government's evidence, must be considered. *Wedgewood Vill. Pharmacy* v. *DEA,* 509 F.3d 541, 549 (DC Cir. 2007); *Humphreys,* 96 F.3d at 663. The ultimate disposition of the case must be in accordance with the weight of the evidence, not simply supported by enough evidence to justify, if the trial were to a jury, a refusal to direct a verdict when the conclusion sought to be drawn from it is one of fact for the jury. *Steadman,* 450 U.S. at 99 (internal quotation marks omitted).

Regarding the exercise of discretionary authority, the courts have recognized that gross deviations from past agency precedent must be adequately supported, *Morall,* 412 F.3d at 183, but mere unevenness in application does not, standing alone, render a particular discretionary action unwarranted. *Chein* v. *DEA,* 533 F.3d 828, 835 (DC Cir. 2008) (citing *Butz* v. *Glover Livestock Comm. Co., Inc.,* 411 U.S. 182, 188 (1973)), *cert. denied,* __ U.S. __, 129 S.Ct. 1033 (2009). It is well-settled that since the Administrative Law Judge has had the opportunity to observe the demeanor and conduct of hearing witnesses, the factual findings set forth in this recommended decision are entitled to significant deference, *Universal Camera Corp.* v. *NLRB,* 340 U.S. 474, 496 (1951), and that this recommended decision constitutes an important part of the record that must be considered in the Deputy Administrator's decision, *Morall,* 412 F.3d at 179. However, any recommendations set forth herein regarding the exercise of discretion are by no means binding on the Deputy Administrator and do not limit the exercise of that discretion. 5 U.S.C. 557(b); *River Forest Pharmacy, Inc.* v. *DEA,* 501 F.2d 1202, 1206 (7th Cir. 1974); *Attorney General's Manual on the Administrative Procedure Act* 8 (1947).

Factors 1 and 3: The Recommendation of the Appropriate State Licensing Board or Professional Disciplinary Authority and Conviction Record Under Federal or State Laws Relating to the Manufacture, Distribution, or Dispensing of Controlled Substances

In this case, it is undisputed that the Respondent holds a valid and current State license to practice medicine. The record contains no evidence of a recommendation regarding the Respondent's medical privileges by any cognizant State licensing board or professional disciplinary authority. However, that a State has not acted against a registrant's medical license is not dispositive in this administrative determination as to whether continuation of a registration is consistent with the public interest. *Patrick W. Stodola, M.D.,* 74 FR 20727, 20730 (2009); *Jayam Krishna-Iyer,* 74 FR at 461. It is well-established Agency precedent that a "state license is a necessary, but not a sufficient condition for registration." *Leslie,* 68 FR at 15230; *John H. Kennedy, M.D.,* 71 FR 35705, 35708 (2006). Even the reinstatement of a State medical license does not affect

the DEA's independent responsibility to determine whether a registration is in the public interest. *Mortimer B. Levin, D.O.,* 55 FR 9209, 8210 (1990). The ultimate responsibility to determine whether a registration is consistent with the public interest has been delegated exclusively to the DEA, not to entities within State government. *Edmund Chein, M.D.,* 72 FR 6580, 6590 (2007), *aff'd, Chein* v. *DEA,* 533 F.3d 828 (DC Cir. 2008), *cert. denied,* __ U.S. __, 129 S.Ct. 1033 (2009). Congress vested authority to enforce the CSA in the Attorney General and not State officials. *Stodola,* 74 FR at 20375. Thus, on these facts, the fact that the record contains no evidence of a recommendation by a State licensing board does not weigh for or against a determination as to whether continuation of the Respondent's DEA certification is consistent with the public interest.

Similarly, regarding Factor 3, while testimony was received at the hearing that indicated that a criminal search warrant was executed regarding the Respondent and American Pain, the record contains no evidence that the Respondent has ever been convicted of any crime or even arrested in connection with any open criminal investigation. Thus, consideration of the record evidence under the first and third factors does not militate in favor of revocation.

Factors 2, 4 and 5: The Respondent's Experience in Dispensing Controlled Substances, Compliance With Applicable State, Federal or Local Laws Relating to Controlled Substances, and Such Other Conduct Which May Threaten the Public Health and Safety

In this case, the gravamen of the allegations in the OSC/ISO, as well as the factual concentration of much of the evidence presented, share as a principal focus the manner in which the Respondent has managed that part of her practice relative to prescribing and dispensing controlled substances and acts allegedly committed in connection with her practice at American Pain. Thus, it is analytically logical to consider public interest factors two, four and five together. That being said, factors two, four and five involve analysis of common and distinct considerations.

Regarding Factor 2, the qualitative manner and the quantitative volume in which a registrant has engaged in the dispensing of controlled substances, and how long she has been in the business of doing so are factors to be evaluated in reaching a determination as to whether she should be entrusted with a DEA certificate. In some cases, viewing a registrant's actions against a backdrop of how she has performed activity within the scope of the certificate can provide a contextual lens to assist in a fair adjudication of whether continued registration is in the public interest.

There are two principal considerations embedded within a consideration of this public interest factor. In considering a similar factor under the List I chemical context, the Agency has recognized that the level of experience held by those who will be charged with recognizing and taking steps to minimize diversion factors greatly in determining whether entrusting a COR will be in the public interest. *See Volusia Wholesale,* 69 FR 69409, 69410 (2004); *Xtreme Enters., Inc.,* 67 FR 76195, 76197–98 (2004); *Prachi Enters.,* 69 FR 69407, 69409 (2004); *J&S Distribs.,* 69 FR 62089, 62090 (2004); *K.V.M. Enters.,* 67 FR 70968, 70969 (2002). The Agency has also recognized that evidence that a registrant may have conducted a significant level of sustained activity within the scope of the registration for a sustained period is a relevant and correct consideration, which must be accorded due weight. However, this factor can be outweighed by acts held to be inconsistent with the public interest. Experience which occurred prior and subsequent to proven allegations of malfeasance may be relevant. Evidence that precedes proven misconduct may add support to the contention that, even acknowledging the gravity of a particular registrant's transgressions, they are sufficiently isolated and/or attenuated that adverse action against its registration is not compelled by public interest concerns. Likewise, evidence presented by the Government that the proven allegations are consistent with a consistent past pattern of poor behavior can enhance the Government's case.

In this case, the Respondent introduced no evidence regarding her level of knowledge and experience, or even the quality or length of her experience as a physician-registrant, but the Government has elected to do so.

Regarding the Government's presentation, Agency precedent has long held that in DEA administrative proceedings "the parameters of the hearing are determined by the prehearing statements." *CBS Wholesale Distribs.,* 74 FR 36746, 36750 (2009) (citing *Darrel Risner, D.M.D.,* 61 FR 728, 730 (1996); *see also Roy E. Berkowitz, M.D.,* 74 FR 36758, 36759–60 (2009) ("pleadings in administrative proceedings are not judged by the standards applied to an indictment at common law" and "the rules governing DEA hearings do not require the formality of amending a show cause order to comply with the evidence"). That being said, however, the marked difference between the amount of evidence that the Government noticed in its OSC/ISO and the amount that it introduced at the hearing is striking. For example, contrary to its allegations, there was no evidence that the Respondent "prescribe[d] and dispense[d] *inordinate* amounts of controlled substances," that the "*majority*" of the Respondent's patients were "from states other than Florida," and there was no evidence that American Pain patients were issued "*pre-signed* prescriptions to obtain MRI[s]," nor was there evidence that individuals positioned outside the American Pain building were there to "monitor the activity of patients in the parking lot *to prevent patients from selling their recently obtained controlled substances*." Likewise, no evidence was introduced at the hearing that could support the allegations that "employees of American Pain [] *frequently* ma[d]e announcements to patients in the clinic advising them on how to avoid being stopped by law enforcement upon departing the pain clinic" and "*frequently* ma[d]e announcements [] advising [patients], among other things, not to attempt to fill their prescriptions at out-of State pharmacies and warning them against trying to fill their prescriptions at particular local retail pharmacies." ALJ Ex. 1 (emphasis supplied).

In like fashion, the Government's prehearing statement proffered that SA Burt would testify to several of the items described but not established in the OSC/ISO. Among the list of allegations that were *not supported by any evidence introduced at the hearing,* were representations that SA Burt would testify concerning the following:

> Law enforcement in Florida and [other states that correspond to license plates seen in the American Pain parking lot] frequently arrest people for illegal possession and/or illegal distribution of controlled substances who have obtained the controlled substances from American Pain;
>
> American Pain hired individuals to "roam" the parking lot of the clinic to dissuade people from selling their recently obtained controlled substances on the property;
>
> [The reason American Pain placed] signs within American Pain warning individuals not to have their prescriptions filled at Walgreens pharmacies [is] because Walgreens refuses to dispense the prescriptions;
>
> Walgreens has flagged all American Pain doctors and will not fill any of their prescriptions;
>
> [Physical exams at American Pain are] usually no more than a blood pressure check and some bending and stretching;

Dismissed patients would be routed to other doctors within the clinic;

[There was] co-mingling of [American Pain] physician's drugs;

[American Pain maintained] no inventories of drugs dispensed;

[Details surrounding] the death of [American Pain] patient OB [where] [t]he cause of death was determined to be drug intoxication—opiate and benzodiazepine;

[Information] from a confidential source [who indicated] that she traveled to American Pain in order to obtain controlled substances that were later sold in Kentucky for $25 per pill[,] [that] [the American Pain physician she encountered] did not spend any significant time conducting a physical examination of [her] [,] [that she would simply ask questions regarding [her] well being and would then "stamp" a prescription for [controlled substances][,] * * * that on one visit [during a power failure a] security guard working for the clinic instructed everyone to be patient and that the doctors would be with them shortly to "get your fix."

ALJ Ex. 6 at 3–9.

To be clear, it is not that the evidence was introduced and discredited; no evidence to support these (and other) allegations was introduced at all. To the extent the Government had this evidence, it left it home. While the stunning disparity between the allegations proffered and those that were supported with any evidence does not raise due process concerns, it is worthy of noting, without deciding the issue, that Agency precedent has acknowledged the Supreme Court's recognition of the applicability of the *res judicata* doctrine in DEA administrative proceedings. *Christopher Henry Lister, P.A.,* 75 FR 28068, 28069 (2010) (citing *University of Tennessee* v. *Elliot,* 478 U.S. 788, 797–98 (1986) ("When an administrative agency is acting in a judicial capacity and resolves disputed issues of fact properly before it which the parties have had an adequate opportunity to litigate, the courts have not hesitated to apply *res judicata*[.]")

The evidence the Government did present raises issues regarding not only Factor 2 (experience dispensing [55] controlled substances), but also Factors 4 (compliance with Federal and State law relating to controlled substances) and 5 (other conduct which may threaten public health and safety). Succinctly put, the Government's evidence related to the manner in which the Respondent practiced, and whether her practice complied with the law and/or was a threat to the public.

While true that GS Langston convincingly testified about the course of her investigation and laid an adequate foundation for numerous database results, the Government provided no foundational context for any relevant uses for those database results. Without some insight into what types of results from these databases should be expected when compared to similarly-situated registrants engaged in acceptable prescribing practices, the raw data is without use. In short, there was no evidence elicited wherein the percentage of the Respondent's in-State to out-of State patients could be assessed, and no reasonable measuring stick based on sound principles upon which to evaluate such data. Likewise, there was no reliable yardstick upon which to measure the amount of controlled substances reflected in the databases compared to what a reasonable regulator would expect to see regarding a compliant registrant. To the extent Langston possessed this information (and she well may have) it was not elicited from her. The same could be said of the allegation set forth in the Government's Prehearing Statement that alleges that from a given period the Respondent "was the 12th largest practitioner purchaser of oxycodone in the United States." [56] No evidence to support that allegation (or its relevance) was ever brought forth at the hearing. To the extent that fact may have been true or relevant, it was never developed. What's more, the Florida Administrative Code specifically eschews pain medication prescribing analysis rooted only in evaluation of medication quantity. Fla. Admin. Code r. 64B8–9.013(g). Lastly, there was no indication that despite Langston's obvious qualifications to do so, that she or anyone else ever conducted an audit of the controlled-substance-inventory-related recordkeeping practices at American Pain.

SA Burt testified that, during a temporally limited period of time, he observed some of the images captured by a pole camera positioned outside American Pain, and that he observed what in his view was a high percentage of vehicles in the parking lot with out-of-State license tags. This testimony arguably provides some support for the Government's contention that out-of-State patients (or at least patients being dropped off by cars with out-of-State tags) were being seen at the clinic, but his testimony did not provide much else in terms of relevant information. In any event, recent Agency precedent holds that details such as "where [a registrant's] patients were coming from," without additional factual development, can support a "strong suspicion that [a respondent was not engaged in a legitimate medical practice" but that "under the substantial evidence test, the evidence must 'do more than create a suspicion of the existence of the fact to be established.'" *Alvin Darby, M.D.,* 75 FR 26993, 26999, n.31 (2010) (citing *NLRB* v. *Columbian Enameling & Stamping Co.,* 306 U.S. 292, 300 (1939).

Likewise, without additional details or at least some context, Burt's testimony that individuals with "staff" written on their shirts appeared to be directing patients into the clinic reveals virtually nothing about the Respondent's prescribing practices. Tr. at 818, 910. Furthermore, that Burt observed an individual on a videotape, who he believed to be an American Pain employee, on a single occasion, instruct patients not to "snort [their] pills" in the parking lot,[57] or advising them to comply with vehicle and traffic laws,[58] does not shed illumination on the Respondent's prescribing practices. There was no evidence that the Respondent knew that these isolated incidents occurred, nor was there contextual evidence from which the relevance to these proceedings could be gleaned. Even if this tribunal was inclined to engage in the unsupported assignment of motives to the actions of these employees, under these circumstances, such an exercise could not constitute substantial evidence that could be sustained at any level of appeal.

Burt's testimony regarding his conversations with Dr. Sollie, who was formerly employed by American Pain, was also not received in a manner that could meaningfully assist in the decision process. According to Burt, Sollie told him that some (unnamed) physicians at American Pain were inadequately documenting their patient charts in some manner that was apparently never explained to Burt,[59] and that some patients were intentionally evading the American Pain urinalysis process. Also, as highlighted in Respondent's Post-Hearing Brief (Respondent's Brief), Sollie did not work at American Pain at the same time the Respondent did,[60] and did not specifically name any physician as being connected with his allegations of misconduct. Respt's Br. at 11. Thus, this tribunal is at something of a loss as to how the information, as presented, would tend to establish a fact relevant to whether the continuation of *this* Respondent's authorization to handle

[55] The statutory definition of the term "dispense" includes the prescribing and administering of controlled substances. 21 U.S.C. 802(10).

[56] ALJ Ex. 6 at 11–12.

[57] Tr. at 825.

[58] Tr. at 826.

[59] Tr. at 898.

[60] Tr. at 1026–27.

controlled substances is in the public interest.

The Government's evidence targeted not only the Respondent's experience practicing under Factor 2, but also her compliance with applicable State and Federal laws relating to controlled substances under Factor 4. To effectuate the dual goals of conquering drug abuse and controlling both legitimate and illegitimate traffic in controlled substances, "Congress devised a closed regulatory system making it unlawful to manufacture, distribute, dispense, or possess any controlled substance except in a manner authorized by the CSA." *Gonzales* v. *Raich,* 545 U.S. 1, 13 (2005). Consistent with the maintenance of that closed regulatory system, subject to limited exceptions not relevant here, a controlled substance may only be dispensed upon a prescription issued by a practitioner, and such a prescription is unlawful unless it is "issued for a legitimate medical purpose by an individual practitioner acting in the usual course of her professional practice." 21 U.S.C. 829; 21 CFR 1306.04(a). Furthermore, "an order purporting to be a prescription issued not in the usual course of professional treatment * * * is not a prescription within the meaning and intent of [21 U.S.C. 829] and the person knowingly * * * issuing it, shall be subject to the penalties provided for violations of the provisions of law related to controlled substances." *Id.*

A registered practitioner is authorized to dispense,[61] which the CSA defines as "to deliver a controlled substance to an ultimate user[62] * * * by, or pursuant to the lawful order of a practitioner." 21 U.S.C. 802(10); *see also Rose Mary Jacinta Lewis,* 72 FR 4035, 4040 (2007). The prescription requirement is designed to ensure that controlled substances are used under the supervision of a doctor, as a bulwark against the risk of addiction and recreational abuse. *Aycock,* 74 FR at 17541 (citing *Gonzales* v. *Oregon,* 546 U.S. 243, 274 (2006); *United States* v. *Moore,* 423 U.S. 122, 135, 142–43 (1975) (noting that evidence established that a physician exceeded the bounds of professional practice when she gave inadequate examinations or none at all, ignored the results of the tests she did make, and took no precautions against misuse and diversion)). The prescription requirement likewise stands as a proscription against doctors "peddling to patients who crave the drugs for those prohibited uses." *Id.* The courts have sustained criminal convictions based on the issuing of illegitimate prescriptions where physicians conducted no physical examinations or sham physical examinations. *United States* v. *Alerre,* 430 F.3d 681, 690–91 (4th Cir. 2005), *cert. denied,* 574 U.S. 1113 (2006); *United States* v. *Norris,* 780 F.2d 1207, 1209 (5th Cir. 1986).

While true that the CSA authorizes the "regulat[ion] of medical practice so far as it bars doctors from using their prescription-writing powers as a means to engage in illicit drug dealing and trafficking as conventionally understood," *Gonzales,* 546 U.S. at 266–67, an evaluation of cognizant State standards is essential. *Joseph Gaudio, M.D.,* 74 FR 10083, 10090 (2009); *Kamir Garces-Mejias, M.D.,* 72 FR 54931, 54935 (2007); *United Prescription Servs., Inc.,* 72 FR 50397, 50407 (2007). In this adjudication, the evaluation of the Respondent's prescribing practices must be consistent with the CSA's recognition of State regulation of the medical profession and its bar on physicians from peddling to patients who crave drugs for prohibited uses. The analysis must be "tethered securely" to State law and Federal regulations in application of the public interest factors, and may not be based on a mere disagreement between experts as to the most efficacious way to prescribe controlled substances to treat chronic pain sufferers. *Volkman* v. *DEA,* 567 F.3d 215, 223 (6th Cir. 2009) (citing *Gonzales,* 546 U.S. at 272, 274).

Under the CSA, it is fundamental that a practitioner must establish a bonafide doctor-patient relationship in order to act "in the usual course of * * * professional practice" and to issue a prescription for a legitimate medical purpose." *Stodola,* 74 FR at 20731; *Shyngle,* 74 FR at 6057–58 (citing *Moore,* 423 U.S. at 141–43). The CSA looks to State law to determine whether a bonafide doctor-patient relationship existed. *Stodola,* 74 FR at 20731; *Shyngle,* 74 FR at 6058; *Garces-Mejias,* 72 FR at 54935; *United Prescription Servs.,* 72 FR at 50407. It was Dr. Kennedy's uncontroverted opinion that his evaluation of chart entries convinced him that they were so defective that the Respondent did not establish a sufficient doctor-patient relationship to justify the prescribing of controlled substances, and that "this was not the practice of medicine in [his] opinion." Tr. at 160–61.

Under Florida law, grounds for disciplinary action or denial of State licensure include "prescribing * * * any controlled substance, other than in the course of the physician's professional practice," and prescribing such substances "inappropriately or in excessive or inappropriate quantities is not in the best interest of the patient and is not in the course of the physician's professional practice, without regard to his or her intent." Fla. Stat. § 458.331(q) (2009). Florida law further provides that grounds for such disciplinary action also include:

> Failing to keep legible, as defined by department rule in consultation with the board, medical records that identify the licensed physician * * * and that justify the course of treatment of the patient, including, but not limited to, patient histories; examination results; test results; records of drugs prescribed, dispensed, or administered; and reports of consultations and hospitalizations.

Id. § 458.331(m).

In exercising its rulemaking function,[63] the Florida Board of Medicine (Florida Board) promulgated a regulation addressing "Standards for Adequacy of Medical Records" applicable to all physicians. Fla. Admin. Code r. 64B8–9.003 (2009). That regulation provides, in pertinent part:

> (2) A licensed physician shall maintain patient medical records in English, in a legible manner and with sufficient detail to clearly demonstrate why the course of treatment was undertaken.
>
> (3) The medical record shall contain sufficient information to identify the patient, support the diagnosis, justify the treatment and document the course and results of treatment accurately, by including, at a minimum, patient histories; examination results; test results; records of drugs prescribed, dispensed or administered; reports of consultations and hospitalizations; and copies of records or reports or other documentation obtained from other health care practitioners at the request of the physician and relied upon by the physician in determining the appropriate treatment of the patient.
>
> (4) All entries made into the medical records shall be accurately dated and timed. Late entries are permitted, but must be clearly and accurately noted as late entries and dated and timed accurately when they are entered in to the record * * *.

Fla. Admin. Code r. 64B8–9.003 (2009).

With respect to defining the parameters of what constitutes "professional practice" in the context of pain management prescribing, Florida State law provides:

> Notwithstanding any other provision of law, a physician may prescribe or administer

[61] 21 U.S.C. 823(f).

[62] "Ultimate user" is defined as "a person who has lawfully obtained, and who possesses, a controlled substance for his own use or for the use of a member of his household or for an animal owned by him or by a member of his household." 21 U.S.C. 802(27).

[63] Rulemaking authority regarding the practice of medicine within the State of Florida has been delegated to the Florida Board of Medicine (Florida Board). Fla. Stat. § 458.309(1)(2009).

any controlled substance under Schedules II–V * * * to a person for the treatment of intractable pain,[64] provided the physician does so in accordance with that level of care, skill, and treatment recognized by a reasonably prudent physician under similar conditions and circumstances.

Fla. Stat. § 458.326 (2009). Moreover, the Florida Board has adopted,[65] albeit in modified version, the *Model Policy for the Use of Controlled Substances for the Treatment of Pain* (*Model Policy*), a document drafted by the Federation of State Medical Boards (FSMB) to provide professional guidelines for the treatment of pain with controlled substances. The standards adopted by Florida share the key tenants of the *Model Policy's* standards for pain management prescribing, including the emphasis on diligent efforts by physicians to prevent drug diversion, prescribing based on clear documentation of unrelieved pain and thorough medical records, and compliance with applicable Federal and State law.

Like the *Model Policy,* which was promulgated "to encourage the legitimate medical uses of controlled substances for the treatment of pain while stressing the need to safeguard against abuse and diversion," Florida's regulation providing "Standards for the Use of Controlled Substances for Treatment of Pain," Fla. Admin. Code r. 64B8–9.013 (2009) (Florida Standards), recognizes that "inappropriate prescribing of controlled substances * * * may lead to drug diversion and abuse by individuals who seek them for other than legitimate medical use." The language employed by the regulation under the preamble section titled "Pain Management Principles" makes clear that the standards "are not intended to define *complete or best practice,* but rather to communicate what the [Florida Board] considers to be *within the boundaries of professional practice*" (emphasis supplied), *id.* at 9.013(1)(g); thus, the plain text supports an inference that the standards provide the *minimum* requirements for establishing conduct that comports with the professional practice of controlled substance-based pain management within the State. Likewise, the level of integral range of acceptable practice that is built into the regulation underscores the importance of seeking an expert professional opinion in reaching a correct adjudication of whether a registrant has met the applicable Florida standard. It is clear that in assessing whether the controlled substance prescribing practices of a Florida practitioner fall within the acceptable range of what constitutes being within the bounds of being "issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice," [66] resort must be had to an expert.

The Florida Standards direct that "[p]hysicians should be diligent in preventing the diversion of drugs for illegitimate purposes," *id.* at 9.013(1)(d), and provide that the prescribing of controlled substances for pain will be considered

> to be for a legitimate medical purpose if based on accepted scientific knowledge of the treatment of pain or if based on sound clinical grounds. All such prescribing must be based on *clear documentation* of unrelieved pain and in compliance with applicable State or Federal law.

Id. at 9.013(1)(e) (emphasis supplied).

The Florida Standards further provide that the validity of prescribing will be judged "based on the physician's treatment of the patient and *on available documentation,* rather than on the quantity and chronicity of prescribing" (emphasis supplied). *Id.* at 9.013(1)(g). Furthermore, the Standards advise that physicians should not fear disciplinary action for "prescribing controlled substances * * * for a legitimate medical purpose and that is supported by *appropriate documentation* establishing a valid medical need and treatment plan" (emphasis supplied), or "for failing to adhere strictly to the provisions of these standards, *if good cause is shown for such deviation*" (emphasis supplied). *Id.* at 9.013(1)(b), (f).

Although, as discussed above, the Florida Board instituted general guidance applicable to all physicians regarding medical records, it also promulgated a separate set of documentation requirements in the Florida Standards applicable specifically to those physicians who prescribe controlled substances in the pain-management context. The Florida Standards, under the subheading "Medical Records," state that "[t]he physician is required to keep *accurate and complete records*" (emphasis supplied) including, though not limited to:

> 1. The medical history and physical examination, including history of drug abuse or dependence, as appropriate;
> 2. Diagnostic, therapeutic, and laboratory results;
> 3. Evaluations and consultations;
> 4. Treatment objectives;
> 5. Discussion of risks and benefits;
> 6. Treatments;
> 7. Medications (including date, type, dosage, and quantity prescribed);
> 8. Instructions and agreements; and
> 9. Periodic reviews.

Id. at 9.013(3)(f). The same section directs that "[r]ecords must remain current and be maintained in an acceptable manner and readily available for review. *Id.*

The Florida Standards similarly emphasize the need for proper documentation in the patient evaluation context by specifying:

> A complete [67] medical history and physical examination must be conducted and documented in the medical record. The medical record should document the nature and intensity of the pain, current and past treatments for pain, underlying or coexisting diseases or conditions, the effect of the pain on physical and psychological function, and history of substance abuse. The medical record also should document the presence of one or more recognized medical indications for the use of a controlled substance.

Id. at 9.013(3)(a).

Furthermore, the Florida Standards require a written treatment plan that "should state objectives that will be used to determine treatment success, such as pain relief and improved physical and psychosocial function, and should indicate if any further diagnostic evaluations or other treatments are planned." *Id.* at 9.013(3)(b). Subsequent to the initiation of treatment, "the physician should *adjust* drug therapy to the individual medical needs of each patient. Other treatment modalities or a rehabilitation program may be necessary depending on the etiology of the pain and the extent to which the pain is associated with physical and psychosocial impairment." (emphasis supplied). *Id.*

Another standard adopted by the Florida Board, under the subheading "Informed Consent and Agreement for Treatment," is the directive that

> [t]he physician should discuss the risks and benefits of the use of controlled substances with the patient, persons designated by the patient, or with the patient's surrogate or guardian if the patient

[64] Florida defines "intractable pain" to mean "pain for which, in the generally accepted course of medical practice, the cause cannot be removed and otherwise treated." Fla. Stat. § 458.326 (2009).

[65] Pursuant to authority vested in the Florida Board by the Florida legislature to promulgate rules regarding State standards for pain management clinical practice specifically. Fla. Stat. § 458.309(5) (2009).

[66] 21 CFR 1306.04(a).

[67] The original *Model Policy* version of the guidelines does not contain a reference to the need for a *complete* medical history, instead only requiring a medical history generally. Thus, the Florida Board has adopted a higher standard than the measure that has been set in the *Model Policy* by the FSMB.

is incompetent. The patient should receive prescriptions from one physician and one pharmacy where possible. If the patient is determined to be at high risk for medication abuse or have a history of substance abuse, the physician should employ the use of a written agreement between the physician and patient outlining patient responsibilities, including, but not limited to:

1. Urine/serum medication levels screening when requested;

2. Number and frequency of all prescription refills; and

3. Reasons for which drug therapy may be discontinued (*i.e.,* violation of agreement.

Id. at 9.003(3)(c).

The Florida Standards contain a further requirement to periodically review "the course of pain treatment and any new information about the etiology of the pain or the patient's state of health." *Id.* at 9.013(3)(d) The Florida Standards explain the importance of periodic review in the following manner:

> Continuation or modification of therapy depends on the physician's evaluation of the patient's progress. If treatment goals are not being achieved, despite medication *adjustments,* the physician should reevaluate the appropriateness of continued treatment. The physician should monitor patient compliance in medication usage and related treatment plans.

Id.

Under the subheading "Consultation," the Florida Board promulgated the instruction that

> [t]he physician should be willing to refer the patient as necessary for additional evaluation and treatment in order to achieve treatment objectives. Special attention should be given to those pain patients who are at risk for misusing their medications and those whose living arrangements pose a risk for medication misuse or diversion. The management of pain in patients with a history of substance abuse or with a comorbid psychiatric disorder requires extra care, monitoring, and documentation, and may require consultation with or referral to an expert in the management of such patients.

Id. at 9.003(3)(e).

It is abundantly clear from the plain language of the Florida Standards that the Florida Board places critical emphasis on physician implementation of adequate safeguards in their practice to minimize diversion and the need to document the objective signs and rationale employed in the course of pain treatment utilizing the prescription of controlled substances. Conscientious documentation is repeatedly emphasized as not just a ministerial act, but a key treatment tool and a vital indicator to evaluate whether the physician's prescribing practices are "within the usual course of professional practice." Here, the uncontroverted expert opinion of Dr. Kennedy, the only expert witness to testify at these proceedings, reflects that the documentation he reviewed in the Respondent's patient charts reflected care that was markedly below the standard of care set by the Florida Medical Board. Dr. Kennedy's expert assessment was consistent with the State statutory and regulatory guidance. In Kennedy's view, the Respondent's charts demonstrated minimalistic, incomplete, and otherwise medically inadequate documentation of her contacts with patients and the prescribing rationale for her issuance of controlled substance prescriptions to those patients for alleged pain management purposes. The boilerplate-style, "one high-dosage controlled substances treatment plan fits all" nature of nearly all of the patient medical records at issue, at least in the view of the uncontroverted expert, evidences a failure on the part of the Respondent to conduct her practice of medicine in a manner to minimize the potential of controlled substance abuse and diversion, and supports a conclusion that she failed to even substantially comply with the minimum obligations for professional practice imposed under the Florida Standards—and without "good cause [] shown for such deviation." *Id.* at 9.013(1)(f). The same can be said of the multiple ignored red flags of diversion risk, such as the seeking of premature controlled substance prescription refills and the urinalysis anomalies highlighted by Dr. Kennedy in his testimony.

In his brief, the Respondent's counsel has prepared and submitted a thoughtful and detailed review of the patient charts analyzed by Dr. Kennedy. Respt's Br. at 5–10. While counsel argues that the patient chart entries were satisfactory, the expert's opinion at the hearing remained unchanged. Unfortunately, counsel's analysis is the product of a lay evaluation of standards applicable to the nuanced and sophisticated science that is the practice of medicine. An example of the problem encountered here can be seen where counsel urges that the medication contract clause requiring patients to follow-up with their primary care physicians was somehow satisfied by the patient following up with the Respondent. *Id.* at 7. Whether a pain specialist can serve as (or morph into) a primary care physician sufficiently to satisfy a medication contract term is beyond the expertise of this tribunal, and requires the input of an expert witness. Also illustrative of the potential risks of blurring the line between expert and lay opinion is counsel's argument that regarding the reviewed charts, "[s]ections that were not filled in include details that are not necessarily indicated for [the Respondent's] evaluation of a patient for chronic pain therapy." *Id.* at 9. A lay person is simply not in a position to contradict otherwise reliable expert testimony regarding which details are "necessarily indicated" for inclusion in the chart of a pain management specialist. Where the opinion of counsel offered through argument and the opinion of the only accepted medical expert to provide an expert opinion in these proceedings conflict, counsel's opinion cannot and will not be afforded controlling deference. Argument supplied by counsel (albeit a diligent and persuasive counsel) that the relevant standards were satisfactorily applied as evidenced by the protocols and procedures documented in the patient charts cannot supplant the unrefuted view of an accepted expert witness.

The Respondent, who was in a unique position to conclusively refute Dr. Kennedy's views and explain the format and nuances of the reviewed documentation, elected not to testify in this matter. At a DEA administrative hearing, it is permissible to draw an adverse inference from the silence of the Respondent, even in the face of a Fifth Amendment invocation. *Hoxie* v. *DEA,* 419 F.3d 477, 483 (6th Cir. 2005) (citing *United States* v. *Hale,* 422 U.S. 171, 176 (1975) ("silence gains more probative weight where it persists in the face of accusation, since it is assumed in such circumstances that the accused would be more likely than not to dispute an untrue accusation.")); *Joseph Baumstarck, M.D.,* 74 FR 17525, 17528, n.3 (2009) (citing *Ohio Adult Parole Auth.* v. *Woodward,* 523 U.S. 272, 286 (1998)). On the facts of this case, where the allegations are of a nature that a registrant would be more likely than not to dispute them if untrue, an adverse inference based on the Respondent's silence is appropriate. Where, as here, the Government, through its expert, has alleged that the Respondent's charts do not reflect genuine analysis, but rather (at least in its view and the opinion of its expert), a sort of sham-by-check-box form designed specifically to present a false impression of a compliant registrant, it is precisely the type of allegation that would naturally all but oblige a registrant to spring to offer a contradictory account. The Respondent's choice to remain silent in the face of such allegations, where she

could have related her version of her practice as a registrant, adds at least some additional credence to the factual and analytical views of the Government's expert in this regard.

In the Social Security context, where an Administrative Law Judge has received expert medical opinions on the issue of the claimant's ability to work and they are not repudiated in any respect by substantial evidence, an adverse decision should be set aside as based on "suspicion and speculation." *Miracle* v. *Celebrezze,* 351 F.2d 361, 378 (6th Cir. 1965); *see also Hall* v. *Celebrezze,* 314 F.2d 686, 689–90 (6th Cir. 1963); *cf. Harris* v. *Heckler,* 756 F.2d 431, 436 (6th Cir. 1985) (improper to reject uncontroverted evidence supporting complaints of pain simply because of claimant's demeanor at hearing). When an administrative tribunal elects to disregard the uncontradicted opinion of an expert, it runs the risk of improperly declaring itself as an interpreter of medical knowledge. *Ross* v. *Gardner,* 365 F.2d 554 (6th Cir. 1966). While in this case it is ironically true, much like in the Social Security context, that the opinion of a treating physician should be afforded greater weight than the opinion of an expert whose opinion is limited to a review of the patient file, *see Magallenes* v. *Bowen,* 881 F.2d 747, 751 (9th Cir. 1989), the treating-source Respondent in this case offered no evidence, not even her own opinion, regarding the treatment rendered. Thus, in this adjudication, the record contains no dispute between experts to be resolved; instead, there is but one, unrefuted, uncontroverted, credible expert opinion. To ignore that expert opinion on this record and replace it with the opinion of this tribunal, Respondent's counsel, or any other lay source would be a dangerous course and more importantly, a plainly erroneous one.

Accordingly, after carefully balancing the admitted evidence, the evidence establishes, by a preponderance of the evidence, that the prescriptions the Respondent issued in Florida were not issued within "the usual course of [the Respondent's] professional practice." 21 CFR 1306.04(a). Consideration of the evidence under the second and fourth factors support the COR revocation sought by the Government in this case.

To the extent that the Respondent's prescribing practices fell below the requisite standard in Florida, that conduct also impacts upon the Fifth statutory factor. Under Factor 5, the Deputy Administrator is authorized to consider "other conduct which may threaten the public health and safety." 21 U.S.C. 823(f)(5). Although this factor authorizes consideration of a somewhat broader range of conduct reaching beyond those activities typically associated with a registrant's practice, an adverse finding under this factor requires some showing that the relevant conduct actually constituted a threat to public safety. *See Holloway Distrib.,* 72 FR 42118, 42126 (2007).

Although admittedly not argued in the Government's brief, nowhere is the application of this fifth public interest factor more crystallized on this evidence than it is regarding the handling of SM. Inasmuch as there is no question that multiple controlled substances were identified in the decedent's body at the moment of death that were prescribed by multiple physicians, it would be difficult-to-impossible to precisely discern whether there was a specific one that could be isolated as the sole cause of his demise. An analysis centered on which physician's name appeared on the vial that produced the ultimately fatal dose misses the point. Even if it were conclusively established that a medication that was legitimately prescribed in the usual course of a professional practice resulted in an adverse consequence—even death—that fact alone would not necessarily decide the issue here. The practice of medicine has not yet developed to a condition of such mathematical precision that it is free of adverse consequences resulting from good-faith efforts on the part of treating physicians. The real focus of this aspect of this decision is not to conclusively divine which medication ultimately was the most lethal, or even which practitioner authorized it, but to evaluate whether the Respondent's *prescribing practices* resulted in prescriptions which were not issued in the usual course of a professional practice and whether her *prescribing practices* contributed to SM's death. The patient chart relative to SM reflected that no efforts were made to procure prior medical records, information from family or friends, or even to perform a Kentucky PMP database query. Performing the tasks that Dr. Kennedy opined were required by a prudent practitioner would have revealed, at a minimum, that SM had an addiction to pain killers, was abusing marijuana, was receiving controlled substance prescriptions from another physician and was in the midst of some manner of significant emotional-psychological event. None of that was done. In the case of SM, the Respondent did what she apparently routinely did: She prescribed controlled substances without performing the steps that were required to ensure that the prescriptions were being issued for a legitimate medical purpose. In the case of SM, while it is possible, even likely, that increased curiosity and professional attention and action on the Respondent's part could have saved his life, that determination is not required for a disposition of this case. While experts could argue the point of which medication actually killed him, there seems very little room for argument that the Respondent's poor *prescribing practices* were very problematic relative to this decedent and serve as a grave reminder of the potential consequences of failing to take the steps required by a prudent registrant to ensure the safety of the public. Consideration of the Respondent's conduct under Factor 5 balances significantly in favor of revocation.

The evidence establishes that the Respondent engaged in a course of practice wherein she prescribed controlled substances to patients irrespective of the patients' need for such medication and ignoring any and all red flags that could or did indicate likely paths of diversion. The testimony of Dr. Kennedy, the DEA regulations, and the Florida Standards make clear that physicians prescribing controlled substances do so under an obligation to monitor the process to minimize the risk of diversion. The patient charts reflect that the Respondent, contrary to her obligations as a DEA registrant, did not follow up in the face of multiple red flags. The Respondent's disregard of her obligations as a DEA registrant and Federal and State laws related to controlled substances militate in favor of revocation.

By ignoring her responsibilities to monitor the controlled substance prescriptions she was authorizing to minimize diversion, and by participating in an insufficiently documented and thoughtful process for the issuance of potentially dangerous controlled substances, the Respondent created a significant potential conduit for the unchecked diversion of controlled substances. *See Holloway Distrib.,* 72 FR at 42124 (a policy of "see no evil, hear no evil" is fundamentally inconsistent with the obligations of a DEA registrant). Agency precedent has long recognized that "[l]egally, there is absolutely no difference between the sale of an illicit drug on the street and the illicit dispensing of a licit drug by means of a physician's prescription." *EZRX, LLC,* 69 FR 63178, 63181 (1988); *Floyd A. Santner, M.D.,* 55 FR 37581 (1988).

Agency precedent has consistently held that where, as here, the

Government has met its burden to establish a prima facie case that a registrant has committed acts demonstrating that continued registration is inconsistent with the public interest, acceptance of responsibility is a condition precedent to continued registration. *Jeri Hassman, M.D.,* 75 FR 8194, 8236 (2010); *Medicine Shoppe,* 73 FR at 387. The record contains no evidence that the Respondent has either acknowledged or accepted responsibility for the misconduct at issue in these proceedings.

Recommendation

Based on the foregoing, the evidence supports a finding that the Government has established that the Respondent has committed acts that are inconsistent with the public interest. A balancing of the statutory public interest factors supports the revocation of the Respondent's Certificate of Registration and a denial of her application to renew. The Respondent has not accepted responsibility for her actions, expressed remorse for her conduct at any level, or presented evidence that could reasonably support a finding that the Deputy Administrator should continue to entrust her with a Certificate of Registration.

Accordingly, the Respondent's Certificate of Registration should be *revoked* and any pending applications for renewal should be *denied.*

Dated: August 10, 2010.

John J. Mulrooney, II,

U.S. Administrative Law Judge.

[FR Doc. 2011–8342 Filed 4–6–11; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–71,287A; TA–W–71,287B]

Masco Builder Cabinet Group Including On-Site Leased Workers From Reserves Network, Reliable Staffing, and Third Dimension Waverly, OH; Masco Builder Cabinet Group Including On-Site Leased Workers From Reserves Network, Reliable Staffing, and Third Dimension Seal Township, OH; Amended Certification Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with Section 223 of the Trade Act of 1974, as amended ("Act"), 19 U.S.C. 2273, the Department of Labor issued a Certification of Eligibility to Apply for Worker Adjustment Assistance on October 16, 2009, applicable to workers of Masco Builder Cabinet Group including on-site leased workers from Reserves Network, Jackson, Ohio. The workers produce cabinets and cabinet frames. The notice was published in the **Federal Register** on December 11, 2009 (74 FR 65797). The notice was amended on December 22, 2010 to include other company locations. The notice was published in the **Federal Register** on January 12, 2011 (76 FR 2145). The notice was amended again February 24, 2011 to include on-site leased workers from Reserves Network and Reliable Staffing. The notice was published in the **Federal Register** on March 10, 2011 (76 FR 13226–13227).

At the request of the State agency, the Department reviewed the certification for workers and former workers of Masco Builder Cabinet Group, Waverly, Ohio (TA–W–71,287A) and Seal Township, Ohio (TA–W–71,287B). The company reports that workers leased from Third Dimension were employed at the Waverly, Ohio and Seal Township, Ohio locations of Masco Builder Cabinet Group.

The Department has determined that these workers were sufficiently under the control of Masco Builder Cabinet Group to be considered leased workers.

Based on these findings, the Department is amending this certification to include workers leased from Third Dimension working on-site at the Waverly, Ohio and Seal Township, Ohio locations of Masco Builder Cabinet Group.

The amended notice applicable to TA–W–71,287A and TA–W–71,287B is hereby issued as follows:

All workers of Masco Builder Cabinet Group, including on-site leased workers from Reserves Network, Reliable Staffing, and Third Dimension, Waverly, Ohio (TA–W–71,287A) and Seal Township, Ohio (TA–W–71,287B), who became totally or partially separated from employment on or after June 11, 2008, through October 16, 2011, and all workers in the group threatened with total or partial separation from employment on the date of certification through two years from the date of certification, are eligible to apply for adjustment assistance under Chapter 2 of Title II of the Trade Act of 1974, as amended.

Signed at Washington, DC this 29th day of March, 2011.

Del Min Amy Chen,

Certifying Officer, Office of Trade Adjustment Assistance.

[FR Doc. 2011–8307 Filed 4–6–11; 8:45 am]

BILLING CODE 4510–FN–P

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–74,895, et al.]

Wellpoint, Inc. D/B/A/Anthem Blue Cross & Blue Shield, et al.; Amended Certification Regarding Eligibility To Apply for Worker Adjustment Assistance

TA–W–74,895
Wellpoint, Inc. D/B/A/Anthem Blue Cross & Blue Shield Enterprise Provider Data Management Team Including On-Site Leased Workers from Kelly Services and Jacobsen Group Indianapolis, Indiana
TA–W–74,895A
Wellpoint, Inc. D/B/A/Anthem Health Plans of Kentucky Enterprise Provider Data Management Team Louisville, Kentucky
TA–W–74,895B
Wellpoint, Inc. Enterprise Provider Data Management Team Saint Louis, Missouri
TA–W–74,895C
Wellpoint, Inc. D/B/A/Anthem Enterprise Provider Data Management Team (Pewaukee) Waukesha, Wisconsin
TA–W–74,895D
Wellpoint, Inc. D/B/A/Anthem Enterprise Provider Data Management Team Richmond, Virginia
TA–W–74,895E
Wellpoint, Inc. D/B/A/Anthem East Enterprise Provider Data Management Team North Haven, Connecticut
TA–W–74,895F
Wellpoint, Inc. D/B/A/Blue Cross Blue Shield of Georgia Enterprise Provider Data Management Team Atlanta, Georgia
TA–W–74,895G
Wellpoint, Inc. D/B/A/Blue Cross Blue Shield Of Georgia Enterprise Provider Data Management Team Columbus, Georgia
TA–W–74,895H
Wellpoint, Inc. D/B/A/Anthem East Enterprise Provider Data Management Team South Portland, Maine
TA–W–74,895I
Wellpoint, Inc. D/B/A/Anthem East Enterprise Provider Data Management Team Manchester, New Hempshire
TA–W–74,895J
Wellpoint, Inc. D/B/A/Empire Blue Cross and Blue Shield Enterprise Provider Data Management Team Albany, New York
TA–W–74,895K
Wellpoint, Inc. D/B/A/Empire Blue Cross and Blue Shield Enterprise Provider Data Management Team Brooklyn, New York
TA–W–74,895L
Wellpoint, Inc. D/B/A/Anthem Enterprise Provider Data Management Team Mason, Ohio

In accordance with Section 223 of the Trade Act of 1974, as amended ("Act"), 19 U.S.C. 2273, the Department of Labor issued a Certification of Eligibility to Apply for Worker Adjustment Assistance on January 12, 2011, applicable to workers of Wellpoint, Inc.,

Enterprise Provider Data Management Team, including on-site leased workers from Kelly Services and Jacobsen Group, Indianapolis, Indiana. The workers provide health insurance transactional services. The notice was published in the **Federal Register** on January 26, 2011 (76 FR 4731).

At the request of the State agency, the Department reviewed the certification for workers of the firm. New findings show that worker separations occurred during the relevant time period at the above mentioned locations of Wellpoint, Inc., Enterprise Provider Data Management Team. Each location operates in conjunction with the Indianapolis, Indiana location. All were part of the overall servicing operation and were impacted by the firm shifting health insurance transactional services to a foreign country.

Accordingly, the Department is amending this certification to include workers at the above mentioned locations of Wellpoint, Inc., Enterprise Provider Data Management Team. The intent of the Department's certification is to include all workers of the firm who were adversely affected by a shift of health insurance transactional services to a foreign country.

The amended notice applicable to TA–W–74,895 is hereby issued as follows:

All workers of Wellpoint, Inc., d/b/A Anthem Blue Cross & Blue Shield, Enterprise Provider Data Management Team, including on-site leased workers from Kelly Services and Jacobsen Group, Indianapolis, Indiana (TA–W–74,895), Wellpoint, Inc., d/b/a/ Anthem Health Plans of Kentucky, Enterprise Provider Data Management Team, Louisville, Kentucky (TA–W–74,895A), Wellpoint, Inc., Enterprise Provider Data Management Team, Saint Louis, Missouri (TA–W–74,895B), Wellpoint, Inc., d/b/a Anthem, Enterprise Provider Data Management Team, (Pewaukee), Waukesha, Wisconsin (TA–W–74,895C), Wellpoint, Inc., d/b/a Anthem, Enterprise Provider Data Management Team, Richmond, Virginia (TA–W–74,895D), Wellpoint, Inc., d/b/a Anthem East, Enterprise Provider Data Management Team, North Haven, Connecticut (TA–W–74,895E), Wellpoint, Inc., d/b/a Blue Cross Blue Shield of Georgia, Enterprise Provider Data Management Team, Atlanta, Georgia (TA–W–74,895F), Wellpoint, Inc., d/b/a Blue Cross Blue Shield of Georgia, Enterprise Provider Data Management Team, Columbus, Georgia (TA–W–74,895G), Wellpoint, Inc., d/b/a Anthem East, Enterprise Provider Data Management Team, South Portland, Maine (TA–W–74,895H), Wellpoint, Inc., d/b/a Anthem East, Enterprise Provider Data Management Team, Manchester, New Hampshire (TA–W–74,895I) Wellpoint, Inc., d/b/a Empire Blue Cross, Enterprise Provider Data Management Team, Albany, New York (TA–W–74,895J) Wellpoint, Inc., d/b/a Empire Blue Cross and Blue Shield, Enterprise Provider Data Management Team, Brooklyn, New York (TA–W–74,895K) Wellpoint, Inc., d/b/a Anthem, Enterprise Provider Data Management Team, Mason, Ohio (TA–W–74,895L), who became totally or partially separated from employment on or after November 15, 2009, through January 12, 2013, and all workers in the group threatened with total or partial separation from employment on the date of certification through two years from the date of certification, are eligible to apply for adjustment assistance under Chapter 2 of Title II of the Trade Act of 1974, as amended.

Signed in Washington, DC, this 30th day of March, 2011.

Michael W. Jaffe,

Certifying Officer, Office of Trade Adjustment Assistance.

[FR Doc. 2011–8306 Filed 4–6–11; 8:45 am]

BILLING CODE 4510–FN–P

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–73,303]

Weyerhaeuser Company, Corporate Headquarters Including On-Site Leased Workers From Volt Services, Adecco, Manpower, Express Personnel, and Tek Systems; Federal Way, Washington; Amended Certification Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with section 223 of the Trade Act of 1974, as amended ("Act"), 19 U.S.C. 2273, the Department of Labor issued a Certification of Eligibility to Apply for Worker Adjustment Assistance on June 2, 2010, applicable to workers of Weyerhaeuser Company, Corporate Headquarters, including on-site leased workers from Volt Services, Adecco, and Manpower, Federal Way, Washington. The workers supply corporate and administrative services for the firm. The notice was published in the **Federal Register** on June 16, 2010 (75 FR 34177). The notice was amended on November 18, 2010 to include on-site leased workers from Express Personnel. The notice was published in the **Federal Register** on December 7, 2010 (75 FR 76040).

At the request of the State agency, the Department reviewed the certification for workers of the subject firm. The company reports that workers leased from Tek Systems were employed on-site at the Federal Way, Washington location of Weyerhaeuser Company, Corporate Headquarters. The Department has determined that these workers were sufficiently under the control of Weyerhaeuser Company, Corporate Headquarters to be considered leased workers.

Based on these findings, the Department is amending this certification to include workers leased from Tek Systems working on-site at the Federal Way, Washington location of Weyerhaeuser Company, Corporate Headquarters.

The amended notice applicable to TA–W–73,303 is hereby issued as follows:

All workers of Weyerhaeuser Company, Corporate Headquarters, including on-site leased workers from Volt Services, Adecco, Manpower, Express Personnel, and Tek Systems, Federal Way, Washington, who became totally or partially separated from employment on or after January 7, 2009, through June 2, 2012, and all workers in the group threatened with total or partial separation from employment on the date of certification through two years from the date of certification, are eligible to apply for adjustment assistance under Chapter 2 of Title II of the Trade Act of 1974, as amended.

Signed at Washington, DC, this 28th day of March 2011.

Michael W. Jaffe,

Certifying Officer, Office of Trade Adjustment Assistance.

[FR Doc. 2011–8242 Filed 4–6–11; 8:45 am]

BILLING CODE 4510–FN–P

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–73,851]

Mueller Steam Specialty Formerly Known As Core Industries Including Workers Whose Unemployment Insurance (UI) Wages are Reported Through Watts Regulator, Watts Water Technologies Including On-Site Leased Workers From Staffing Alliance, Two Hawk Employment Agency and Robert Half Accountemps; St. Pauls, NC; Amended Certification Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with section 223 of the Trade Act of 1974, as amended ("Act"), 19 U.S.C. 2273, the Department of Labor issued a Certification of Eligibility to Apply for Worker Adjustment Assistance on October 7, 2010, applicable to workers of Mueller Steam Specialty, including on-site leased workers from Staffing Alliance, Two Hawk Employment Agency and Robert Half Accountemps, St. Pauls, North Carolina. The workers produce strainers and valves. The notice was published in the **Federal Register** on October 25, 2010 (75 FR 65519).

At the request of the State agency, the Department reviewed the certification for workers of the subject firm.

New information shows that workers separated from employment at the St. Pauls, North Carolina location of Mueller Steam Specialty had their wages reported through two separated unemployment insurance (UI) tax accounts under the names Core Industries and Watts Regulator, Watts Water Technologies.

Accordingly, the Department is amending this certification to properly reflex this matter.

The intent of the Department's certification is to include all workers the St. Pauls, North Carolina location of Mueller Steam Specialty, formerly known as Core Industries, including workers whose unemployment Insurance (UI) wages are reported through Watts Regulator, Watts Water Technologies who were adversely affected by increased imports of strainers and valves.

The amended notice applicable to TA–W–73,851 is hereby issued as follows:

All workers of Mueller Steam Specialty, formerly known as Core Industries, including workers whose unemployment insurance (UI) wages are reported through Watts regulator, Watts Water Technologies, including on-site leased workers from Staffing Alliance, Two Hawk Employment Agency and Robert Half Accountemps, St. Pauls, North Carolina, who became totally or partially separated from employment on or after April 5, 2009, through October 7, 2012, and all workers in the group threatened with total or partial separation from employment on date of certification through two years from the date of certification, are eligible to apply for adjustment assistance under Chapter 2 of Title II of the Trade Act of 1974, as amended.

Signed in Washington, DC, this 28th day of March 2011.

Michael W. Jaffe,

Certifying Officer, Office of Trade Adjustment Assistance.

[FR Doc. 2011–8236 Filed 4–6–11; 8:45 am]

BILLING CODE 4510–FN–P

DEPARTMENT OF LABOR

Employment and Training Administration

Amended Certification Regarding Eligibility To Apply for Worker Adjustment Assistance

TA–W–72,075 Assembly & Test Worldwide, Inc., Currently Known As ATW Automation, Inc., Livonia Michigan

TA–W–72,075A Assembly & Test Worldwide, Inc., Currently Known As ATW Automation, Inc., Saginaw, Michigan

In accordance with Section 223 of the Trade Act of 1974, as amended ("Act"), 19 U.S.C. 2273, the Department of Labor issued a Certification of Eligibility to Apply for Worker Adjustment Assistance on January 27, 2010, applicable to workers of Assembly & Test Worldwide, Inc., Livonia, Michigan, Saginaw, Michigan, Lebanon, Missouri and Dayton, Ohio. The workers design, engineer, manufacture and integrate custom component assembly and test systems. The notice was published in the **Federal Register** on March 5, 2010 (75 FR 10321). The notice was amended on April 6, 2010 to include the Lake Zurich, Illinois and the Shelton, Connecticut locations of the subject firm. The amended notice was published in the **Federal Register** on April 19, 2010 (75 FR 20387).

At the request of the State agency, the Department reviewed the certification for workers of the subject firm. The company reports that as the result of a January 2011 acquisition, the Livonia, Michigan and Saginaw, Michigan locations of Assembly & Test Worldwide, Inc., are currently known as ATW Automation, Inc. Some workers separated from employment at the Livonia Michigan and Saginaw, Michigan locations of Assembly & Test Worldwide, Inc., had their wages reported under a separate unemployment insurance (UI) tax account under the name ATW Automation, Inc.

Accordingly, the Department is amending this certification to show that the Livonia, Michigan and Saginaw, Michigan locations of Assembly & Test Worldwide, Inc., are currently known as ATA Automation, Inc.

The intent of the Department's certification is to include all workers of the subject firm who were adversely affected by the shift in production of custom component assembly and test systems to Brazil, China and Germany.

The amended notice applicable to TA–W–72,075 is hereby issued as follows:

All workers of Assembly & Test Worldwide, Inc., currently known as ATW Automation, Inc., Livonia, Michigan (TA–W–72,075); Assembly & Test Worldwide, Inc., currently known as ATW Automation, Inc., Saginaw, Michigan (TA–W–72,075A); Assembly & Test Worldwide, Inc., Lebanon, Missouri (TA–W–72,075B); Assembly & Test Worldwide, Inc., Dayton, Ohio (TA–W–72,075C); Assembly & Test Worldwide, Lake Zurich, Illinois (TA–W–72,075D); and Assembly & Test Worldwide, Shelton, Connecticut (TA–W–72,075E), who became totally or partially separated from employment on or after August 10, 2008, through January 27, 2012, and all workers in the group threatened with total or partial separation from employment on date of certification through two years from the date of certification, are eligible to apply for adjustment assistance under Chapter 2 of Title II of the Trade Act of 1974, as amended.

Signed at Washington, DC this 28th day of March 2011.

Michael W. Jaffe,

Certifying Officer, Office of Trade Adjustment Assistance.

[FR Doc. 2011–8241 Filed 4–6–11; 8:45 am]

BILLING CODE 4510–FN–P

DEPARTMENT OF LABOR

Employment and Training Administration

Notice of Determinations Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with Section 223 of the Trade Act of 1974, as amended (19 U.S.C. 2273) the Department of Labor herein presents summaries of determinations regarding eligibility to apply for trade adjustment assistance for workers by (TA–W) number issued during the period of *March 14, 2011 through March 18, 2011.*

In order for an affirmative determination to be made for workers of a primary firm and a certification issued regarding eligibility to apply for worker adjustment assistance, each of the group eligibility requirements of Section 222(a) of the Act must be met.

I. Under Section 222(a)(2)(A), the following must be satisfied:

(1) A significant number or proportion of the workers in such workers' firm have become totally or partially separated, or are threatened to become totally or partially separated;

(2) The sales or production, or both, of such firm have decreased absolutely; and

(3) One of the following must be satisfied:

(A) Imports of articles or services like or directly competitive with articles produced or services supplied by such firm have increased;

(B) Imports of articles like or directly competitive with articles into which one or more component parts produced by such firm are directly incorporated, have increased;

(C) Imports of articles directly incorporating one or more component parts produced outside the United States that are like or directly competitive with imports of articles incorporating one or more component

parts produced by such firm have increased;

(D) Imports of articles like or directly competitive with articles which are produced directly using services supplied by such firm, have increased; and

(4) The increase in imports contributed importantly to such workers' separation or threat of separation and to the decline in the sales or production of such firm; or

II. Section 222(a)(2)(B) all of the following must be satisfied:

(1) A significant number or proportion of the workers in such workers' firm have become totally or partially separated, or are threatened to become totally or partially separated;

(2) One of the following must be satisfied:

(A) There has been a shift by the workers' firm to a foreign country in the production of articles or supply of services like or directly competitive with those produced/supplied by the workers' firm;

(B) There has been an acquisition from a foreign country by the workers' firm of articles/services that are like or directly competitive with those produced/supplied by the workers' firm; and

(3) The shift/acquisition contributed importantly to the workers' separation or threat of separation.

In order for an affirmative determination to be made for adversely affected workers in public agencies and a certification issued regarding eligibility to apply for worker adjustment assistance, each of the group eligibility requirements of Section 222(b) of the Act must be met.

(1) A significant number or proportion of the workers in the public agency have become totally or partially separated, or are threatened to become totally or partially separated;

(2) The public agency has acquired from a foreign country services like or directly competitive with services which are supplied by such agency; and

(3) The acquisition of services contributed importantly to such workers' separation or threat of separation.

In order for an affirmative determination to be made for adversely affected secondary workers of a firm and a certification issued regarding eligibility to apply for worker adjustment assistance, each of the group eligibility requirements of Section 222(c) of the Act must be met.

(1) A significant number or proportion of the workers in the workers' firm have become totally or partially separated, or are threatened to become totally or partially separated;

(2) The workers' firm is a Supplier or Downstream Producer to a firm that employed a group of workers who received a certification of eligibility under Section 222(a) of the Act, and such supply or production is related to the article or service that was the basis for such certification; and

(3) Either—

(A) The workers' firm is a supplier and the component parts it supplied to the firm described in paragraph (2) accounted for at least 20 percent of the production or sales of the workers' firm; or

(B) A loss of business by the workers' firm with the firm described in paragraph (2) contributed importantly to the workers' separation or threat of separation.

In order for an affirmative determination to be made for adversely affected workers in firms identified by the International Trade Commission and a certification issued regarding eligibility to apply for worker adjustment assistance, each of the group eligibility requirements of Section 222(f) of the Act must be met.

(1) The workers' firm is publicly identified by name by the International Trade Commission as a member of a domestic industry in an investigation resulting in—

(A) An affirmative determination of serious injury or threat thereof under section 202(b)(1);

(B) An affirmative determination of market disruption or threat thereof under section 421(b)(1); or

(C) An affirmative final determination of material injury or threat thereof under section 705(b)(1)(A) or 735(b)(1)(A) of the Tariff Act of 1930 (19 U.S.C. 1671d(b)(1)(A) and 1673d(b)(1)(A));

(2) The petition is filed during the 1-year period beginning on the date on which—

(A) A summary of the report submitted to the President by the International Trade Commission under section 202(f)(1) with respect to the affirmative determination described in paragraph (1)(A) is published in the **Federal Register** under section 202(f)(3); or

(B) Notice of an affirmative determination described in subparagraph (1) is published in the **Federal Register**; and

(3) The workers have become totally or partially separated from the workers' firm within—

(A) The 1-year period described in paragraph (2); or

(B) Notwithstanding section 223(b)(1), the 1-year period preceding the 1-year period described in paragraph (2).

Affirmative Determinations for Worker Adjustment Assistance

The following certifications have been issued. The date following the company name and location of each determination references the impact date for all workers of such determination.

The following certifications have been issued. The requirements of Section 222(a)(2)(A) (increased imports) of the Trade Act have been met.

TA–W No.	Subject firm	Location	Impact date
74,929	John C. Lincoln Health Network, Medical Transcription Department	Phoenix, AZ	November 6, 2009.
75,118	Fairbanks Morse Engine, Enpro Industries	Beloit, WI	January 18, 2010.
75,222	American Standard America, Inc., d/b/a American Standard Brands; Bath Lifestyles Division.	Salem, OH	June 20, 2010.
75,295	Katahdin Paper Company, LLC, Leased Workers of Kelly Services	East Millinocket, ME	February 14, 2010.
75,295A	Katahdin Paper Company, LLC, Leased Workers of Kelly Services	Millinocket, ME	February 14, 2010.

The following certifications have been issued. The requirements of Section 222(a)(2)(B) (shift in production or services) of the Trade Act have been met.

TA–W No.	Subject firm	Location	Impact date
74,803	Clinicient, Inc., Accounting and Billing Department; Leased Workers and Tele-workers; etc.	Portland, OR	October 28, 2009.
74,906	MOL (America) , Inc.	Long Beach, CA	November 19, 2009.
75,065	Bank of America, N.A., Global Trade Div.; Bank of America Corp.; Leased Workers and Tele-workers, etc.	Los Angeles, CA	January 3, 2010.
75,085	Hyde Tools, Inc., Hyde Group, Inc., Leased Workers from Diamond Staffing	Southbridge, MA	January 29, 2010.
75,121	Maine Industrial Tire, LLC, Workers Wages Reported under GPX International Tire Corp; Leased Workers, etc.	Gorham, ME	January 19, 2010.
75,148	United Parcel Service, Inc., D/B/A UPS; Des Moines Billing Site	Des Moines, IA	January 28, 2010.
75,156	Abbott Point of Care	Princeton, NJ	January 31, 2010.
75,196	PriceWaterhouseCoopers LLP, Internal Firm Services Division, Client Account Administrators.	St. Louis, MO	February 8, 2010.
75,230	Evergreen Solar, Inc., Devens Manufacturing; Leased Workers Advantage Technical Resourcing and Kelly.	Devens, MA	February 10, 2010.
75,230A	Evergreen Solar, Inc., Research and Dev.; Leased Workers Advantage Technical Resourcing and Kelly.	Marlboro, MA	February 10, 2010.
75,230B	Evergreen Solar, Inc., Corporate HQ; Leased Wkrs Advantage Technical Resourcing and Kelly.	Marlboro, MA	February 10, 2010.
75,245	Biomerieux, Inc., PPM Division, Leased Workers Adecco, Employment Services and Kelly Services.	Wilsonville, OR	February 11, 2010.
75,274	Abbott Laboratories, Diagnostics Division, Leased Workers Advanced Clinical Services, etc.	Abbott Park, IL	February 14, 2010.
75,275	Wellpoint, Inc., Cash Applications, WellPoint Co., BC of CA, Leased Workers Bender, etc.	Woodland Hills, CA	February 14, 2010.
75,280	YKK Snap Fasteners America Inc., Leased Workers from Employment Plus and Nesco.	Lawrence-burg, KY	February 14, 2010.
75,282	I.C. System, Inc., Transfer Agents	Mason City, IA	February 14, 2010.
75,284	CGI Technologies and Solutions, Inc., Processing Services	Andover, MA	February 14, 2010.
75,285	VisLink, Inc., VisLink, PLC; Leased Workers from Bradley Hume, Black Diamond Networks, etc.	North Billerica, MA	February 14, 2010.
75,285A	VisLink, Inc. (PMR), VisLink, PLC	Vista, CA	February 14, 2010.
75,300	Key Plastics, LLC, Exterior Division; Leased Workers from All Star Staffing	Hartford City, IN	February 14, 2010.
75,309	Dallas Group of America, Inc.	Jefferson-ville, IN	February 14, 2010.

The following certifications have been issued. The requirements of Section 222(c) (supplier to a firm whose workers are certified eligible to apply for TAA) of the Trade Act have been met.

TA–W No.	Subject firm	Location	Impact date
75,259	Four Star Plastics	Richmond, KY	February 11, 2010.

Negative Determinations for Worker Adjustment Assistance

In the following cases, the investigation revealed that the eligibility criteria for worker adjustment assistance have not been met for the reasons specified.

The investigation revealed that the criterion under paragraph (a)(1), or (b)(1), or (c)(1)(employment decline or threat of separation) of section 222 has not been met.

TA–W No.	Subject firm	Location	Impact date
74,911	Emerson Network Power, Connectivity Solutions Division.	Bannockburn, IL.	

The investigation revealed that the criteria under paragraphs (a)(2)(A) (increased imports) and (a)(2)(B) (shift in production or services to a foreign country) of section 222 have not been met.

TA–W No.	Subject firm	Location	Impact date
74,705	Moll Industries	Seagrove, NC.	
74,904	Jacobs Engineering Group, Inc., Southern Region.	Cypress, CA.	

The investigation revealed that the criteria under paragraphs (b)(2) and (b)(3) (public agency acquisition of services from a foreign country) of section 222 have not been met.

TA–W No.	Subject firm	Location	Impact date
75,184	Maine Military Authority, Defense, Veterans and Emergency Management Division.	Augusta and Limestone, ME.	

Determinations Terminating Investigations of Petitions for Worker Adjustment Assistance

After notice of the petitions was published in the **Federal Register** and on the Department's Web site, as required by Section 221 of the Act (19 U.S.C. 2271), the Department initiated investigations of these petitions.

The following determinations terminating investigations were issued in cases where these petitions were not

filed in accordance with the requirements of 29 CFR 90.11. Every petition filed by workers must be signed by at least three individuals of the petitioning worker group. Petitioners separated more than one year prior to the date of the petition cannot be covered under a certification of a petition under Section 223(b), and therefore, may not be part of a petitioning worker group. For one or more of these reasons, these petitions were deemed invalid.

TA–W No.	Subject firm	Location	Impact date
75,250	Burner Systems International	Chattanooga, TN.	

The following determinations terminating investigations were issued because the petitioning groups of workers are covered by active certifications. Consequently, further investigation in these cases would serve no purpose since the petitioning group of workers cannot be covered by more than one certification at a time.

TA–W No.	Subject firm	Location	Impact date
75,191	Faribo Woolens, Inc.	Faribault, MN.	

I hereby certify that the aforementioned determinations were issued during the period of *March 14, 2011 through March 18, 2011.* Copies of these determinations may be requested under the Freedom of Information Act. Requests may be submitted by fax, courier services, or mail to FOIA Disclosure Officer, Office of Trade Adjustment Assistance (ETA), U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210 or *tofoiarequest@dol.gov.* These determinations also are available on the Department's Web site at *http://www.doleta.gov/tradeact* under the searchable listing of determinations.

Dated: March 29, 2011.

Michael W. Jaffe,

Certifying Officer, Office of Trade Adjustment Assistance.

[FR Doc. 2011–8239 Filed 4–6–11; 8:45 am]

BILLING CODE 4510–FN–P

DEPARTMENT OF LABOR

Employment and Training Administration

Investigations Regarding Certifications of Eligibility To Apply for Worker Adjustment Assistance and Alternative Trade Adjustment Assistance

Petitions have been filed with the Secretary of Labor under section 221 (a) of the Trade Act of 1974 ("the Act") and are identified in the Appendix to this notice. Upon receipt of these petitions, the Director of the Division of Trade Adjustment Assistance, Employment and Training Administration, has instituted investigations pursuant to section 221 (a) of the Act.

The purpose of each of the investigations is to determine whether the workers are eligible to apply for adjustment assistance under Title II, Chapter 2, of the Act. The investigations will further relate, as appropriate, to the determination of the date on which total or partial separations began or threatened to begin and the subdivision of the firm involved.

The petitioners or any other persons showing a substantial interest in the subject matter of the investigations may request a public hearing, provided such request is filed in writing with the Director, Office of Trade Adjustment Assistance, at the address shown below, not later than April 18, 2011.

Interested persons are invited to submit written comments regarding the subject matter of the investigations to the Director, Office of Trade Adjustment Assistance, at the address shown below, not later than April 18, 2011.

The petitions filed in this case are available for inspection at the Office of the Director, Office of Trade Adjustment Assistance, Employment and Training Administration, U.S. Department of Labor, Room N–5428, 200 Constitution Avenue, NW., Washington, DC 20210.

Signed at Washington, DC this 29th day of March 2011.

Michael W. Jaffe,

Certifying Officer, Office of Trade Adjustment Assistance.

APPENDIX

[19 TAA petitions instituted between 3/14/11 and 3/18/11]

TA–W	Subject firm (petitioners)	Location	Date of institution	Date of petition
80038	Fac-Ette Manufacturing Inc. (Company)	Leland, NC	03/14/11	03/10/11
80039	Michael Wrights Framing Concepts, Inc. (Company)	Kissimmee, FL	03/14/11	03/11/11
80040	Times Fiber Communication (Union)	Chatham, VA	03/15/11	03/15/11
80041	Quad Graphics (Union)	Depew, NY	03/15/11	03/15/11
80042	Capstar Drilling, Inc. (Company)	Wooster, OH	03/15/11	03/11/11
80043	The Smead Manufacturing Company (State/One-Stop)	Hastings, MN	03/15/11	03/14/11
80044	The Huck Group (Union)	Quincy, IL	03/15/11	03/14/11
80045	Brookline Furniture, LLC (Company)	High Point, NC	03/15/11	03/07/11
80046	General Aluminum (Company)	Rome, GA	03/16/11	03/14/11
80047	Cenveo (State/One-Stop)	Springfield, MA	03/16/11	03/14/11
80048	Hancock Company (Company)	Ashland, PA	03/16/11	03/15/11
80049	E. J. Victor, Inc. (Company)	Morganton, NC	03/16/11	03/11/11
80050	Marelco Power Systems, Inc. (Company)	Howell, MI	03/17/11	03/15/11
80051	Disston Company (State/One-Stop)	South Deerfield, MA	03/17/11	03/10/11
80052	Lancaster Eagle Gazette (Workers)	Lancaster, OH	03/17/11	11/30/10
80053	Shiloh Steel Fabricators, Inc. (State/One-Stop)	Bethel Heights, AR	03/18/11	03/17/11
80054	W.M. Glenn Construction (Company)	Durham, NC	03/18/11	03/17/11
80055	Milbank Manufacturing Company (Company)	Kokomo, IN	03/18/11	03/16/11
80056	Wellpoint, Inc. (Workers)	Mason, OH	03/18/11	03/17/11

[FR Doc. 2011–8237 Filed 4–6–11; 8:45 am]

BILLING CODE 4510–FN–P

DEPARTMENT OF LABOR

Employment and Training Administration

Investigations Regarding Certifications of Eligibility To Apply for Worker Adjustment Assistance and Alternative Trade Adjustment Assistance

Petitions have been filed with the Secretary of Labor under section 221(a) of the Trade Act of 1974 ("the Act") and are identified in the Appendix to this notice. Upon receipt of these petitions, the Director of the Division of Trade Adjustment Assistance, Employment and Training Administration, has instituted investigations pursuant to section 221(a) of the Act.

The purpose of each of the investigations is to determine whether the workers are eligible to apply for adjustment assistance under Title II, Chapter 2, of the Act. The investigations will further relate, as appropriate, to the determination of the date on which total or partial separations began or threatened to begin and the subdivision of the firm involved.

The petitioners or any other persons showing a substantial interest in the subject matter of the investigations may request a public hearing, provided such request is filed in writing with the Director, Office of Trade Adjustment Assistance, at the address shown below, not later than April 18, 2011.

Interested persons are invited to submit written comments regarding the subject matter of the investigations to the Director, Office of Trade Adjustment Assistance, at the address shown below, not later than April 18, 2011.

The petitions filed in this case are available for inspection at the Office of the Director, Office of Trade Adjustment Assistance, Employment and Training Administration, U.S. Department of Labor, Room N–5428, 200 Constitution Avenue, NW., Washington, DC 20210.

Signed at Washington, DC this 29th day of March 2011.

Michael W. Jaffe,

Certifying Officer, Office of Trade Adjustment Assistance.

APPENDIX

[17 TAA petitions instituted between 2/28/11 and 3/4/11]

TA–W	Subject firm (petitioners)	Location	Date of institution	Date of petition
80011	Allegheny Dimension, LLC (Company)	Petersburg, WV	02/28/11	02/28/11
80012	Siemens (Workers)	Malvern, PA	02/28/11	02/23/11
80013	Robb and Stucky Limited, LLP (Company)	Fort Myers, FL	02/28/11	02/25/11
80014	Geneon Entertainment (USA), Inc. (Company)	Santa Monica, CA	03/01/11	03/01/11
80015	ACS (State/One-Stop)	Liberty, KY	03/01/11	02/22/11
80016	Quad Graphics (Company)	Mt. Morris, IL	03/01/11	02/09/11
80017	Project Resources Group, Inc. (State/One-Stop)	La Junta, CO	03/02/11	02/25/11
80018	Cranston Print Works Company (Company)	Cranston, RI	03/02/11	03/01/11
80019	Sea Gull Lighting Products LLC (Workers)	Riverside, NJ	03/02/11	03/01/11
80020	Hankook Tire Co., LTD (Company)	Uniontown, OH	03/02/11	03/01/11
80021	Pitney Bowes (State/One-Stop)	Purchase, NY	03/02/11	03/01/11
80022	Sulberg USA (Union)	Havana, IL	03/03/11	03/02/11
80023	Fenton Art Glass Company (Union)	Willamstown, WV	03/03/11	03/01/11
80024	Midi Music Center, Inc. (Company)	LaGrange Park, IL	03/03/11	02/16/11
80025	Samuels Jewelers (Worker)	Austin, TX	03/03/11	03/02/11
80026	Computer Task Group, Inc. (Workers)	Buffalo, NY	03/04/11	03/02/11
80027	William Kelly & Sons California, Inc. (State/One-Stop)	El Cajon, CA	03/04/11	03/03/11

[FR Doc. 2011–8238 Filed 4–6–11; 8:45 am]

BILLING CODE 4510–FN–P

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–73,579]

Consolidated Glass and Mirror Corporation, a Subsidiary of Guardian Industries Corporation, Galax, VA; Notice of Negative Determination on Reconsideration

On September 21, 2010, the Department of Labor issued an Affirmative Determination Regarding Application for Reconsideration for the workers and former workers of Consolidated Glass and Mirror Corporation, a Subsidiary of Guardian Industries Corporation, Galax, Virginia (subject firm). The Notice was published in the **Federal Register** on September 29, 2010 (75 FR 60139). Workers are engaged in employment related to the production of mirrored and/or laminated glass articles used in furniture, automotives and architecture.

Pursuant to 29 CFR 90.18(c), reconsideration may be granted under the following circumstances:

(1) If it appears on the basis of facts not previously considered that the determination complained of was erroneous;

(2) If it appears that the determination complained of was based on a mistake in the determination of facts not previously considered; or

(3) If in the opinion of the Certifying Officer, a mis-interpretation of facts or of the law justified reconsideration of the decision.

The initial investigation resulted in a negative determination based on the findings that the subject firm did not, during the period under investigation, shift to/acquire from a foreign country the production of articles like or directly competitive with the mirrored and/or laminated glass products manufactured by the workers; that increased imports of articles like or directly competitive with the mirrored and/or laminated glass products manufactured by the workers did not contribute importantly to the workers' separation, or threat of separation; and that the workers did not produce a component part that was directly used in the production of an article or the supply of service by a firm that employed a worker group that is eligible to apply for Trade Adjustment Assistance (TAA) based on the aforementioned article.

The request for reconsideration, filed by former workers of the subject firm, stated that the Galax, Virginia facility is owned by "Guardian Industries, a

company that has plants all over the world" and identified customers with worker groups eligible to apply for TAA ("Pulaski Furniture certified 1/17/07, Woodmaster certified 5/19/06, Ridgeway Furniture certified 11/6/07, Hooker Furniture certified 10/5/06, American Pride certified 8/25/09 and Stanley Furniture 5/5/10"). The workers also supplied an article, dated February 24, 2010, that stated "Guardian is a diversified global manufacturing company * * * Guardian * * * operates facilities throughout North America, Europe, South America, Asia, Africa, and the Middle East."

During the reconsideration investigation, the Department obtained from the subject firm additional information related to those customers identified in the request for reconsideration that both employed workers groups eligible to apply for TAA and conducted business with the subject firm during the relevant period.

Information obtained during the reconsideration investigation confirmed that, during the relevant period, the subject firm did not shift to/acquire from a foreign country import articles like or directly competitive with mirrored and/or laminated glass products manufactured by the subject workers. Further, the subject firm confirmed that, on a firm-wide basis, they do not import articles like or directly competitive with mirrored/laminated glass products nor did the subject firm import articles directly incorporating component parts produced outside the United States that are like or directly competitive with imports of articles incorporating one or more component parts produced by the subject firm.

While the subject firm may have produced and supplied a component part used by a firm that both employed a worker group that is currently eligible to apply for TAA and directly incorporated the glass products in the production of that article that was the basis for the TAA certification, information obtained during the reconsideration investigation revealed that the customer accounted for an insignificant percentage of the subject firm sales. Therefore, the Department confirms that the subject workers are not adversely affected secondary workers.

Conclusion

After reconsideration, I affirm the original notice of negative determination of eligibility to apply for worker adjustment assistance for workers and former workers of Consolidated Glass and Mirror Corporation, a Subsidiary of Guardian Industries Corporation, Galax, Virginia.

Signed in Washington, DC, on this 29th day of March, 2011.

Del Min Amy Chen,

Certifying Officer, Office of Trade Adjustment Assistance.

[FR Doc. 2011–8309 Filed 4–6–11; 8:45 am]

BILLING CODE 4510–FN–P

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–73,458]

Chrysler Financial Services Americas, LLC, a Subsidiary of FinCo Intermediate Holding Co., LLC, Troy Customer Contact Center; Troy, MI; Notice of Negative Determination on Reconsideration

On September 21, 2010, the Department of Labor issued an Affirmative Determination Regarding Application for Reconsideration for the workers and former workers of Chrysler Financial Services Americas, LLC, a subsidiary of FinCo Intermediate Holding Co., LLC, Troy Customer Contact Center, Troy, Michigan (subject firm). The Department's Notice was published in the **Federal Register** on September 29, 2010 (75 FR 60138).

The subject worker group is engaged in employment related to the supply of automotive-related financial services to dealers and consumers, including retail and wholesale financing, remarketing, and customer service and collections.

Pursuant to 29 CFR 90.18(c), reconsideration may be granted under the following circumstances:

(1) If it appears on the basis of facts not previously considered that the determination complained of was erroneous;

(2) if it appears that the determination complained of was based on a mistake in the determination of facts not previously considered; or

(3) if in the opinion of the Certifying Officer, a mis-interpretation of facts or of the law justified reconsideration of the decision.

The initial investigation resulted in a negative determination based on the findings that there have not been increased imports of services like or directly competitive with the financial services supplied by the subject firm, and there has not been a shift in the supply of services by the firm to a foreign country. In addition, the subject firm is not a supplier or downstream producer to a firm that employed a worker group eligible to apply for Trade Adjustment Assistance (TAA). For worker groups that supply a service instead of producing a component part, the term "supplier" means a firm that supplies directly to another firm services used in the production of articles or in the supply of services, as the case may be, that were the basis for the certification of eligibility.

The request for reconsideration states that "the workers at Chrysler Financial Services, Troy, Michigan were engaged in activities that initiated the need to produce automotive vehicles and automotive vehicle parts * * * multiple production facilities within the Chrysler Group has lost production due to imports which resulted in the decrease in sales."

Information collected during the initial investigation confirmed that another domestic entity would be the new financial arm for Chrysler, LLC, and that, as a result, certain functions performed by the subject workers have been realigned domestically.

During the reconsideration investigation, the Department received information that confirmed that the subject firm did not shift to nor acquire from a foreign country the supply of services like or directly competitive with the services supplied by the subject workers.

Further, the Department determined that the services supplied by the subject workers were not used in the production of an article. Rather, the financial services supplied by the subject worker group are post-production.

Conclusion

After reconsideration, I affirm the original notice of negative determination of eligibility to apply for worker adjustment assistance for workers and former workers of Chrysler Financial Services Americas, LLC, a subsidiary of FinCo Intermediate Holding Co., LLC, Troy Customer Contact Center, Troy, Michigan.

Signed in Washington, DC, on this 29th day of March, 2011.

Del Min Amy Chen,

Certifying Officer, Office of Trade Adjustment Assistance.

[FR Doc. 2011–8308 Filed 4–6–11; 8:45 am]

BILLING CODE 4510–FN–P

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–70,110]

Columbia Forest Products, Inc., Presque Isle Division; Presque Isle, Maine; Notice of Revised Determination on Reconsideration

On October 7, 2010, the Department of Labor issued an Affirmative Determination Regarding Application for Reconsideration for the workers and former workers of Columbia Forest Products, Inc., Presque Isle Division, Presque Isle, Maine (subject firm). The Department's Notice of determination was published in the **Federal Register** on October 25, 2010 (75 FR 65514). Workers produced hardwood veneer. The worker group does not include leased workers or workers supplied from a temporary staffing agency.

A careful review of the previously-submitted customer surveys and new information obtained during the reconsideration investigation, including U.S. aggregate imports of like or directly competitive articles and other available material, revealed that, during the period of investigation, imports of articles like or directly competitive with hardwood veneer produced by the subject firm have increased, and that the increased imports of hardwood veneer (or like or directly competitive articles) contributed importantly to the worker group separations and sales/production declines at the subject firm.

Conclusion

After careful review of the additional facts obtained during the reconsideration investigation, I determine that workers of Columbia Forest Products, Inc., Presque Isle Division, Presque Isle, Maine, who are engaged in employment related to the production of hardwood veneer, meet the worker group certification criteria under Section 222(a) of the Act, 19 U.S.C. 2272(a). In accordance with Section 223 of the Act, 19 U.S.C. 2273, I make the following certification:

All workers of Columbia Forest Products, Inc., Presque Isle Division, Presque Isle, Maine, who became totally or partially separated from employment on or after May 18, 2008, through two years from the date of this revised certification, and all workers in the group threatened with total or partial separation from employment on date of certification through two years from the date of certification, are eligible to apply for adjustment assistance under Chapter 2 of Title II of the Trade Act of 1974, as amended.

Signed in Washington, DC this 23rd day of March, 2011.

Del Min Amy Chen,

Certifying Officer, Office of Trade Adjustment Assistance.

[FR Doc. 2011–8240 Filed 4–6–11; 8:45 am]

BILLING CODE 4510–FN–P

NATIONAL FOUNDATION ON THE ARTS AND HUMANITIES

Submission for OMB Review: Comment Request

AGENCY: National Endowment for the Humanities.

ACTION: Notice.

SUMMARY: The National Endowment for the Humanities (NEH) has submitted the following public information collection request (ICR) to the Office of Management and Budget (OMB) for review and approval as required by the provisions of the Paperwork Reduction Act of 1995 (Pub. L. 104–13, 44 U.S.C. chapter 35). Copies of this ICR, with applicable supporting documentation, may be obtained by calling Susan G. Daisey, Director, Office of Grant Management, the National Endowment for the Humanities (202–606–8494) or may be requested by e-mail to *sdaisey@neh.gov*. Comments should be sent to the Office of Information and Regulatory Affairs, Attn: OMB Desk Officer for the National Endowment for the Humanities, Office of Management and Budget, Room 10235, Washington, DC 20503 (202–395–7316), within 30 days from the date of this publication in the **Federal Register**.

SUPPLEMENTARY INFORMATION: The Office of Management and Budget (OMB) is particularly interested in comments which: (1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Enhance the quality, utility, and clarity of the information to be collected; and (4) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submissions of responses.

Agency: National Endowment for the Humanities.

Title of Proposal: General Clearance Authority to Develop Evaluation Instruments for the National Endowment for the Humanities.

OMB Number: N/A.

Affected Public: NEH grantees.

Total Respondents: 1,000.

Frequency of Collection: On occasion.

Total Responses: 1,000.

Average Time per Response: 30 minutes.

Estimated Total Burden Hours: 500 hours.

Total Annualized capital/startup costs: 0.

Total annual costs (operating/maintaining systems or purchasing services): 0.

Description: The NEH is seeking a general clearance authority to develop evaluation instruments for its grant programs. These evaluation instruments will be used to collect information from NEH grantees from one to three years after the grantee has submitted the final performance report.

FOR FURTHER INFORMATION CONTACT: Ms. Susan G. Daisey, Director, Office of Grant Management, National Endowment for the Humanities, 1100 Pennsylvania Avenue, NW., Room 311, Washington, DC 20506, or by e-mail to: *sdaisey@neh.gov.* Telephone: 202–606–8494.

Carole Watson,

Deputy Chairman.

[FR Doc. 2011–8224 Filed 4–6–11; 8:45 am]

BILLING CODE 7536–01–P

NATIONAL SCIENCE FOUNDATION

Notice of Intent to Seek Approval To Extend a Current Information Collection

AGENCY: National Science Foundation.

ACTION: Notice and request for comments.

SUMMARY: The National Science Foundation (NSF) is announcing plans to request clearance of this collection. In accordance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 (Pub. L. 104–13), we are providing an opportunity for public comment on this action. After obtaining and considering public comment, NSF will prepare the submission requesting that OMB approve clearance of this collection for no longer than 3 years.

DATES: Written comments on this notice must be received by June 6, 2011 to be assured of consideration. Comments received after that date will be considered to the extent practicable.

ADDRESSES: Written comments regarding the information collection and requests for copies of the proposed information collection request should be addressed to Suzanne Plimpton, Reports Clearance Officer, National Science Foundation, 4201 Wilson Blvd., Rm. 295, Arlington, VA 22230, or by e-mail to *splimpto@nsf.gov.*

FOR FURTHER INFORMATION CONTACT: Contact Suzanne H. Plimpton, Reports Clearance Officer, National Science Foundation, 4201 Wilson Boulevard, Suite 295, Arlington, Virginia 22230; telephone (703) 292–7556; or send e-mail to *splimpto@nsf.gov.* Individuals who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 between 8 a.m. and 8 p.m., Eastern time, Monday through Friday.

SUPPLEMENTARY INFORMATION:

Title of Collection: Application for NATO Advanced Study Institutes Travel Award and NATO Advanced Study Institutes Travel Award Report Form.

OMB Approval Number: 3145–0001.

Expiration Date of Approval: June 30, 2011.

Type of Request: Intent to seek approval to extend a current information collection for three years.

Abstract: The North Atlantic Treaty Organization (NATO) initiated its Advanced Study Institutes Program in 1958 modeled after a small number of very successful summer science "courses" that were held in Europe and that sought to rebuild Europe's science strength following World War II. The goal was to bring together both students and researchers from the leading centers of research in highly targeted fields of science and engineering to promote the "American" approach to advanced learning, spirited give-and-take between students and teachers, that was clearly driving the rapid growth of U.S. research strength. Today the goal remains the same; but due to the expansion of NATO, each year an increasing number of ASIs are held in NATO Partner Countries along with those held in NATO Member Countries. In the spirit of cooperation with this important activity, the Foundation inaugurated in 1959 a small program of travel grants for advanced graduate students to assist with the major cost of such participation, that of transatlantic travel. It remains today a significant means for young scientists and engineers to develop contact with their peers throughout the world in their respective fields of specialization.

The Advanced Study Institutes (ASI) travel awards are offered to advanced graduate students, to attend one of the NATO's ASIs held in the NATO-member and partner countries of Europe. The NATO ASI program is targeted to those individuals nearing the completion of their doctoral studies in science, technology, engineering and mathematics (STEM) who can take advantage of opportunities to become familiar with progress in their respective fields of specialization in other countries.

The Division of Graduate Education (DGE) in the Education and Human Resources (EHR) Directorate administers the NATO ASI Travel Awards Program. The following describes the procedures for the administration of the Foundation's NATO Advanced Study Institute (ASI) Travel Awards, which provide travel support for a number of U.S. graduate students to attend the ASIs scheduled for Europe.

• Advanced Study Institute Determination

Once NATO has notified DGE that the schedule of institutes is final, and DGE has received the descriptions of each institute, DGE determines which institutes NSF will support. The ASI travel award program supports those institutes that offer instruction in the STEM fields traditionally supported by NSF as published in *Guide to Programs.* The program will not support institutes that deal with clinical topics, biomedical topics, or topics that have disease-related goals. Examples of areas of research that will not be considered are epidemiology; toxicology; the development or testing of drugs or procedures for their use; diagnosis or treatment of physical or mental disease, abnormality, or malfunction in human beings or animals; and animal models of such conditions. However, the program does support institutes that involve research in bioengineering, with diagnosis or treatment-related goals that apply engineering principles to problems in biology and medicine while advancing engineering knowledge. The program also supports bioengineering topics that aid persons with disabilities. Program officers from other Divisions in NSF will be contacted should scientific expertise outside of DGE be required in the determination process.

• Solicitation for Nominations

Following the final determination as to which Advanced Study Institutes NSF will support, DGE contacts each institute director to ask for a list of up to 5 nominations to be considered for NSF travel support.

• DGE/EHR Contact With the Individuals Nominated

Each individual who is nominated by a director will be sent the rules of eligibility, information about the amount of funding available, and the forms (NSF Form 1379, giving our Division of Financial Management (DFM) electronic banking information; NSF Form 1310 (already cleared), and NSF Form 192 (Application for International Travel Grant)) necessary for our application process.

• The Funding Process

Once an applicant has been selected to receive NSF travel award support, his or her application is sent to DFM for funding. DFM electronically transfers the amount of $1000 into the bank or other financial institution account identified by the awardee.

Our plan is to have the $1000 directly deposited into the awardee's account prior to the purchase of their airline ticket. An electronic message to the awardee states that NSF is providing support in the amount of $1000 for transportation and miscellaneous expenses. The letter also states that the award is subject to the conditions in F.L. 27, *Attachment to International Travel Grant,* which states the U.S. flag-carrier policy.

As a follow-up, each ASI director may be asked to verify whether all NSF awardees attended the institute. If an awardee is identified as not utilizing the funds as prescribed, we contact the awardee to retrieve the funds. However, if our efforts are not successful, we will forward the awardee's name to the Division of Grants and Agreements (DGA), which has procedures to deal with that situation.

We also ask the awardee to submit a final report on an NSF Form 250, which we provide as an attachment to the electronic award message.

• Selection of Awardees

The criteria used to select NSF Advanced Study Institute travel awardees are as follows:

1. The applicant is an advanced graduate student.

2. We shall generally follow the order of the nominations, listed by the director of the institute, within priority level.

3. Those who have not attended an ASI in the past will have a higher priority than those who have.

4. Nominees from different institutions and research groups have higher priority than those from the same institution or research group. (Typically, no more than one person is invited from a school or from a research group.)

Use of the Information: For NSF Form 192, information will be used in order to verify eligibility and qualifications for the award. For NSF Form 250, information will be used to verify attendance at Advanced Study Institute and will be included in Division reports.

Estimate of Burden: Form 192—1.5 hours; Form 250—2 hours

Respondents: Individuals.

Estimated Number of Responses per Award: 150 responses, broken down as follows: For NSF Form 250, 75 respondents; for NSF Form 192, 75 respondents.

Estimated Total Annual Burden on Respondents: 262.5 hours, broken down by 150 hours for NSF Form 250 (2 hours per 75 respondents); and 112.5 hours for NSF Form 192 (1.5 hours per 75 respondents).

Frequency of Responses: Annually.

Comments: Comments are invited on (a) whether the proposed collection of information is necessary for the proper performance of the functions of the Agency, including whether the information shall have practical utility; (b) the accuracy of the Agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information on respondents, including through the use of automated collection techniques or other forms of information technology; or (d) ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Dated: April 4, 2011.

Suzanne H. Plimpton,

Reports Clearance Officer, National Science Foundation.

[FR Doc. 2011–8277 Filed 4–6–11; 8:45 am]

BILLING CODE 7555–01–P

NUCLEAR REGULATORY COMMISSION

[Docket Nos. 50–277 and 50–278; NRC–2010–0303]

Exelon Generation Company, LLC, Peach Bottom Atomic Power Station, Unit Nos. 2 and 3; Exemption

1.0 Background

Exelon Generation Company, LLC (the licensee, Exelon) is the holder of Renewed Facility Operating License Nos. DPR–44 and DPR–56, which authorizes operation of the Peach Bottom Atomic Power Station (PBAPS), Units 2 and 3. The license provides, among other things, that the facility is subject to all rules, regulations, and orders of the Nuclear Regulatory Commission (NRC, the Commission) now or hereafter in effect.

The facility consists of two boiling-water reactors located partly in Peach Bottom Township, York County, partly in Drumore Township, Lancaster County, and partly in Fulton Township, Lancaster County, in southeastern Pennsylvania.

2.0 Request/Action

Title 10 of the *Code of Federal Regulations* (10 CFR), Part 50, Section 50.48(b), requires that nuclear power plants that were licensed before January 1, 1979, satisfy the requirements of 10 CFR Part 50, Appendix R, "Fire Protection Program for Nuclear Power Facilities Operating Prior to January 1, 1979," Section III.G, "Fire protection of safe shutdown capability." PBAPS, Units 2 and 3 were licensed to operate prior to January 1, 1979. As such, the licensee's Fire Protection Program (FPP) must provide the established level of protection as intended by Section III.G of 10 CFR Part 50, Appendix R.

By letter dated March 6, 2009, "Request for Exemption from 10 CFR 50, Appendix R, Section III.G, 'Fire Protection of Safe Shutdown Capability'" available at Agencywide Documents Access and Management System (ADAMS), Accession No. ML090680141, and supplemented by letter dated February 12, 2010, "Response to Request for Additional Information Request for Exemption from 10 CFR 50, Appendix R, Section III.G, 'Fire Protection of Safe Shutdown Capability'" (ADAMS Accession No. ML100470774), the licensee requested an exemption for PBAPS, Units 2 and 3, from certain technical requirements of 10 CFR Part 50, Appendix R, Section III.G.2 (III.G.2) for the use of operator manual actions (OMAs) in lieu of meeting the circuit separation and protection requirements contained in III.G.2 for Fire Areas 2, 6N, 6S, 13N, 26, 30, 36, 37, 43, 50, and 58 at the plant.

3.0 Discussion

Pursuant to 10 CFR 50.12, the Commission may, upon application by any interested person or upon its own initiative, grant exemptions from the requirements of 10 CFR Part 50 when: (1) The exemptions are authorized by law, will not present an undue risk to public health or safety, and are consistent with the common defense and security; and (2) when special circumstances are present. The licensee has stated that special circumstances are present in that the application of the regulation in this particular circumstance is not necessary to achieve the underlying purpose of the rule, which is consistent with the language included in 10 CFR 50.12(a)(2)(ii).

In letters dated March 6, 2009, and February 12, 2010, the licensee discussed financial implications associated with plant modifications that may be necessary to comply with the regulation. 10 CFR 50.12(a)2(iii) states that if such costs have been shown to be significantly in excess of those contemplated at the time the regulation was adopted, or are significantly in excess of those incurred by others similarly situated, this may be considered a basis for considering an exemption request. However, financial implications were not considered in the regulatory review of the request since no substantiation was provided regarding such financial implications. Even though no financial substantiation was provided, the licensee did submit sufficient regulatory basis to support a technical review of the exemption request in that the application of the regulation in this particular circumstance is not necessary to achieve the underlying purpose of the rule.

In accordance with 10 CFR 50.48(b), nuclear power plants licensed before January 1, 1979, are required to meet Section III.G, of 10 CFR Part 50, Appendix R. The underlying purpose of Section III.G of 10 CFR Part 50, Appendix R, is to ensure that the ability to achieve and maintain safe shutdown is preserved following a fire event. The regulation intends for licensees to accomplish this by extending the concept of defense-in-depth to:

(1) Prevent fires from starting;

(2) Rapidly detect, control, and extinguish promptly those fires that do occur;

(3) Provide protection for structures, systems, and components important to safety, so that a fire that is not promptly extinguished by the fire suppression activities will not prevent the safe shutdown of the plant.

The stated purpose of 10 CFR Part 50, Appendix R, Section III.G.2 (III.G.2) is to ensure that one of the redundant trains necessary to achieve and maintain hot shutdown conditions remains free of fire damage in the event of a fire. III.G.2 requires one of the following means to ensure that a redundant train of safe shutdown cables and equipment is free of fire damage, where redundant trains are located in the same fire area outside of primary containment:

a. Separation of cables and equipment by a fire barrier having a 3-hour rating;

b. Separation of cables and equipment by a horizontal distance of more than 20 feet with no intervening combustibles or fire hazards and with fire detectors and an automatic fire suppression system installed in the fire area; or

c. Enclosure of cables and equipment of one redundant train in a fire barrier having a 1-hour rating and with fire detectors and an automatic fire suppression system installed in the fire area.

Exelon has requested an exemption from the requirements of III.G.2 for PBAPS, Units 2 and 3 to the extent that one of the redundant trains of systems necessary to achieve and maintain hot shutdown is not maintained free of fire damage in accordance with one of the required means, for a fire occurring in Fire Areas 2 (Radwaste Building), 6S (Unit 2 Reactor Building), 6N (Unit 2 Reactor Building, North side), 13N (Unit 3 Reactor Building), 26 (Unit 3 Motor-Generator (MG) Set Ventilation Equipment Room), 30 (Unit 3 B/D Battery Room), 36 (E42 Switchgear Room), 37 (E22 Switchgear Room), 43 (E–4 Emergency Diesel Generator Room), 50 (Turbine Building), and 58 (Unit 3 MG Set Room).

In its submittals, the licensee described elements of the FPP that provide justification that the concept of defense-in-depth that is in place in the above fire areas is consistent with that intended by the regulation. To accomplish this, the licensee utilizes various protective measures. Specifically, the licensee stated that the purpose of its request was to credit the use of OMAs, in conjunction with other defense-in-depth features, in lieu of the separation and protective measures required by III.G.2 for a fire in the fire areas stated above.

3.1 Fire Prevention

In its March 6, 2009, and February 12, 2010, letters, the licensee provided an analysis that described how fire prevention is addressed for each of the fire areas for which the OMAs may be required. Unless noted otherwise in Section 3.4 below, all of the fire areas included in this exemption have a combustible fuel load that is considered to be low with fuel sources consisting primarily of fire retardant cable insulation and limited floor-based combustibles. Unless noted otherwise, there are no high energy ignition sources located in the areas. The fire areas included in the exemption are not shop areas, so hot work activities are infrequent with administrative control programs (*e.g.,* hot work permits, fire watch, and supervisory controls). The administrative control programs are described in the PBAPS FPP, which is incorporated into the Updated Final Safety Analysis Report.

3.2 Detection, Control and Extinguishment

PBAPS has been divided into fire areas, as described in the PBAPS FPP. Three-hour fire barriers are normally used to provide fire resistive separation between adjacent fire areas. In some cases, barriers with a fire resistance rating of less than 3 hours are credited, but exemptions have been approved or engineering evaluations performed in accordance with Generic Letter 86–10, "Implementation of Fire Protection Requirements," to demonstrate that the barriers are sufficient for the hazard. Walls separating rooms and zones within fire areas are typically constructed of concrete. In addition to these boundaries, the licensee provided a hazard analysis that described how detection, control, and extinguishment of fire are addressed for each of the fire areas for which the OMAs may be required.

Unless noted otherwise below, fire areas are provided with ionization smoke detectors in various locations within a particular fire area. Although not installed in accordance with a recognized standard with regard to spacing, the detectors are located near equipment such that they are likely to adequately detect a fire. Upon detecting smoke, the detectors initiate an alarm in the Control Room enabling fire brigade response. The licensee stated that in most cases, no automatic fire suppression systems are provided in the areas included in this exemption but that fire suppression systems are installed in plant areas with significant fire hazards, such as lube oil. Suppression systems have also been installed in areas with 1-hour barrier walls and 1-hour rated electrical raceway encapsulation.

The automatic suppression systems are not credited in reducing fire exposure to redundant equipment unless they are indicated as being full-area or specifically described as being effective for redundant equipment. Equipment operators are trained fire brigade members and would likely identify and manually suppress or extinguish a fire using the portable fire extinguishers and manual hose stations located throughout the fire areas.

3.3 Preservation of Safe Shutdown Capability

Each OMA included in this review consists of a sequence of tasks that occur in various fire areas. The OMAs are initiated upon confirmation of a fire in a particular fire area. The licensee stated that the postulated fire events that may require the use of the OMAs would include multiple failures of various components or equipment. In most cases, it is considered highly unlikely that the sequence of events required to necessitate the OMAs would fully evolve because of the fire prevention, fire protection, and physical separation features in place. However, in the event that the sequence does evolve, the OMAs are available to provide assurance that safe shutdown can be achieved.

This analysis postulates that OMAs may be needed to assure safe shutdown capability in addition to the traditional fire protection features described above. For each of the fire areas included in this exemption, the licensee evaluated the OMAs against the criteria of NUREG–1852, "Demonstrating the Feasibility and Reliability of Operator Manual Actions in Response to Fire," October 2007, in the March 6, 2009, submittal. A Fire Hazards Analysis was provided for each of the OMAs in the licensee's February 12, 2010, supplement.

3.3.1 Licensee's Bases for Establishing Feasibility and Reliability

The licensee's analysis addresses factors such as environmental concerns, equipment functionality and accessibility, available indications, communications, portable equipment, personnel protection equipment, procedures and training, staffing and demonstrations.

In its March 6, 2009, submittal, and further supported by its February 12, 2010, supplement, the licensee stated that environmental considerations such as radiological concerns, emergency lighting, temperature and humidity conditions and smoke and toxic gases were evaluated and found to not represent a negative impact on the operators' abilities to complete the OMA. The licensee stated that the dose limits contained in 10 CFR Part 20 are never challenged at any point along the travel path of any of the OMAs included in this exemption.

The licensee confirmed that each of the OMA locations addressed by this exemption is provided with emergency lighting that illuminates both the location where the manual action is performed and the access route to the manual action location. Where travel is required to buildings outside of the power block, portable lights are staged in the fire safe shutdown equipment locker which is inventoried and maintained by performance of a periodic routine test. The emergency

lights are periodically checked for operation and aim at the target location.

The licensee also confirmed that temperature and humidity conditions will not challenge the operators performing the OMAs. Additionally, the licensee indicated that heat and smoke or gas generation from a fire will not impact the operator performing the OMAs. This is further supported by the fact that the locations of the postulated fire events are in different fire areas than the locations for where the actions are performed. In most cases, the initiating fire area and manual action location fire area are in separate buildings and have separate ventilation systems. Other than smoke, CO_2 is another toxic gas that could present a hazard. However, all of the CO_2 fire suppression systems at PBAPS are manually actuated to prevent an inadvertent discharge of a system.

The licensee stated that the equipment to be operated as part of the OMAs will be functional and maintained free of fire damage and will be accessible to the operators performing the action. Additionally, PBAPS maintains Transient Response Implementing Plan procedures and T–300 Fire Guides. T–300 Fire Guides provide the operators with specific instructions in the event of a fire in a specific fire area. The T–300 Fire Guides provide a list of the key protected instruments available for a fire in the fire area and list any "prompt" actions that are needed to restore an instrument for a fire in that area (*i.e.,* those that need to be performed within 30 minutes). The applicable T–300 Fire Guide lists the "prompt" actions at the front of the document. In addition, the licensee stated that where specific indications may be lost due to a postulated event, the applicable T–300 Fire Guide for that fire area identifies which indications may be lost and how to recover the loss of that indication. Most required shutdown parameter indications are provided by multiple instruments; therefore, even with the loss of certain instruments or power supplies, redundant instruments are available to provide indications to assist operators.

With regard to communications, the licensee stated that PBAPS has radios and phones available as part of the normal communications between the Control Room and the operators. Although the communication system is not specifically hardened for post-fire survivability, the radio and phone systems are robustly designed such that they will be available following most fire scenarios. In the event that the radio and phone systems are inoperable, face-to-face communication, and adequate time, is available to dispatch the safe shutdown operators from the Control Room to perform the tasks and return to the Control Room for reassignment when the task is complete. With the exception of Action H, none of the operator manual actions addressed by this exemption require immediate or concurrent coordination with the Control Room while performing the task.

The licensee stated that if any keys, tools or equipment are required to perform the OMAs, the T–300 Fire Guides provide instructions on where to find them and how to use them. In addition, the licensee stated that operators are provided with standard personal protective equipment (PPE) (*i.e.,* hardhat, safety glasses, hearing protection, gloves, etc.) and that additional PPE is not required for any of the OMAs, with the exception of actions that require that an electrical enclosure be opened to manipulate an insulated handle of a manual transfer switch. For these tasks, a PBAPS corporate safety procedure requires the use of additional electrical safety PPE when performing this task.

The licensee stated that the T–300 Fire Guides provide in-depth safe shutdown direction for fires in specific fire areas and that the procedures included in the guides include specific instructions on assessing plant indications and events as well as instructions on how to perform each of the OMAs. The procedures are then used to train the operators on the OMAs, which consist primarily of activities that are considered to be similar to those performed as part of typical work activity and are considered straightforward with minimal training demands. In addition, the licensee stated that licensed operators are trained biennially on the use of the T–300 Fire Guides using simulator scenarios that start with a fire in a specific fire area.

With regard to staffing, the licensee stated that PBAPS maintains a minimum of three operators on each shift to perform safe shutdown duties in the event of a fire, which may be comprised of equipment operators, reactor operators or senior reactor operators. Additionally, the licensee stated that PBAPS performed several demonstrations using what is considered to be the most challenging initiating fire area, the Turbine Building (Fire Area 50), because it encompasses both Unit 2 and Unit 3, includes an action that is a prompt action in other fire areas, and includes a number of OMAs to perform within the first 60 minutes.

3.3.2 NRC Staff Evaluation of Feasibility

The NRC staff has determined that the licensee's analysis demonstrates that, for the expected scenarios, the OMAs can be diagnosed and executed within the amount of time necessary to complete them. The licensee's analysis also demonstrates that various factors, as discussed above, have been considered to address uncertainties in estimating the time available. Therefore, the NRC staff finds that the OMAs included in this review are feasible because there is adequate time available for the operator to perform the required OMAs to achieve and maintain hot shutdown following a postulated fire event. The following table summarizes the "required" verses "allowable" times for each OMA. Where a diagnosis time has been identified, it is included as part of the required time for a particular action. Where an action has multiple times or contingencies associated with the "allowable" completion time, the lesser time is used. This approach is considered to represent a conservative approach to analyzing the timelines associated with each of the OMAs with regard to the feasibility and reliability of the actions included in this exemption. In some cases, the margin between the required time and allowable time is small. Specifically actions D, U, V, and X, have 20 percent or less margin. This limited margin is based on using the most limiting information from the licensee. For example, if the licensee postulated up to 30 minutes for diagnosis, the higher value of the required time range noted in the table below includes the time to complete the action plus the full 30 minutes.

Finally, these numbers should not be considered without the understanding that the manual actions are a fall back in the unlikely event that the fire protection defense-in-depth features are insufficient. In most cases, there is no credible fire scenario that would necessitate the performance of these OMAs. The licensee provided a discussion of the times and circumstances associated with each of the actions in its March 6, 2009, and February 12, 2010, correspondence.

Fire area of fire origin	OMA	Required time (min)	Allowable time (min)
Fire Area 2 (Radwaste Building)	Action B	15—45*	120
	Action C	15	25 **
	Action D	18—48*	60
Fire Area 6S (Unit 2 Reactor Building)	Action G	14—44*	60
Fire Area 6N (Unit 2 Reactor Building, North Side)	Action H	7	25 **
Fire Area 13N (Unit 3 Reactor Building)	Action J	12—42*	60
Fire Area 26 (Unit 3 MG Set Ventilation Equipment Room)	Action K	12—42*	60
Fire Area 30 (Unit 3 B/D Battery Room)	Action M	9—39*	60
Fire Area 36 (E42 Switchgear Room)	Action R	12—42*	60
Fire Area 37 (E22 Switchgear Room)	Action S	12—42*	60
Fire Area 43 (E–4 Emergency Diesel Generator Room)	Action T	9—39*	60
Fire Area 50 (Turbine Building)	Action U	26—56*	60
	Action V	26—56*	60
	Action X	24—54*	60
	Action Y	15—45*	120
Fire Area 58 (Unit 3 MG Set Room)	Action BB	12—42*	60
	Action CC	12	25**

* The higher value of the required time range accounts for a generic 30-minute diagnosis time to assess the need for OMAs.
** Prompt actions are those having allowable completion times of 30 minutes or less.

3.3.3 NRC Staff Evaluation of Reliability

The completion times noted in the table above provide reasonable assurance that the OMAs can reliably be performed under a wide range of conceivable conditions by different plant crews. This is because the completion time, in conjunction with the time margins associated with each action and other installed fire protection features, account for sources of uncertainty such as variations in fire and plant conditions, factors unable to be recreated in demonstrations and human-centered factors. Therefore, the NRC staff finds that the OMAs included in this review are reliable because there is adequate time available to account for uncertainties not only in estimates of the time available, but also in estimates of how long it takes to diagnose a fire and execute the OMAs (*i.e.,* as based, at least in part, on a plant demonstration of the actions under non-fire conditions).

For each of the fire areas included in this exemption, the postulated fire scenarios and pertinent details are summarized in Section 3.4 below.

3.4 NRC Staff Fire Area Evaluations

3.4.1 Fire Area 2 (Radwaste Building)

Fire Prevention

The licensee stated that the floor-based combustibles include health physics cleaning supplies, such as mops, vacuums and other Class A combustibles as well as several steel carts containing new resins in paper or plastic bags. The total weight of the plastic bags is estimated to be less than 5 pounds and empty resin bags are immediately removed.

Detection, Control, and Extinguishment

The licensee stated that Fire Area 2 has fire suppression systems installed within the fire area but not within the rooms containing redundant cables. The licensee has further stated that the detection systems in the rooms containing redundant cables are not code compliant in terms of overall spacing in the fire area. However, a smoke detector is located within 5 feet of redundant cable ZA2B1021A. There is also a smoke detector located within 15 feet of both cables ZD3A1806A and ZD3A1321A. The licensee also stated that the Radwaste Control Room is located directly adjacent to these three rooms and that it is normally occupied by an equipment operator. Because of this, it is likely that any fire would be quickly identified by an operator in the area. Additionally, the licensee stated that a fully trained onsite fire brigade is provided, which is dispatched via plant page in the event of a fire. The fire brigade is composed of plant operators that are separate from operators assigned safe shutdown duties and are instructed to provide information about a fire event over the operations radio to assist in mitigating the event. Fire Area 2 is provided with manual fire fighting equipment such as portable fire extinguishers and manual hose stations throughout the area.

Preservation of Safe Shutdown Capability

The licensee stated that Fire Area 2 is a large fire area containing a number of rooms on several elevations and that spatial separation of redundant cables is provided as discussed below.

OMAs Credited for a Fire in This Area

Action B

The licensee stated that the redundant cables located in Fire Area 2 (cables ZA2B1021A and ZD3B1321A or ZD3A1806A) are located a minimum of approximately 30 feet from each other and that no intervening combustibles are present between the two trains of cables. This physical separation with the available fire detection system will provide the site fire brigade an opportunity to extinguish the fire before redundant trains are damaged. The licensee also stated that the cables are located a minimum of approximately 9 feet above the floor and that they are enclosed in rigid conduit, such that transient fire exposures and self-ignited cable fires are unlikely to affect the circuits.

In the unlikely event that both trains of cable are lost due to a fire in Fire Area 2, an OMA (Action B) is available to restore or maintain the necessary function to the effected equipment (SU–25 Breaker). Action B directs an operator to transfer SU–25 breaker auxiliary equipment from the normal power source to its alternate power source, by operating manual transfer switch 00S306, which is located in the Unit 2 Startup Building. The Unit 2 Startup Building is located in the exterior yard area.

Action C

The potential need to perform this action is low since this action is only needed if two of three offsite power sources are unavailable, power to the 2SU transformer tap changer is lost, and the tap changer is in the wrong position. The licensee stated that offsite power is provided to each of the 4kV Class 1E switchgear by two of three redundant

sources (2SU, 3SU, and 343SU) and that control cables for the sources have been physically separated by rerouting selected cables, such that one of the redundant sources remains free of fire damage for fires in most plant areas. In particular, the licensee stated that cables associated with the 2SU source have been relocated out of the Turbine Building (Fire Area 50), and portions of the Radwaste Building (Fire Areas 2 and 58).

The licensee stated that balance of plant (BOP) cables are routed through Fire Area 2, but that the routing of the cables was not part of the analysis. In the licensee's February 12, 2010, supplement, the licensee described the circumstances that would determine the availability of the safe shutdown equipment located in this area; namely the 2SU power source, which includes a transformer tap changer that is powered by BOP power. Since the BOP cable routing was not part of the analysis, the loss of BOP power was assumed for a fire in these three fire areas. The licensee's analysis also assumed that the transformer tap changer, which is powered by the BOP and responsible for maintaining power to the 4kV Bus, was not in the correct position. When the tap changer is not in the correct position, the voltage could vary resulting in actuation of the 4kV trip relays.

In the unlikely event that all of the conditions discussed above exist and fire damage occurs to the redundant cables, Action C can be utilized, which directs operators to pull the fuse blocks for the degraded voltage trip relays to ensure that the 4kV busses remain available. Action C is a "prompt" action, with an allowable completion time of 30 minutes or less, however, the licensee stated that its analysis assumed that the redundant cables were lost regardless of their location and that the tap changer was not in the correct position. The licensee stated that the loss of certain equipment in a fire area due to a fire will result in a Control Room alert. Off Normal procedure ON–114, "Actual Fire Reported in the Power Block, Diesel Generator Building, Emergency Pump, Inner Screen or Emergency Cooling Tower Structures," is immediately entered upon confirmation of a fire condition. Procedure ON–114 directs immediate entry into the Fire Guide for the affected fire area. The licensee also stated that a note is provided in the applicable safe shutdown fire guide series (T–300 Fire Guides) providing guidance on how to determine whether the 2SU transformer tap changer has lost power using indications within the Control Room. Therefore, the Control Room will know immediately if this action is required and a generic diagnosis time is not necessary.

The licensee's T–300 Fire Guides also provide the following guidance to assist operators in evaluating a postulated event, "If 2SU is the only offsite power source available, and a loss of power to the 2SU Transformer Tap Change has occurred, then perform the manual action to remove the fuses." Additionally, the 2SU transformer and associated auxiliaries are located in the yard area and would not be exposed by a fire in Fire Area 2. Lastly, the location of the OMA to remove the fuses in the 4kV Switchgear Rooms is in a separate fire area, with ventilation systems that are separate from Fire Area 2.

Action D

The licensee stated that this action would only be required if the conduit containing cable, which is located above the suspended ceiling with the only exposing combustible being a tray with fire retardant cables, is damaged by fire. There is a lack of ignition sources and a relatively short length (approximately 6 feet) of cable that passes through Fire Area 2. In addition, there is a smoke detector located within 5 feet of the conduit containing the cable, which would result in rapid plant notification of an exposure fire.

In the unlikely event that a fire in Fire Area 2 damages cable ZA2B1014A, normal power to the 2AD003 battery charger could be lost, which is needed to maintain long term DC power through the station batteries. A loss of ZA2B1014A would necessitate a manual action to transfer battery charger 2AD003 to an alternate power source within 60 minutes since the batteries can operate for 60 minutes prior to the initiation of recharging. The alternate power source is routed in separate fire areas, so a single fire cannot damage both the normal and alternate power feed. Action D is available to transfer the alternate power supply to the battery charger 2AD003. The action entails closing a breaker located in the E13 4kV Switchgear Room (Fire Area 33) and then operating a manual transfer switch located in the E32 4kV Switchgear Room (Fire Area 38), both of which are separate fire areas from Fire Area 2.

NRC Staff Evaluation

Given the limited amount of combustible materials and ignition sources, it is unlikely that a fire would occur and go undetected by the smoke detection system noted above or unsuppressed by personnel, and damage the safe shutdown equipment. Even if such circumstances exist, Actions B, C, and D are available to provide additional assurance that safe shutdown capability is maintained.

3.4.2 Fire Area 6S (Unit 2 Reactor Building)

Fire Prevention

The licensee stated that conduits are routed primarily through a transient combustible-free zone where a permit and review are required prior to the placement of combustibles in this area.

Detection, Control, and Extinguishment

The licensee stated that Fire Area 6S has ionization smoke detectors installed in the overhead area but that these smoke detectors do not have code compliant spacing due to ceiling height and beam pockets. However, there are three smoke detectors located above the general routing of the redundant cable conduits, which would be expected to activate in the event of a fire occurring in close proximity to the redundant cables. Additionally, the licensee stated that a fully trained onsite fire brigade is provided, which is dispatched via plant page in the event of a fire. The fire brigade is composed of plant operators that are separate from operators assigned safe shutdown duties and are instructed to provide information about a fire event over the operations radio to assist in mitigating the event.

Preservation of Safe Shutdown Capability

The licensee stated that Room 403 in Fire Area 6S has a ceiling height of approximately 29' and an approximate floor area of 6,848 square feet, so it is unlikely that smoke and heat would accumulate at the height of the safe shutdown equipment and cause a failure due to fire damage.

OMAs Credited for a Fire in This Area

Action G

The licensee stated that recent plant experience with faults and malfunctions in similar load centers has been that even when energetic failures have occurred, its damage has been contained within the breaker cubicle, with some heat and smoke damage to immediately adjacent cubicles. Therefore, it is considered unlikely that the cables routed above the load centers would be affected by a fault within the load centers since there is not a credible fire scenario that would be capable of damaging the cables within the conduits.

A fire in Fire Area 6S has the potential to damage cables ZA2B1014A, ZA2A1505A, and ZA2B1021A. The licensee stated that there are three 480V

load centers in the room containing the redundant cables and that the cables are routed to one of the load centers. As a result, each cable is routed over a 480V load center and in two cases the conduit passes over two load centers prior to entering the third load center. The conduits are located above the two adjacent load centers, which consist of a 4kv to 480v sealed gas cooled step-down transformer and a 480v switchgear.

The loss of these cables could result in a loss of the normal power supply to the 2AD003 battery charger, which is needed to maintain long term DC power through the station batteries. A loss of ZA2B1014A, ZA2A1505A, and ZA2B1021A would necessitate a manual action to transfer battery charger 2AD003 to an alternate power source within 60 minutes since the batteries can operate for 60 minutes prior to the initiation of recharging. The alternate power source is routed in separate fire areas, so a single fire cannot damage both the normal and alternate power feed. Action G is available to transfer the alternate power supply to the battery charger 2AD003. The action entails closing a breaker located in the E13 4kV Switchgear Room (Fire Area 33) and then operating a manual transfer switch located in the E32 4kV Switchgear Room (Fire Area 38), both of which are separate fire areas from Fire Area 6S.

NRC Staff Evaluation

Given the limited amount of combustible materials, ignition sources, and the large volume of the space, it is unlikely that a fire would occur and go undetected by the smoke detection system noted above or unsuppressed by personnel, and damage the safe shutdown equipment. Even if such circumstances exist, Action G is available to provide additional assurance that safe shutdown capability is maintained.

3.4.3 Fire Area 6N (Unit 2 Reactor Building, North side)

Fire Prevention

The licensee stated that the only floor-based combustibles in this area are trash cans and cables. Trash can lids are designed to provide self-extinguishing capability to the trash cans. Cables in the area are qualified to the Institute of Electrical and Electronics Engineers, Inc. Standard-383, "IEEE Standard For Qualifying Class 1E Electrical Cables And Field Splices for Nuclear Power Generating Stations" (IEEE 383), or equivalent.

Detection, Control, and Extinguishment

The licensee stated that Fire Area 6N has a smoke detection system installed, but that the spacing is not in compliance with National Fire Protection Association Code 72, "National Fire Alarm and Signaling Code" (NFPA 72), due to deep beam pockets at the ceiling of this area. However, there is a smoke detector within the vicinity (approximately 25 feet) of each of the cases where cable ZA2Q1280B and a "B" residual heat removal (RHR) cable intersect, which would be expected to activate in the event of a fire in close proximity to the redundant equipment. There is also an automatic water curtain on the west side of the Unit 2 Reactor Building that separates Fire Area 6N from Fire Area 6S, thus reducing any anticipated exposure from Fire Area 6S. Additionally, the licensee stated that a fully trained onsite fire brigade is provided, which is dispatched via plant page in the event of a fire. The fire brigade is composed of plant operators that are separate from operators assigned safe shutdown duties and are instructed to provide information about a fire event over the operations radio to assist in mitigating the event.

Preservation of Safe Shutdown Capability

The licensee stated that Fire Area 6N is the Unit 2 Reactor Building 135' elevation, north side, which is in a separate building from the Cable Spreading Room, Fire Area 25, which is the location of the OMA.

OMAs Credited for a Fire in This Area

Action H

The licensee stated that the cables associated with "B" RHR are located in trays and in conduit and that cables for both "A" and "B" RHR trains cross within 2 feet of each other. However, there are no high energy ignition sources where cable ZA2Q1280B and a "B" RHR train cable cross and only a small amount of combustibles in the area overall. Therefore, it is unlikely that a single fire could damage both the "A" train RHR cable and "B" RHR cables and necessitate the use of Action H. Action H, which requires coordination with the control room, directs an operator to insert a plug-in test switch into Panel 20C032, located in the Cable Spreading Room (Fire Area 25), to bypass the reactor low pressure permissive for opening MO–2–025A.

In the unlikely event that a fire does damage the pressure permissive instrumentation circuit for opening MO–2–025A, operators will be aware of the condition, either by electronic indications in the Control Room, a smoke detection alarm annunciation in the Control Room, or physical observation by operators, and will initiate Action H, which is the only OMA required to achieve hot shutdown for a fire in Fire Area 6N. Therefore, the Control Room will know immediately if this action is required and a generic diagnosis time is not necessary.

A fire in Fire Area 6N has the potential to damage cable ZA2Q1280B. This cable is associated with the pressure permissive circuit needed to open valve MO–2–10–025A. This valve needs to open to permit injection of Low Pressure Core Injection ("A" train RHR) following depressurization. Fire Area 6N also contains a number of cables associated with the "B" train of RHR. Any number of "B" RHR train cables could be damaged as a result of a fire in Fire Area 6N, so the licensee's analysis assumed that the "B" RHR was considered to be unavailable for a fire in Fire Area 6N.

NRC Staff Evaluation

Given the limited amount of combustible materials and ignition sources, it is unlikely that a fire would occur and go unsuppressed by personnel, and damage the safe shutdown equipment. Even if such circumstances exist, Action H is available to provide additional assurance that safe shutdown capability is maintained.

3.4.4 Fire Area 13N (Unit 3 Reactor Building)

Fire Prevention

The licensee stated that limited amounts of Class A combustible materials, including step-off pads, are present in this area. The three cables addressed in this area are routed such that they terminate at either a 480V load center or a motor control center (MCC) cabinet or both.

Detection, Control, and Extinguishment

The licensee stated that both elevations containing redundant equipment within Fire Area 13N have smoke detection systems installed that produce an alarm in the Control Room, but that due to the room height and steel beams at the ceiling, the spacing of the smoke detectors on both elevations does not meet the spacing listed in NFPA 72. Although not entirely compliant with NFPA 72, this system is considered to provide adequate coverage to detect a fire and alert operators of a fire. Additionally, the licensee stated that a fully trained onsite fire brigade is provided, which is dispatched via plant

page in the event of a fire. The fire brigade is composed of plant operators that are separate from operators assigned safe shutdown duties and are instructed to provide information about a fire event over the operations radio to assist in mitigating the event.

Preservation of Safe Shutdown Capability

The licensee stated that the 135' elevation of Fire Area 13N has a ceiling height of approximately 29' and an approximate floor area of 4,033 square feet and the 165' elevation has a ceiling height of approximately 29' and an approximate floor area of 6,848 square feet, so it is unlikely that smoke and heat would accumulate at the height of the safe shutdown equipment and cause a failure due to fire damage.

OMAs Credited for a Fire in This Area

Action J

The licensee stated that while it is possible that any one of the three redundant cables located in Fire Area 13N could potentially be damaged as a result of a fault or failure within its associated 480V load center or MCC, the impact of a fire on the ability to perform this action is low since Fire Area 13N is in a separate building with a separate ventilation system from the E43 4kV Switchgear Room and ample time is available to complete the action. However, the other installed fire protection features such as the smoke detection system, cable conduit, and fire brigade response would likely minimize the impact of a fire on the cables themselves.

A fire in Fire Area 13N has the potential to damage cables ZD3B1313A, ZD3A1806A, and ZD3B3983A. The loss of any of these cables could result in a loss of the normal power supply to the 3DD003 battery charger. A loss of ZD3B1313A, ZD3A1806A, or ZD3B3983A, would necessitate a manual action to transfer battery charger 3DD003 to an alternate power source to within 60 minutes since the batteries can operate for 60 minutes prior to the initiation of recharging. Battery charger 3DD003 can also be fed from an alternate power source, which is routed in separate fire areas, so a single fire cannot damage both the normal and alternate power feed. Action J is available to transfer the alternate power supply to the battery charger 3DD003. The action entails first closing a breaker and then operating a manual transfer switch. The breaker and manual transfer switch are located in the E43 4kV Switchgear Room (Fire Area 34).

NRC Staff Evaluation

Given the limited amount of combustible materials, ignition sources, and the large volume of the space, it is unlikely that a fire would occur and go undetected by the smoke detection system noted above or unsuppressed by personnel, and damage the safe shutdown equipment. Even if such circumstances exist, Action J is available to provide additional assurance that safe shutdown capability is maintained.

3.4.5 Fire Area 26 (Unit 3 MG Set Ventilation Equipment Room)

Fire Prevention

The licensee stated that the primary combustible material in Fire Area 26 is fire retardant cable insulation and that there are no in situ ignition sources in the vicinity of the cables.

Detection, Control, and Extinguishment

The licensee stated that in Fire Area 26, there are two ionization smoke detectors located in the portion of the room containing the cables of concern, but that the overall detector placement for the fire area as a whole does not comply with the layout and spacing requirements of NFPA 72; however, the two smoke detectors are located in the immediate vicinity of the cables and would provide an alarm of a fire condition. Additionally, the licensee stated that a fully trained onsite fire brigade is provided, which is dispatched via plant page in the event of a fire. The fire brigade is composed of plant operators that are separate from operators assigned safe shutdown duties and are instructed to provide information about a fire event over the operations radio to assist in mitigating the event.

Preservation of Safe Shutdown Capability

The licensee stated that Fire Area 26 has a ceiling height of approximately 25' and an approximate floor area of 2,100 square feet, so it is unlikely that smoke and heat would accumulate at the height of the safe shutdown equipment and cause a failure due to fire damage.

OMAs Credited for a Fire in This Area

Action K

The licensee stated that it is unlikely that Action K will be necessary because there is reasonable assurance that both of the cables would not be damaged in the event of a fire in Fire Area 26 since there are no in situ ignition sources in Fire Area 26 in the vicinity of the cables, there are no combustible materials, other than fire retardant cable insulation exposing the two cables, and there are two smoke detectors provided in the area to notify operators of a fire. In the event that the action is necessary, the impact of a fire on the ability to perform this action is low since Fire Area 26N is in a separate building with a separate ventilation system from the E43 4kV Switchgear Room and ample time is available to complete the action.

A fire in Fire Area 26 has the potential to damage cables ZD3B1313A, ZD3A1806A, and ZD3B3983A. The loss of any of these cables could result in a loss of the normal power supply to the 3DD003 battery charger. A loss of ZD3B1313A, ZD3A1806A, or ZD3B3983A, would necessitate a manual action to transfer battery charger 3DD003 to an alternate power source within 60 minutes since the batteries can operate for 60 minutes prior to the initiation of recharging. Battery charger 3DD003 can also be fed from an alternate power source, which is routed in separate fire areas, so a single fire cannot damage both the normal and alternate power feed. Action K is available to transfer the alternate power supply to the battery charger 3DD003. The action entails first closing a breaker and then operating a manual transfer switch. The breaker and the manual transfer switch are located in the E43 4kV Switchgear Room (Fire Area 34).

NRC Staff Evaluation

Given the limited amount of combustible materials, ignition sources, and the large volume of the space, it is unlikely that a fire would occur and go undetected by the smoke detection system noted above or unsuppressed by personnel, and damage the safe shutdown equipment. Even if such circumstances exist, Action K is available to provide additional assurance that safe shutdown capability is maintained.

3.4.6 Fire Area 30 (Unit 3 B/D Battery Room)

Fire Prevention

The licensee stated that the combustible loading in this area is considered to be low with the primary combustible material in this area being liquid filled plastic battery cases and that there are no cables in trays in this fire area. Additionally, the potential for hydrogen buildup due to the battery charging process is mitigated by the ventilation system in the room. The ventilation system is monitored, alarmed, and programmatically controlled. The licensee also stated that there are no significant ignition sources in this area.

Detection, Control, and Extinguishment

The licensee stated that for Fire Area 30 there are three smoke detectors located in the room and that the spacing of the detectors is compliant with NFPA 72 with regard to ceiling height, beam configuration and air flow. Additionally, two of the three smoke detectors are located directly above the encapsulated conduits that contain redundant cables. Additionally, the licensee stated that a fully trained onsite fire brigade is provided, which is dispatched via plant page in the event of a fire. The fire brigade is composed of plant operators that are separate from operators assigned safe shutdown duties and are instructed to provide information about a fire event over the operations radio to assist in mitigating the event.

Preservation of Safe Shutdown Capability

The licensee stated that Fire Area 30 has a ceiling height of approximately 14′ and an approximate floor area of 525 square feet, so it is unlikely that smoke and heat would accumulate at the height of the safe shutdown equipment and cause a failure due to fire damage.

OMAs Credited for a Fire in This Area

Action M

The licensee stated that it is unlikely that both of the redundant cables located in Fire Area 30 would be damaged in the event of a fire in Fire Area 30 since the conduits containing cables ZA3B1014A and ZA3A1505A are both encapsulated in abandoned Thermo-Lag, the primary combustible material in the room is liquid filled plastic battery cases, there are no cable trays or high voltage components located in the fire area, there are three smoke detectors located in close proximity to the cables, and the potential for hydrogen release from the battery charging process is mitigated by the ventilation system that is monitored for operation and addressed by the Technical Requirements Manual.

A fire in Fire Area 30 has the potential to damage cables ZA3B1014A and ZA3A1505A, which the licensee stated are located approximately 16 inches from one another at their closest location. The loss of either of these cables could result in a loss of the normal power supply to the 3AD003 battery charger (located in Fire Area 32). A loss of ZA3B1014A or ZA3A1505A would necessitate a manual action to transfer battery charger 3AD003 to an alternate power source within 60 minutes since batteries can operate for 60 minutes prior to the initiation of recharging. Battery charger 3AD003 can also be fed from an alternate power source, which is routed in separate fire areas, so a single fire cannot damage both the normal and alternate power feed. Action M is available to transfer the alternate power supply to the battery charger 3AD003. The action entails operating a manual transfer switch located in the E33 4kV Switchgear Room (located in a different fire area).

NRC Staff Evaluation

Given the ventilation system located in the room, limited amount of combustible materials, lack of ignition sources, and the volume of the space, it is unlikely that a fire would occur and go undetected by the smoke detection system noted above or unsuppressed by personnel, and damage the safe shutdown equipment. Even if such circumstances exist, Action M is available to provide additional assurance that safe shutdown capability is maintained.

3.4.7 Fire Area 36 (E42 Switchgear Room)

Fire Prevention

The licensee stated that the cables in this area are qualified to IEEE 383, or equivalent. The licensee also indicated that there are several sections of Thermo-Lag in the room. Thermo-Lag is a fire barrier material that is also considered a combustible. The licensee determined that this material does not create a credible fire exposure to the conduit and that the overall combustible material loading for the area is low. Additionally, Fire Area 36 contains 4kV switchgear which can create a high energy fault in the event of a failure and is considered an ignition source. However, the conduit containing the cables of concern is routed 4 feet horizontally from the front of the switchgear cabinet, not routed over the switchgear, and is not expected to be damaged in the event of a switchgear failure. Conduit containing four cables of concern is routed over two battery chargers, which convert 480 volt AC into 125 volt DC for the batteries. However, these chargers are not anticipated to provide a sustained fault current like a 4kV switchgear, but heat from a failure could expose the conduit and, therefore, represent an ignition source.

Detection, Control, and Extinguishment

The licensee stated that Fire Area 36 has an NFPA 72-compliant smoke detection system installed, comprised of six smoke detectors, and that the room is also provided with a pre-action sprinkler system designed in accordance with NFPA Standard 13, "Standard for the Installation of Sprinkler Systems" (NFPA 13). Additionally, the licensee stated that a fully trained onsite fire brigade is provided, which is dispatched via plant page in the event of a fire. The fire brigade is composed of plant operators that are separate from operators assigned safe shutdown duties and are instructed to provide information about a fire event over the operations radio to assist in mitigating the event.

Preservation of Safe Shutdown Capability

The licensee stated that Fire Area 36 has a ceiling height of approximately 14′ and an approximate floor area of 525 square feet, so it is unlikely that smoke and heat would accumulate at the height of the safe shutdown equipment and cause a failure due to fire damage.

OMAs Credited for a Fire in This Area

Action R

The licensee stated that while it is possible that the redundant cables located in Fire Area 36 could potentially be damaged by heat resulting from a battery charger failure, it is unlikely that the cables within the conduits would be damaged since Fire Area 36 has full area smoke detection and pre-action sprinkler systems, the conduit is not routed directly above the 4kV switchgear, the combustible loading in the room is low consisting primarily of fire retardant cable insulation and Thermo-Lag, and there are no cable trays routed below the conduit.

A fire in Fire Area 36 has the potential to damage cables ZA2A1501E, ZA2A1501F, ZA2A1508E, and ZA2A1508F, which the licensee stated are routed together in a single conduit, located approximately 9 feet above the floor, for their entire length in Fire Area 36. The loss of these cables could result in the loss of power to the E12 bus from the E1 Emergency Diesel Generator. Since Fire Area 36 is the E42 4kV Switchgear Room, the switchgear in this room is primarily associated with the B and D electrical trains. Therefore, a fire in this room is assumed to result in the loss of the components associated with the B and D trains. In the event that these are lost due to a fire in Fire Area 36, Action R is available, which directs an operator to enter the E12 Switchgear Room (located in Fire Area 39) and pull two fuse blocks, open two breakers by depressing the mechanical breaker trip button and taking a Main Control Room breaker control switch to "Close."

NRC Staff Evaluation

Given the limited amount of combustible materials and the volume of the space, it is unlikely that a fire would occur and go undetected by the smoke detection system noted above or unsuppressed by personnel, and damage the safe shutdown equipment. Even if such circumstances exist, Action R is available to provide additional assurance that safe shutdown capability is maintained.

3.4.8 Fire Area 37 (E22 Switchgear Room)

Fire Prevention

The licensee stated that the cables in this area are qualified to IEEE 383, or equivalent. Thermo-Lag is also present, but does not create a credible fire exposure to the conduit. The licensee determined that this material does not create a credible fire exposure to the conduit and that the overall combustible material loading for the area is low. Fire Area 37 also contains 4kV switchgear which can create a high energy fault in the event of a failure and is considered an ignition source. However, the conduit containing the cables of concern is routed 4 feet horizontally from the front of the switchgear cabinet, not routed over the switchgear, and is not expected to be damaged in the event of a switchgear failure. Additionally, a bank of 480V MCCs exposes conduit containing four cables of concern to an exposure hazard in the event that an MCC fails.

Detection, Control, and Extinguishment

The licensee stated that Fire Area 37 has an NFPA 72-compliant smoke detection system installed, comprised of three smoke detectors, and that the room is also provided with a pre-action sprinkler system designed in accordance with NFPA 13. Additionally, the licensee stated that a fully trained onsite fire brigade is provided, which is dispatched via plant page in the event of a fire. The fire brigade is composed of plant operators that are separate from operators assigned safe shutdown duties and are instructed to provide information about a fire event over the operations radio to assist in mitigating the event.

Preservation of Safe Shutdown Capability

The licensee stated that Fire Area 37 has a ceiling height of approximately 14' and an approximate floor area of 525 square feet, so it is unlikely that smoke and heat would accumulate at the height of the safe shutdown equipment and cause a failure due to fire damage.

OMAs Credited for a Fire in This Area

Action S

The licensee stated that while it is possible that the redundant cables located in Fire Area 37 could potentially be damaged by failure of the bank of 480V MCCs located below the conduit, it is unlikely that the cables within the conduits would be damaged since Fire Area 37 has full area smoke detection and pre-action sprinkler systems, the conduit is not routed directly above the 4kV switchgear, the combustible loading in the room is low consisting primarily of fire retardant cable insulation and Thermo-Lag, and there are no cable trays routed below the conduit.

A fire in Fire Area 37 has the potential to damage cables ZA2A1501E, ZA2A1501F, ZA2A1508E, and ZA2A1508F, which the licensee stated are routed together in a single conduit, located approximately 9 feet above the floor, for their entire length in Fire Area 37. The loss of these cables could result in the loss of power to the E12 bus from the E1 Emergency Diesel Generator. Since Fire Area 37 is the E22 4kV Switchgear Room, the switchgear in this room is primarily associated with the B and D electrical trains, so a fire in this room is assumed to result in the loss of the components associated with the B and D trains. In the event that these are lost due to a fire in Fire Area 36, Action R is available, which directs an operator to enter the E12 Switchgear Room (located in Fire Area 39) and pull two fuse blocks, open two breakers by depressing the mechanical breaker trip button and taking a Main Control Room breaker control switch to "Close."

NRC Staff Evaluation

Given the limited amount of combustible materials and the volume of the space, it is unlikely that a fire would occur and go undetected by the smoke detection system noted above or unsuppressed by personnel, and damage the safe shutdown equipment. Even if such circumstances exist, Action S is available to provide additional assurance that safe shutdown capability is maintained.

3.4.9 Fire Area 43 (E–4 Emergency Diesel Generator Room)

Fire Prevention

The licensee stated that other than the diesel fuel and lube oil in the EDG Rooms, the combustible material loading is considered to be low. The fuel oil day tank is located within the fire area, but in a separate room with heavy concrete walls and a 3-hour Underwriters Laboratory (UL)-listed fire door. Additionally, failure of an operating diesel generator represents a significant ignition source. There are also high voltage electrical components associated with the generator in the room. However, these ignition sources are only credible when the diesel is in operation. During routine diesel operations, an equipment operator is stationed in the room to monitor the diesel and would be available to immediately suppress any small fires that occurred, or to secure the diesel if a significant malfunction occurred.

Detection, Control, and Extinguishment

The licensee stated that Fire Area 43 has eight heat detectors installed that annunciate an alarm in the Control Room and that the room also has a manually-actuated carbon dioxide (CO_2) fire suppression system installed. Additionally, the licensee stated that a fully trained on-site fire brigade is provided, which is dispatched via plant page in the event of a fire. The fire brigade is composed of plant operators that are separate from operators assigned safe shutdown duties and are instructed to provide information about a fire event over the operations radio to assist in mitigating the event.

Preservation of Safe Shutdown Capability

The licensee stated that the emergency diesel generator rooms are located in a separate building from the rest of the plant and that each of the emergency diesel generators are separated from one another with a three-hour rated fire barrier. Additionally, the OMA for this area is performed in the E42 Switchgear room, Fire Area 36, which is located in the turbine building.

OMAs Credited for a Fire in This Area

Action T

The licensee stated that while it is possible that the redundant cables in Fire Area 43 could potentially be damaged by a lube or fuel oil fire, it is unlikely that the cables within the conduits would be damaged since they are located in conduit that is embedded in the floor slab for much of the length they are in Fire Area 43, and there would have to be a sufficient amount of oil present on the floor which then spreads across the floor to expose the control panels. Even if these two circumstances occur, a manually-actuated CO_2 fire suppression system is available to extinguish any fires in the area.

A fire in Fire Area 43 has the potential to damage cables ZD2A1807E or ZD2A1807H, which the licensee stated are located in conduits embedded in the concrete floor slab, control

panels, and a junction box. Failure of these cables via a hot short could cause the Unit 2 emergency diesel generator breaker to close into the E42 bus, either out of phase or not running, which would cause a protective trip of the E42 bus. This could result in a loss of the normal power supply to the 2DD003 battery charger. The battery charger is needed to maintain long term DC power through the station batteries. The batteries can operate for 60 minutes prior to the initiation of recharging. Battery charger 2DD003 can also be fed from an alternate power source, which is routed in separate fire areas, so a single fire cannot damage both the normal and alternate power feed. Action T is available to transfer the alternate power supply to the battery charger 2DD003 (located in Fire Area 36). The action entails operating a manual transfer switch located in the E42 4kV Switchgear Room which is a separate fire area in a separate building.

NRC Staff Evaluation

Given the limited amount of combustible materials and monitoring of credible ignition sources in this area, it is unlikely that a fire would occur and go undetected by the heat detection system or unsuppressed by the suppression system noted above or by personnel, and damage the safe shutdown equipment. Even if such circumstances exist, Action T is available to provide additional assurance that safe shutdown capability is maintained.

3.4.10 Fire Area 50 (Turbine Building)

Fire Prevention

The licensee stated that limited amounts of Thermo-Lag and various Class A combustible materials are present in the fire area. The licensee also stated that the room containing the cables of concern contains two rows of 13kV switchgear cabinets, which would be capable of exposing the cables in the event of a 13 kV switchgear failure.

Detection, Control, and Extinguishment

The licensee stated that Fire Area 50 includes most of the Unit 2 and Unit 3 Turbine Building and as such is a large fire area including several rooms located on multiple elevations. However, the cables of concern with regard to the associated OMA are only routed through Room 126. This room contains a full room smoke detection system with spacing in accordance with NFPA 72. In addition, a full room pre-action sprinkler system is provided in Room 126 with sprinkler head placement in accordance with NFPA 13. There is also an automatic sprinkler system in the adjacent open areas of the Turbine Building. The remainder of the Turbine Building is separated from Room 126 by heavy concrete radiation barriers and a water curtain (which is part of the Room 126 pre-action system) at the doorways. Additionally, the licensee stated that a fully trained onsite fire brigade is provided, which is dispatched via plant page in the event of a fire. The fire brigade is composed of plant operators that are separate from operators assigned safe shutdown duties and are instructed to provide information about a fire event over the operations radio to assist in mitigating the event.

Preservation of Safe Shutdown Capability

The primary basis for preserving safe shutdown capability is included in the discussion of prevention, detection, suppression, and control above or included in the OMAs discussed below.

OMAs Credited for a Fire in This Area

Action U

The licensee stated that while it is possible that one of the redundant cables located in Fire Area 50 could potentially be damaged by failure of the 13kV switchgear, it is unlikely that additional redundant cables would be damaged since the conduit containing cable ZD2A1807E runs above the 13kV switchgear, there is approximately 5 feet of separation between it and the next closest conduit which contains cable ZA2A1503E, and this conduit is not located above the 13kV switchgear. The area is also provided with a smoke detection system and a pre-action sprinkler system and the presence of abandoned, but intact, Thermo-Lag to protect the cables that are needed to ensure power to the "A" and "C" train switchgear to power credited shutdown components.

There is a cable associated with each of the four 4kV busses routed through Fire Area 50. There is the potential for any of the four diesel generator output breakers to spuriously close, rendering the bus unavailable until the diesel generator breaker is opened and lockouts are reset. The four cables associated with the Unit 2 4kV busses are: Bus E12 breaker cable ZA2A1503E; bus E22 breaker cable ZB2A1606E; bus E32 breaker ZC2A1704E; and bus E42 breaker cable ZD2A1807E. Loss of any one of these cables will only affect the associated 4kV bus and all four cables are routed in separate conduits. Cables ZA2A2503E and ZC2A1704E are routed in conduits that remain encapsulated in abandoned Thermo-Lag for their entire routing through Fire Area 50 while cables ZB2A1606E and ZD2A1807E are routed in conduit that is not encapsulated. The conduit containing cable ZB2A1606E is located within 5 feet of the conduits containing cables ZA2B1503E and ZD2A1807E.

Only cables ZA2A1503E and ZC2A1704E are necessary to power the busses credited for safe shutdown. However, Action U would restore power to all four busses. Only three of the four busses would require restoration within 60 minutes and only one bus is assumed to require restoration, since only one bus is assumed to spuriously operate. Nevertheless, a 26-minute performance time is credited for restoration of all four Unit 2 busses.

In the unlikely event that a fire does occur and goes undetected by the smoke detection system or unsuppressed by the suppression system and damages multiple redundant cables, Action U is available to restore power to the busses, which entails tripping the breaker and pulling a fuse block for each of the busses. The location of Action U is in the associated Switchgear Room for each associated bus. Additionally, the Switchgear Rooms are separate fire areas from the Turbine Building and from each other and have separate ventilation systems from the Turbine Building. Therefore, a fire in Fire Area 50 would not impact the location of the action.

Action V

Action V is the same as Action U above but for Unit 3. There is a cable associated with each of the four 4kV busses routed through Fire Area 50. There is the potential for any of the four diesel generator output breakers to spuriously close, rendering the bus unavailable until the diesel generator breaker is opened and lockouts are reset. The four cables associated with the Unit 3 4kV busses are: bus E13 breaker cable ZA3A1503E; bus E23 breaker cable ZB3A1606E; bus E33 breaker cable ZC3A1704E; and bus E43 breaker cable ZD3A1807E. Loss of any one of these cables will only affect the associated 4kV bus and all four cables are routed in separate conduits. Cables ZA3A1503E and ZC3A1704E are routed in conduits that remain encapsulated in abandoned Thermo-Lag for their entire routing through Fire Area 50 while cables ZB3A1606E and ZD3A1807E are routed in conduit that is not encapsulated. The conduit containing cable ZB3A1606E is located within 5 feet of the conduits containing cables ZA3A1503E and ZC3A1704E.

Only cables ZA3A1503E and ZC3A1704E are necessary to power the busses credited for safe shutdown. However, Action V would restore power

to all four busses. Only three of the four busses would require restoration within 60 minutes and only one bus is assumed to require restoration, since only one bus is assumed to spuriously operate. Nevertheless, a 26-minute performance time is credited for restoration of all four Unit 3 busses. The licensee stated that while it is possible that one of the cables could potentially be damaged by failure of the 13kV switchgear since the conduit containing cable ZD2A1807E runs above the 13kV switchgear, there is approximately 5 feet of separation between it and the next closest conduit which contains cable ZA2A1503E, and this conduit is not located above the 13kV switchgear. Therefore, it is unlikely that the cables required for safe shut down would be damaged by a fire resulting from failure of the 13kV switchgear since the area is also provided with a smoke detection system and a pre-action sprinkler system and the presence of abandoned, but intact, Thermo-Lag to protect the cables that are needed to ensure power to the "A" and "C" train switchgear to power credited shutdown components.

In the unlikely event that a fire does occur and goes undetected by the smoke detection system or unsuppressed by the suppression system and damages multiple redundant cables, Action V is available to restore power to the busses, which entails tripping the breaker and pulling a fuse block for each of the busses. The location of Action U is in the associated Switchgear Room for each associated bus. Additionally, the Switchgear Rooms are separate fire areas from the Turbine Building and from each other and have separate ventilation systems from the Turbine Building. Therefore, a fire in Fire Area 50 would not impact the location of the action.

Action X

The potential need to perform this action is low since this action is only needed if two of three other offsite power sources are unavailable, power to the 2SU transformer tap changer is lost, and the tap changer is in the wrong position. The licensee stated that offsite power is provided to each of the 4kV Class 1E switchgear by two of three redundant sources (2SU, 3SU, and 343SU) and that control cables for the sources have been physically separated by rerouting selected cables, such that one of the redundant sources remains free of fire damage for fires in most plant areas. In particular, the licensee stated that cables associated with the 2SU source have been relocated out of the Turbine Building (Fire Area 50), and portions of the Radwaste Building (Fire Areas 2 and 58).

The licensee stated that BOP cables are routed through Fire Area 50 but that the routing of the cables was not part of its analysis. In its February 12, 2010, supplement, the licensee described the circumstances that would determine the availability of the safe shutdown equipment located in this area; namely the 2SU power source, which includes a transformer tap changer that is powered by BOP power. Since the BOP cable routing was not part of the analysis, the loss of BOP power was assumed for a fire in these three fire areas. The licensee's analysis also assumed that the transformer tap changer, which is powered by the BOP and responsible for maintaining power to the 4kV Bus 2SU, was not in the correct position. When the tap changer is not in the correct position, the voltage could vary resulting in 4kV trip relays actuating.

In the unlikely event that all of the conditions discussed above exist and fire damage occurs to the redundant cables, Action X can be utilized, which directs operators to pull the fuse blocks for the degraded voltage trip relays to ensure that the 4kV busses remain available.

The licensee's T–300 Fire Guides provide the following guidance to assist operators in evaluating a postulated event, "If 2SU is the only offsite power source available, and a loss of power to the 2SU Transformer Tap Change has occurred, then perform the manual action to remove the fuses."

A note is also provided in the Fire Guide for this step providing guidance on how to determine if the 2SU transformer tap changer has lost power using indications within the Control Room. Therefore, the Control Room will know if this action is required. Additionally, the 2SU transformer and associated auxiliaries are located in the yard area and would not be exposed by a fire in Fire Area 50. Lastly, the location of the OMA to remove the fuses in the 4kV Switchgear Rooms is in a separate fire area, with separate ventilation systems, from Fire Area 50.

Action Y

The licensee stated that while it is possible that the redundant cables in Fire Area 50 could potentially be damaged by a fire resulting from a 13kV switchgear failure, it is unlikely that both of the cables within the conduits would be damaged since the conduit containing cable ZA2B1021B remains encapsulated in Thermo-Lag for the entire length above the 13kV switchgear, the cable ZA2B1021B is not located within the same conduit as cables ZD3B1321B and ZD3B1321D. In addition, the area is provided with a smoke detection system, as well as a pre-action sprinkler system.

The licensee stated that the redundant cables located in Fire Area 50 (cables ZA2B1021B and ZD3B1321B or ZD3A1321D) are located approximately 5 feet from each other and that no intervening combustibles are present between the two trains of cables. Additionally, the conduit containing cable ZA2B1021B remains encapsulated in abandoned Thermo-Lag for the entire routing through Fire Area 50. The licensee also stated that the conduits containing the cables associated with this OMA are routed directly above (approximately 5 feet) the 13kV switchgear cabinets in the room and that the conduits are assumed to be located within the anticipated heat plume in the event of a 13kV switchgear failure.

In the unlikely event that a fire does occur and goes undetected by the smoke detection system or unsuppressed by the suppression system and both trains of cable are lost, an OMA (Action V) is available to restore or maintain the necessary function to the effected equipment (SU–25 Breaker). Action V directs an operator to transfer SU–25 breaker auxiliary equipment from the normal power source to its alternate power source, by operating manual transfer switch 00S306, which is located in the Unit 2 Startup Building, which is located in the exterior yard area.

NRC Staff Evaluation

Given the limited amount of combustible materials and the volume of the space, it is unlikely that a fire would occur and go undetected by the smoke detection system noted above or unsuppressed by the suppression systems noted above or by personnel, and damage the safe shutdown equipment. Even if such circumstances exist, Actions U, V, X, and Y are available to provide additional assurance that safe shutdown capability is maintained.

3.4.11 Fire Area 58 (Unit 3 MG Set Room)

Fire Prevention

The licensee stated that the combustible loading in Fire Area 58 is considered to be moderate and consists primarily of lube oil from the MG set. Other combustible materials in the area include fire retardant cable insulation and Thermo-Lag. Additionally, the MG set and the MCCs located in the room represent ignition sources.

Detection, Control, and Extinguishment

The licensee stated that Fire Area 58 has a pre-action sprinkler system

installed that is designed to provide localized protection of the MG set with sprinkler heads located over the MG set itself and not at the ceiling. Although this is not considered to be an area-wide system and does not comply with NFPA 13, this system was an original plant installation designed to provide localized protection of the MG set. The pre-action system is actuated automatically by any one of the six smoke detectors in the room, which are also located directly above the MG set and not at the ceiling. Since the detectors are not located at the ceiling level, the smoke detection system does not comply with NFPA 72, but still provides some smoke detection capability for the area as a whole and would be expected to alert operators of the credible fire scenarios for this area. Additionally, the licensee stated that a fully trained onsite fire brigade is provided, which is dispatched via plant page in the event of a fire. The fire brigade is composed of plant operators that are separate from operators assigned safe shutdown duties and are instructed to provide information about a fire event over the operations radio to assist in mitigating the event.

Preservation of Safe Shutdown Capability

The licensee stated that Fire Area 58 has a ceiling height of approximately 29' and an approximate floor area of 3,525 square feet, so it is unlikely that smoke and heat would accumulate at the height of the safe shutdown equipment and cause a failure due to fire damage.

OMAs Credited for a Fire in This Area

Action BB

The licensee stated that while it is possible that the two redundant cables in Fire Area 58 associated with the normal power supply to the 3DD003 battery charger could potentially be damaged by a lube oil or MG set fire, it is unlikely that the cables within the conduits would be damaged since the conduit containing cable ZD3B3983A is not located above the MG set. In addition, there is a smoke detection system provided in the area, as well as a pre-action sprinkler system located above the MG set. In the unlikely event that both cables are lost, the location of the action is in a different fire area from Fire Area 58.

A fire in Fire Area 58 has the potential to damage cables ZD3A1806A and ZD3B3983A, which the licensee stated are located in conduits embedded in the concrete floor slab, control panels, and a junction box. The loss of either of these cables could result in a loss of the normal power supply to the 3DD003 battery charger. The battery charger is needed to maintain long term DC power through the station batteries. The batteries can operate for 60 minutes prior to the initiation of recharging. Battery charger 3DD003 can also be fed an alternate power source, which is routed in separate fire areas, so a single fire cannot damage both the normal and alternate power feed.

In the unlikely event that a fire does occur and goes undetected by the smoke detection system or unsuppressed by the suppression system and the cables are damaged, Action BB is available to transfer the alternate power supply to battery charger 3DD003. The action entails closing a breaker and then operating a manual transfer switch, both located in the E43 4kV Switchgear Room (Fire Area 34), which is a separate fire area from Fire Area 58.

Action CC

The potential need to perform this action is low since this action is only needed if two of three other offsite power sources are unavailable, power to the 2SU transformer tap changer lost, and the tap changer is in the wrong position. The licensee stated that offsite power is provided to each of the 4kV Class 1E switchgear by two of three redundant sources (2SU, 3SU, and 343SU) and that control cables for the sources have been physically separated by rerouting selected cables, such that one of the redundant sources remains free of fire damage for fires in most plant areas. In particular, the licensee stated that cables associated with the 2SU source have been relocated out of the Turbine Building (Fire Area 50), and portions of the Radwaste Building (Fire Areas 2 and 58).

The licensee stated that BOP cables are routed through Fire Area 58 but that the routing of the cables was not part of its analysis. In its February 12, 2010, supplement, the licensee described the circumstances that would determine the availability of the safe shutdown equipment located in this area; namely the 2SU power source, which includes a transformer tap changer that is powered by BOP power. Since the BOP cable routing was not part of the analysis, the loss of BOP was assumed for a fire in these three fire areas. The licensee's analysis also assumed that the transformer tap changer, which is powered by the BOP and responsible for maintaining power to the 4kV Bus 2SU, was not in the correct position. When the tap changer is not in the correct position, the voltage could vary resulting in the actuation of the 4kV trip relays.

In the unlikely event that a fire does occur and goes undetected by the smoke detection system or unsuppressed by the suppression system and fire damage occurs to the redundant cables, Action CC can be utilized, which directs operators to pull the fuse blocks for the degraded voltage trip relays to ensure that the 4kV busses remain available.

Action CC is a "prompt" action, however, the licensee stated that its analysis assumed that the redundant cables were lost regardless of their location and that the tap changer was not in the correct position. The licensee also stated that a note is provided in the applicable T–300 Fire Guide providing guidance on how to determine whether the 2SU transformer tap changer has lost power using indications within the Control Room. Therefore, the Control Room will know immediately if this action is required and a generic diagnosis time is not necessary.

The licensee's T–300 Fire Guides also provide the following guidance to assist operators in evaluating a postulated event, "If 2SU is the only offsite power source available and a loss of power to the 2SU Transformer Tap Changer has occurred, then perform the manual action to remove the fuses."

Additionally, the 2SU transformer and associated auxiliaries are located in the yard area and would not be exposed by a fire in Fire Area 58. Lastly, the location of the OMA to remove the fuses in the 4kV Switchgear Rooms is in a separate fire area, with separate ventilation systems, from Fire Area 58.

NRC Staff Evaluation

Given the moderate amount of combustible materials, ignition sources, and the large volume of the space, it is unlikely that a fire would occur and go undetected by the smoke detection system noted above or unsuppressed by the suppression system noted above or by personnel, and damage the safe shutdown equipment. Even if such circumstances exist, Actions BB and CC are available to provide additional assurance that safe shutdown capability is maintained.

3.5 Summary of Defense-in-Depth and Operator Manual Actions

In summary, the NRC staff finds that the defense-in-depth concept for a fire in the fire areas discussed above provides a level of safety that results in the unlikely occurrence of fires, rapid detection, control and extinguishment of fires that do occur and the protection of structures, systems and components important to safety. As discussed above, the licensee has provided preventative and protective measures in addition to

feasible and reliable OMAs that together demonstrate the licensee's ability to preserve or maintain safe shutdown capability in the event of a fire in the analyzed fire areas.

Authorized by Law

This exemption would allow PBAPS to rely on OMAs, in conjunction with the other installed fire protection features, to ensure that at least one means of achieving and maintaining hot shutdown remains available during and following a postulated fire event, as part of its FPP, in lieu of meeting the requirements specified in III.G.2 for a fire in the analyzed fire areas. As stated above, 10 CFR 50.12 allows the NRC to grant exemptions from the requirements of 10 CFR Part 50. The NRC staff has determined that granting of this exemption will not result in a violation of the Atomic Energy Act of 1954, as amended, or the Commission's regulations. Therefore, the exemption is authorized by law.

No Undue Risk to Public Health and Safety

The underlying purpose of 10 CFR Part 50, Appendix R, Section III.G is to ensure that at least one means of achieving and maintaining hot shutdown remains available during and following a postulated fire event. Based on the above, no new accident precursors are created by the use of the specific OMAs, in conjunction with the other installed fire protection features, in response to a fire in the analyzed fire areas. Thus, the probability of postulated accidents is not increased. Also, based on the above, the consequences of postulated accidents are not increased. Therefore, there is no undue risk to public health and safety.

Consistent with Common Defense and Security

The proposed exemption would allow PBAPS to credit the use of the specific OMAs, in conjunction with the other installed fire protection features, in response to a fire in the analyzed fire areas, discussed above, in lieu of meeting the requirements specified in III.G.2. This change, to the operation of the plant, has no relation to security issues. Therefore, the common defense and security is not diminished by this exemption.

Special Circumstances

Pursuant to 10 CFR 50.12(a)(2)(ii) special circumstances are present whenever application of the regulation in the particular circumstances is not necessary to achieve the underlying purpose of the rule. The underlying purpose of 10 CFR Part 50, Appendix R, Section III.G is to ensure that at least one means of achieving and maintaining hot shutdown remains available during and following a postulated fire event. Therefore, since the underlying purpose of Appendix R, Section III.G is achieved, the special circumstances for granting an exemption from 10 CFR Part 50, Appendix R, Section III.G exist, as required by 10 CFR 50.12(a)(2)(ii).

4.0 Conclusion

Accordingly, the Commission has determined that, pursuant to 10 CFR 50.12(a), the exemption is authorized by law, will not present an undue risk to the public health and safety, and is consistent with the common defense and security. Also, special circumstances are present. Therefore, the Commission hereby grants Exelon an exemption from the requirements of Section III.G.2 of Appendix R of 10 CFR Part 50, to utilize the OMAs discussed above at PBAPS.

Pursuant to 10 CFR 51.32, the Commission has determined that the granting of this exemption will not have a significant effect on the quality of the human environment (75 FR 58445).

This exemption is effective upon issuance.

Dated at Rockville, Maryland, this 30th day of March 2011.

For The Nuclear Regulatory Commission.

Joseph G. Giitter,

Director, Division of Operating Reactor Licensing, Office of Nuclear Reactor Regulation.

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NUCLEAR REGULATORY COMMISSION

[Docket No. 50–219; NRC–2010–0200]

Exelon Generation Company, LLC, Oyster Creek Nuclear Generating Station; Exemption

1.0 Background

Exelon Generation Company, LLC (Exelon or the licensee) is the holder of Facility Operating License No. DPR–16 that authorizes operation of the Oyster Creek Nuclear Generating Station (Oyster Creek). The license provides, among other things, that the facility is subject to all rules, regulations, and orders of the U.S. Nuclear Regulatory Commission (NRC or the Commission) now or hereafter in effect.

The facility consists of a boiling-water reactor located in Ocean County, New Jersey.

2.0 Request/Action

Title 10 of the *Code of Federal Regulations* (10 CFR), Part 50, Section 50.48 requires that nuclear power plants that were licensed before January 1, 1979, must satisfy the requirements of 10 CFR Part 50, Appendix R, Section III.G, "Fire protection of safe shutdown capability." Oyster Creek was licensed to operate prior to January 1, 1979. As such, the licensee's Fire Protection Program must provide the established level of protection as intended by Section III.G of 10 CFR Part 50, Appendix R.

By letter dated March 4, 2009, "Request for Exemption from 10 CFR 50, Appendix R, Section III.G, 'Fire Protection of Safe Shutdown Capability (Phase 2)'" available at Agencywide Documents Access and Management System (ADAMS), Accession No. ML090640225, and supplemented by letter dated April 2, 2010, "Response to Request for Additional Information Request for Exemption from 10 CFR Part 50, Appendix R, Section III.G, 'Fire Protection of Safe Shutdown Capability'" (ADAMS Accession No. ML100920370), the licensee requested an exemption for Oyster Creek from certain technical requirements of 10 CFR Part 50, Appendix R, Section III.G.2 (III.G.2) for the use of operator manual actions (OMAs) in lieu of meeting the circuit separation and protection requirements contained in III.G.2 for the following 22 plant areas: CW–FA–14, OB–FA–9, OB–FZ–6A, OB–FZ–6B, OB–FZ–8A, OB–FZ–8B, OB–FZ–8C, OB–FZ–10A, RB–FZ–1D, RB–FZ–1E, RB–FZ–1F3, RB–FZ–1F5, RB–FZ–1G, TB–FA–3A, TB–FA–26, TB–FZ–11B, TB–FZ–11C, TB–FZ–11D, TB–FZ–11E, TB–FZ–11F, TB–FZ–11H, and Yard. The 22 plant areas noted above are the subject of this exemption.

3.0 Discussion

Pursuant to 10 CFR 50.12, the Commission may, upon application by any interested person or upon its own initiative, grant exemptions from the requirements of 10 CFR Part 50 when: (1) The exemptions are authorized by law, will not present an undue risk to public health or safety, and are consistent with the common defense and security; and (2) when special circumstances are present. The licensee has stated that special circumstances are present in that the application of the regulation in this particular circumstance is not necessary to achieve the underlying purpose of the rule, which is consistent with the language included in 10 CFR 50.12(a)(2)(ii).

In their March 4, 2009, and April 2, 2010, letters, the licensee discussed financial implications associated with plant modifications that may be necessary to comply with the regulation.

Section 50.12(a)2(iii) of 10 CFR states that if such costs have been shown to be significantly in excess of those contemplated at the time the regulation was adopted, or are significantly in excess of those incurred by others similarly situated, this may be considered a basis for considering an exemption request. However, financial implications were not considered in the regulatory review of their request since no substantiation was provided regarding such financial implications. Even though no financial substantiation was provided, the licensee did submit sufficient regulatory basis to support a technical review of their exemption request in that the application of the regulation in this particular circumstance is not necessary to achieve the underlying purpose of the rule.

In accordance with 10 CFR 50.48(b), nuclear power plants licensed before January 1, 1979, are required to meet Section III.G of 10 CFR Part 50, Appendix R. The underlying purpose of Section III.G of 10 CFR Part 50, Appendix R, is to ensure that the ability to achieve and maintain safe shutdown is preserved following a fire event. The regulation intends for licensees to accomplish this by extending the concept of defense-in-depth to:

(1) Prevent fires from starting;

(2) Rapidly detect, control, and extinguish promptly those fires that do occur;

(3) Provide protection for structures, systems, and components important to safety so that a fire that is not promptly extinguished by the fire suppression activities will not prevent the safe shutdown of the plant.

The stated purpose of 10 CFR Part 50, Appendix R, Section III.G.2 (III.G.2) is to ensure that one of the redundant trains necessary to achieve and maintain hot shutdown conditions remains free of fire damage in the event of a fire. Section III.G.2 requires one of the following means to ensure that a redundant train of safe shutdown cables and equipment is free of fire damage, where redundant trains are located in the same fire area outside of primary containment:

a. Separation of cables and equipment by a fire barrier having a 3-hour rating;

b. Separation of cables and equipment by a horizontal distance of more than 20 feet with no intervening combustibles or fire hazards and with fire detectors and an automatic fire suppression system installed in the fire area; or

c. Enclosure of cables and equipment of one redundant train in a fire barrier having a 1-hour rating and with fire detectors and an automatic fire suppression system installed in the fire area.

Exelon has requested an exemption from the requirements of III.G.2 for Oyster Creek to the extent that redundant trains of systems necessary to achieve and maintain hot shutdown are not maintained free of fire damage in accordance with one of the required means prescribed in III.G.2.

Each OMA included in this review consists of a sequence of tasks that occur in various fire areas. The OMAs are initiated upon confirmation of a fire in a particular fire area. Table 1 lists, in the order of the fire area of fire origin, the OMAs included in this review.

TABLE 1

	Area of fire origin	Area name	Actions	OMA #
1	CW–FA–14	Circulatory Water Intake	Provide makeup control air to the accumulator for V–11–34 for the Isolation Condenser makeup line due to the loss of instrument air.	17
2	OB–FA–9	Office Building (Bldg.) Elev. 23′-6″, 35′-0″, 46′-6″.	Provide makeup control air to the accumulator for V–11–34 for the Isolation Condenser makeup line due to the loss of instrument air.	17
3	OB–FZ–6A	Office Bldg. “A” 480V Switchgear (SWGR) Room Elev. 23′-6″.	Provide makeup control air to the accumulator for V–11–34 for the Isolation Condenser makeup line due to the loss of instrument air.	17
4	OB–FZ–6B	Office Bldg. “B” 480V SWGR Room Elev. 23′-6″.	Provide makeup control air to the accumulator for V–11–36 for the Isolation Condenser makeup line due to the loss of instrument air.	18
5	OB–FZ–8A	Office Bldg. Reactor Recirculation Motor Generator (MG) Set Room Elev. 23′-6″.	Provide makeup control air to the accumulator for V–11–34 for the Isolation Condenser makeup line due to the loss of instrument air.	17
6	OB–FZ–8B	Office Bldg. Mechanical Equipment Room Elev. 35′-0″.	Provide makeup control air to the accumulator for V–11–34 for the Isolation Condenser makeup line due to the loss of instrument air.	17
7	OB–FZ–8C	Office Bldg. A/B Battery Room, Tunnel and Electrical Tray Room Elev. 35′-0″.	Provide makeup control air to the accumulator for V–11–34 for the Isolation Condenser makeup line due to the loss of instrument air.	17
8	OB–FZ–10A	Office Bldg. Monitor and Change Room Area and Operations Support Area Elev. 35′-0″ & 46′-6″.	Provide makeup control air to the accumulator for V–11–36 for the Isolation Condenser makeup line due to the loss of instrument air.	18
9	RB–FZ–1D	Reactor Bldg. Elev. 51′-3″	Provide makeup control air to the accumulator for V–11–34 for the Isolation Condenser makeup line due to the loss of instrument air.	17
10	RB–FZ–1E	Reactor Building Elev. 23′-6″	Provide makeup control air to the accumulator for V–11–34 for the Isolation Condenser makeup line due to the loss of instrument air.	17
11	RB–FZ–1F3	Reactor Bldg. Northwest Corner Elev.-19′-6″.	Provide makeup control air to the accumulator for V–11–34 for the Isolation Condenser makeup line due to the loss of instrument air.	17
12	RB–FZ–1F5	Reactor Bldg. Torus Room Elev. -19′-6″.	Provide makeup control air to the accumulator for V–11–34 for the Isolation Condenser makeup line due to the loss of instrument air.	17

TABLE 1—Continued

	Area of fire origin	Area name	Actions	OMA #
13	RB–FZ–1G	Reactor Bldg. Shutdown Cooling Room Elev. 38′-0″ & 51′-3″.	Provide makeup control air to the accumulator for V–11–34 for the Isolation Condenser makeup line due to the loss of instrument air.	17
14	TB–FA–3A	Turbine Bldg. 4160V Emergency SWGR Vault 1C Elev. 23′-6″.	Provide makeup control air to the accumulator for V–11–34 for the Isolation Condenser makeup line due to the loss of instrument air.	17
15	TB–FA–26	Turbine Bldg. 125V DC Battery Room C Elev. 23′-6″.	Trip Field Breakers for Recirculation Pumps MG Set so that the Fuel Zone Level Indicators can be used.	1
			Provide Fire Water to Isolation Condenser shell by operating valves V–9–2099, V–11–49, V–11–63 and V–11–41 due to loss of power (contingency action).	2
			Manually control 480V USS 1B2 Breakers for control rod drive (CRD) Pump NC08B and 1B2M from Remote Shutdown Panel due to control circuit damage.	3
			Manually open V–11–36 to provide makeup to Isolation Condenser due to loss of power (contingency action).	7
			Check Isolation Condenser Shell level locally due to loss of power (contingency action).	8
			Provide makeup control air to the accumulator for V–11–36 for the Isolation Condenser makeup line due to the loss of instrument air.	18
16	TB–FZ–11B	Turbine Bldg. Lube Oil Storage, Purification and Pumping Area Elev. 0′-0″, 27′-0″, and 36′-0″.	Manually control 480V Unit Substation (USS) 1B2 Breakers for CRD Pump NC08B and 1B2M from Remote Shutdown Panel due to control circuit damage.	3
.....			Provide makeup control air to the accumulator for V–11–36 for the Isolation Condenser makeup line due to the loss of instrument air.	18
17	TB–FZ–11C	Turbine Bldg. SWGR Room 1A and 1B Elev. 23′-6″.	Trip Field Breakers for Recirculation Pumps MG Set so that the Fuel Zone Level Indicators can be used.	1
			Provide Fire Water to Isolation Condenser shell by operating valves V–9–2099, V–11–49, V–11–63 and V–11–41 due to loss of power (contingency action).	2
			Manually control 480V USS 1B2 Breakers for CRD Pump NC08B and 1B2M from Remote Shutdown Panel due to control circuit damage.	3
			Manually open V–11–36 to provide makeup to Isolation Condenser due to loss of power (contingency action).	7
			Check Isolation Condenser Shell level locally due to loss of power (contingency action).	8
			Provide makeup control air to the accumulator for V–11–36 for the Isolation Condenser makeup line due to the loss of instrument air.	18
18	TB–FZ–11D	Turbine Bldg. Basement Floor South End Elev. 3′-6″.	Trip Field Breakers for Recirculation Pumps MG Set so that the Fuel Zone Level Indicators can be used.	1
			Provide Fire Water to Isolation Condenser shell by operating valves V–9–2099, V–11–49, V–11–63 and V–11–41 due to loss of power (contingency action).	2
			Manually control 480V USS 1B2 Breakers for CRD Pump NC08B and 1B2M from Remote Shutdown Panel due to control circuit damage.	3
			Manually open V–11–36 to provide makeup to Isolation Condenser due to loss of power (contingency action).	7
			Check Isolation Condenser Shell level locally due to loss of power (contingency action).	8
			Provide makeup control air to the accumulator for V–11–36 for the Isolation Condenser makeup line due to the loss of instrument air.	18
19	TB–FZ–11E	Turbine Bldg. Condenser Bay Area Elev. 0′-0″.	Manually control 480V USS 1B2 Breakers for CRD Pump NC08B and 1B2M from Remote Shutdown Panel due to control circuit damage.	3
			Provide makeup control air to the accumulator for V–11–36 for the Isolation Condenser makeup line due to the loss of instrument air.	18
20	TB–FZ–11F	Turbine Bldg. Feedwater Pump Room Elev. 0′-0″ & 3′-6″.	Provide makeup control air to the accumulator for V–11–36 for the Isolation Condenser makeup line due to the loss of instrument air.	18
21	TB–FZ–11H	Turbine Bldg. Demineralizer Tank and Steam Jet Air Ejector Area Elev. 3′-6″ & 23′-6″.	Provide makeup control air to the accumulator for V–11–36 for the Isolation Condenser makeup line due to the loss of instrument air.	18

TABLE 1—Continued

	Area of fire origin	Area name	Actions	OMA #
22	Yard	Office Bldg. Roof, Turbine Bldg. Roof, and All Remaining Outside Areas.	Manually open V–15–237, throttle V–15–30 while monitoring flow at FI–225–2 and close V–15–52 to establish CRD flow to Reactor due to the loss of instrument air to the CRD Flow Control Valve.	9
			Provide makeup control air to the accumulator for V–11–34 for the Isolation Condenser makeup line due to the loss of instrument air.	17

In their submittals the licensee described elements of their fire protection program that provide their justification that the concept of defense-in-depth that is in place in the above fire areas is consistent with that intended by the regulation. To accomplish this, the licensee utilizes various protective measures to accomplish the concept of defense-in-depth. Specifically, the licensee stated that the purpose of their request was to credit the use of OMAs, in conjunction with other defense-in-depth features, in lieu of the separation and protective measures required by III.G.2 for a fire in the fire areas stated above.

In their April 2, 2010, letter the licensee provided an analysis that described how fire prevention is addressed for each of the fire areas for which the OMAs may be required. The licensee developed a Fire Hazards Analysis (FHA) for each fire area or zone identified in its exemption request. For each fire area or zone, the FHA describes the physical location and arrangement of equipment, combustible loading, ignition sources, fire protection features, and proximity of redundant safe shutdown equipment to in situ hazards and identifies deviations from fire protection codes and previously approved exemptions. In addition, for each fire area or zone, the licensee's response includes a tabulation of potential ignition sources as well as the equipment that may exhibit high energy arcing faults. For each fire area or zone, the FHA states that the fire protection configuration achieves a level of protection commensurate with that intended by III.G.2.

The 22 areas or zones identified in the request have administratively limited combustible fuel loading with fuel sources consisting primarily of cable insulation and limited floor based combustibles except areas OB–FZ–6A, OB–FZ–6B, and TB–FZ–11B, which contain quantities of transformer liquid or lubricating oil. Combustible fuel loading in most areas is classified as low by the licensee while Fire Areas OB–FZ–6A and OB–FZ–6B have been classified as having a moderate combustible fuel loading and TB–FZ–11B has been classified as having a high combustible fuel loading. In addition, the licensee has stated that they maintain a robust administrative program (e.g., hot work permits, fire watches for hot work, and supervisory controls) to limit and control transient combustible materials and ignition sources in the areas. The fire areas included in the exemption are not shop areas so hot work activities are infrequent and the administrative control programs are in place if hot work activities do occur.

The licensee also stated that 98% of the Oyster Creek cables are jacketed with Vulkene, which passes the horizontal flame test of the Underwriter's Laboratory, therefore reducing the likelihood of the cables themselves contributing to a fire hazard. Furthermore, the areas or zones are of noncombustible construction with typical utilities installed lighting, ventilation, etc., and 3-hour fire resistance-rated barriers normally used to provide fire resistive separation between adjacent fire areas. In some cases, barriers with a fire resistance rating of less than 3 hours are credited, but exemptions have been approved or the licensee has stated they have performed engineering evaluations in accordance with Generic Letter 86–10 to demonstrate that the barriers are sufficient for the hazard. Walls separating rooms and zones within fire areas are typically constructed of heavy concrete. This compartmentalization of the areas reduces the likelihood for fire events in a particular area to spread to or impact other adjacent areas.

Many fire areas included in this exemption have automatic detection systems installed, although the licensee indicated that not all systems are installed in accordance with a recognized standard with regard to spacing in all areas. In such cases, the licensee has stated that the detectors are located near equipment such that they are likely to detect a fire. Upon detecting smoke, the detectors initiate an alarm in the constantly staffed control room. In addition to the automatic suppression systems noted below, equipment operators are trained fire brigade members and may identify and manually suppress or extinguish a fire using the portable fire extinguishers and manual hose stations located throughout the fire areas if a fire is identified in its early stages of growth.

The licensee stated that the postulated fire events that may require the use of the OMAs would include multiple failures of various components or equipment. In most cases, it is considered unlikely that the sequence of events required to necessitate the OMAs would fully evolve because of the fire prevention, fire protection, and physical separation features in place. However, in the event that the sequence does evolve, the OMAs are available to provide assurance that safe shutdown can be achieved. For each of the fire areas included in this exemption, the postulated fire scenarios and pertinent details are summarized in Table 2 below.

Each of the fire areas or zones included in this exemption is analyzed below with regard to how the concept of defense-in-depth is achieved for each area or zone and the role of the OMAs in the overall level of safety provided for each area or zone.

3.1 CW–FA–14 Circulatory Water Intake

3.1.1 Fire Prevention

The licensee stated that combustible loading is not tracked in this area since it is an outside area. The licensee also stated that the primary combustible materials in the area are transformer liquid and electrical motors; although the amount is not quantified since the area is open to the atmosphere with no walls or ceiling to contain the heat or smoke that may be produced during a fire event. Additionally, the main combustible in this area that could result in the need for the OMAs is Dow Corning 561 Silicon transformer liquid, which the licensee states has characteristics that minimize the likelihood of a fire involving the insulating liquid itself.

3.1.2 Detection, Control, and Extinguishment

CW–FA–14 is not equipped with automatic fire detection or suppression systems but since it is an outdoor area with no walls or ceiling, it is not expected that such systems would enhance this element of defense-in-depth in this area since the area is open to the atmosphere with no walls or ceiling to contain the heat or smoke that may be produced during a fire event. However, the licensee stated that a security tower monitors this area continuously. Therefore, any fire of significance would likely be detected and responded to appropriately by the station fire brigade. Manual suppression is also provided by a fire hydrant and fire hose house located approximately 75 feet from the principal fire hazards.

3.1.3 Preservation of Safe Shutdown Capability

Since Fire Area CW–FA–14 is an outdoor space with no walls or ceiling, smoke and heat would not accumulate within the fire area to cause damage to components remote to the initiating fire or obstruct operator actions.

3.1.4 OMAs Credited for a Fire in This Area

3.1.4.1 OMA #17—Provide Makeup Air to Isolation Condenser Valve V–11–34 Accumulator

In order for OMA #17 to be necessary, a loss of instrument air to the isolation condenser valve V–11–34 would have to occur due to fire damage. The licensee stated that they conservatively assume that instrument air is lost for all Appendix R fires based on the fact that instrument air lines run throughout many areas of the plant. The licensee's analysis assumes that the air line could potentially fail in approximately 45 minutes when exposed to the postulated fire.

The licensee also stated that OMA #17 connects a high pressure air cylinder to the accumulator of Condensate Transfer System valve V–11–34 and that these air-operated valves are used to control makeup to the isolation condensers. Each valve is provided with an air accumulator that provides a minimum of six full cycles. As a result, this OMA is only necessary to ensure long-term operation of these valves and makeup to the isolation condensers. Further, this OMA would only be necessary if the plant had to remain in hot shutdown for an extended time.

In addition, the licensee stated that they maintain a fire support procedure (ABN–35, "Loss of Instrument Air") that provides guidance to perform this OMA if instrument air is lost and indicates that there are four annunciator alarm windows that monitor instrument air pressure, plus a pressure gauge on a panel in the control room for instrument air pressure. If all of these instruments are not available, then ABN–35 further indicates that the control rods will start to drift into the core and the main steam isolation valves (MSIVs) will close, as well as multiple air-operated valves changing state. Additionally, reactor pressure vessel (RPV) level indication is also available for all fire areas or zones. All of these indications would help the operator diagnose the loss of instrument air and initiate mitigating procedures.

In the unlikely event that a fire does occur and causes a loss of instrument air to the air-operated valves, OMA #17 is available to provide makeup control air to the accumulator for V–11–34 for the isolation condenser makeup line due to the loss of instrument air. If OMA #17 becomes necessary, the licensee stated that they have assumed a 30-minute diagnosis period and that the required time to perform the action is 26 minutes, while the time available is 300 minutes, which provides a 244-minute margin.

3.1.5 Conclusion

Given the limited amount of combustible materials, ignition sources, and open nature of the area, it is unlikely that a fire would occur and go undetected or unsuppressed by the personnel, and damage the safe shutdown equipment. The low likelihood of damage to safe shutdown equipment due to a fire in this area, combined with the ability of OMA #17 to manipulate the plant in the event of a fire that damages safe shutdown equipment, provides adequate assurance that safe shutdown capability is maintained.

3.2 OB–FA–9 Office Bldg. Elev. 23′-6″, 35′-0″, 46′-6″,

3.2.1 Fire Prevention

The licensee has classified the fire loading in this fire area as low. The licensee also stated that the major combustibles in the multiplexer (MUX) corridor, which is within OC–FA–9, are cable insulation and a wood ceiling on top of the MUX enclosure, which is within the MUX corridor.

3.2.2 Detection, Control, and Extinguishment

The licensee stated that OB–FA–9 has a partial area coverage wet pipe sprinkler system installed. The licensee further stated that the area is not provided with a detection system but that there is an installed detection system in the main hallways and inside of the MUX corridor and that it is a high traffic area so a fire would likely be detected by personnel. The wet pipe sprinkler system, when actuated, will alarm in the control room to notify operators of a potential fire event. Extinguishment of a fire in the majority of this area will be accomplished by the plant fire brigade.

3.2.3 Preservation of Safe Shutdown Capability

The licensee stated that OB–FA–9 has a ceiling height of approximately 10′-6″, and an approximate floor area of 513 square feet in the MUX corridor where the safe shutdown equipment is located so it is unlikely that smoke and heat would accumulate at the height of the safe shutdown equipment and cause a failure due to fire damage.

3.2.4 OMAs Credited for a Fire in this Area

3.2.4.1 OMA #17—Provide Makeup Air to Isolation Condenser Valve V–11–34 Accumulator

In order for OMA #17 to be necessary, a loss of instrument air to the isolation condenser valve V–11–34 would have to occur due to fire damage. The licensee stated that they conservatively assume that instrument air is lost for all Appendix R fires based on the fact that instrument air lines run throughout many areas of the plant. The licensee's analysis assumes that the air line could potentially fail in approximately 45 minutes when exposed to the postulated fire.

The licensee also stated that OMA #17 connects a high pressure air cylinder to the accumulator of Condensate Transfer System valve V–11–34 and that these air-operated valves are used to control makeup to the isolation condensers. Each valve is provided with an air accumulator that provides a minimum of six full cycles. As a result, this OMA is only necessary to ensure long-term operation of these valves and makeup to the isolation condensers. Further, this OMA would only be necessary if the plant had to remain in hot shutdown for an extended time. This scenario is unlikely for this particular area since the plant would likely reach cold shutdown before the action is required.

In addition, the licensee stated that they maintain a fire support procedure (ABN–35, "Loss of Instrument Air") that provides guidance to perform this OMA if instrument air is lost and indicates that there are four annunciator alarm windows that monitor instrument air pressure, plus a pressure gauge on a

panel in the control room for instrument air pressure. If all of these instruments are not available, then ABN–35 further indicates that the control rods will start to drift into the core and the MSIVs will close, as well as multiple air-operated valves changing state. Additionally, RPV level indication will not be compromised by a fire in any zone or area. All of these indications would help the operator diagnose the loss of instrument air and initiate mitigating procedures.

In the unlikely event that a fire does occur and causes a loss of instrument air to the air-operated valves, OMA #17 is available to provide makeup control air to the accumulator for V–11–34 for the isolation condenser makeup line due to the loss of instrument air. If OMA #17 becomes necessary, the licensee stated that they have assumed a 30-minute diagnosis period and that the required time to perform the action is 26 minutes, while the time available is 300 minutes, which provides a 244-minute margin.

3.2.5 Conclusion

Given the limited amount of combustible materials, ignition sources, and volume of the space, it is unlikely that a fire would occur and go undetected or unsuppressed by the sprinkler system noted above, or personnel, and damage the safe shutdown equipment. The low likelihood of damage to safe shutdown equipment due to a fire in this area, combined with the ability of OMA #17 to manipulate the plant in the event of a fire that damages safe shutdown equipment, provides adequate assurance that safe shutdown capability is maintained.

3.3 OB–FZ–6A Office Bldg. "A" 480V Switchgear (SWGR) Room Elev. 23′-6″,

3.3.1 Fire Prevention

The licensee stated that the fire loading in this zone is moderate and that there is an administrative controls program in place to limit additional combustible materials and sources of ignition. The licensee also stated that the main combustibles in this area are cable insulation (approximately 81% of loading) and Dow Corning 561 Silicon transformer liquid (approximately 15% of loading). The transformer liquid has characteristics that minimize the likelihood of a fire involving the insulating liquid itself.

3.3.2 Detection, Control, and Extinguishment

The licensee stated that OB–FZ–6A has an automatic smoke detection system, a total flooding automatic Halon 1301 System, and manual fire fighting capabilities (portable extinguishers and hose stations).

3.3.3 Preservation of Safe Shutdown Capability

The licensee stated that OB–FA–6A has a ceiling height of approximately 10′-8″, and an approximate floor area of 1157 square feet so it is unlikely that smoke and heat would accumulate at the height of the safe shutdown equipment and cause a failure due to fire damage.

3.3.4 OMAs Credited for a Fire in this Zone

3.3.4.1 OMA #17—Provide Makeup Air to Isolation Condenser Valve V–11–34 Accumulator

In order for OMA #17 to be necessary, a loss of instrument air to the isolation condenser valve V–11–34 would have to occur due to fire damage. The licensee stated that they conservatively assume that instrument air is lost for all Appendix R fires based on the fact that instrument air lines run throughout many areas of the plant. The licensee's analysis assumes that the air line could potentially fail in approximately 45 minutes when exposed to the postulated fire.

The licensee also stated that OMA #17 connects a high pressure air cylinder to the accumulator of Condensate Transfer System valve V–11–34 and that these air-operated valves are used to control makeup to the isolation condensers. Each valve is provided with an air accumulator that provides a minimum of six full cycles. As a result, this OMA is only necessary to ensure long-term operation of these valves and makeup to the isolation condensers. Further, this OMA would only be necessary if the plant had to remain in hot shutdown for an extended time.

In addition, the licensee stated that they maintain a fire support procedure (ABN–35, "Loss of Instrument Air") that provides guidance to perform this OMA if instrument air is lost and indicates that there are four annunciator alarm windows that monitor instrument air pressure, plus a pressure gauge on a panel in the control room for instrument air pressure. If all of these instruments are not available, then ABN–35 further indicates that the control rods will start to drift into the core and the MSIVs will close, as well as multiple air-operated valves changing state. Additionally, RPV level indication will not be compromised by a fire in any zone or area. All of these indications would help the operator diagnose the loss of instrument air and initiate mitigating procedures.

In the unlikely event that a fire does occur and causes a loss of instrument air to the air-operated valves, OMA #17 is available to provide makeup control air to the accumulator for V–11–34 for the isolation condenser makeup line due to the loss of instrument air. If OMA #17 becomes necessary, the licensee stated that they have assumed a 30-minute diagnosis period and that the required time to perform the action is 26 minutes, while the time available is 300 minutes, which provides a 244-minute margin.

3.3.5 Conclusion

Given the limited amount of combustible materials, ignition sources, and the volume of the space, it is unlikely that a fire would occur and go undetected or unsuppressed by the smoke detection or Halon system noted above, or personnel, and damage the safe shutdown equipment. The low likelihood of damage to safe shutdown equipment due to a fire in this zone, combined with the ability of OMA #17 to manipulate the plant in the event of a fire that damages safe shutdown equipment, provides adequate assurance that safe shutdown capability is maintained.

3.4 OB–FZ–6B Office Building "B" 480V SWGR Room Elev. 23′-6″,

3.4.1 Fire Prevention

The licensee stated that the fire loading in this zone is moderate and that there is an administrative controls program in place to limit additional combustible materials and sources of ignition. The licensee also stated that the main combustibles in this area are cable insulation (approximately 28% of loading), Thermo-Lag (approximately 29% of loading) and Dow Corning 561 Silicon transformer liquid (approximately 31% of loading). The transformer liquid has characteristics that minimize the likelihood of a fire involving the insulating liquid itself.

3.4.2 Detection, Control, and Extinguishment

The licensee stated that OB–FZ–6B has an automatic smoke detection system, a total flooding Halon 1301 System, and manual fire fighting capabilities (portable extinguishers and hose stations).

3.4.3 Preservation of Safe Shutdown Capability

The licensee stated that OB–FA–6B has a ceiling height of approximately 10′-8″ and an approximate floor area of 679 square feet so it is unlikely that

smoke and heat would accumulate at the height of the safe shutdown equipment and cause a failure due to fire damage.

3.4.4 OMAs Credited for a Fire in This Zone

3.4.4.1 OMA #18—Provide Makeup Air to Isolation Condenser Valve V–11–36 Accumulator

In order for OMA #18 to be necessary, a loss of instrument air to the isolation condenser valve V–11–36 would have to occur due to fire damage. The licensee stated that they conservatively assume that instrument air is lost for all Appendix R fires based on the fact that instrument air lines run throughout many areas of the plant. The licensee's analysis assumes that the air line could potentially fail in approximately 45 minutes when exposed to the postulated fire.

The licensee also stated that OMA #18 connects a high pressure air cylinder to the accumulator of Condensate Transfer System valve V–11–36 and that these air-operated valves are used to control makeup to the isolation condensers. Each valve is provided with an air accumulator that provides a minimum of six full cycles. As a result, this OMA is only necessary to ensure long-term operation of these valves and makeup to the isolation condensers. Further, this OMA would only be necessary if the plant had to remain in hot shutdown for an extended time.

In addition, the licensee stated that they maintain a fire support procedure (ABN–35, "Loss of Instrument Air") that provides guidance to perform this OMA if instrument air is lost and indicates that there are four annunciator alarm windows that monitor instrument air pressure, plus a pressure gauge on a panel in the control room for instrument air pressure. If all of these instruments are not available, then ABN–35 further indicates that the control rods will start to drift into the core and the MSIVs will close, as well as multiple air-operated valves changing state. Additionally, RPV level indication will not be compromised by a fire in any zone or area. All of these indications would help the operator diagnose the loss of instrument air and initiate mitigating procedures.

In the unlikely event that a fire does occur and causes a loss of instrument air to the air-operated valves, OMA #18 is available to provide makeup control air to the accumulator for V–11–36 for the isolation condenser makeup line due to the loss of instrument air. If OMA #18 becomes necessary, the licensee stated that they have assumed a 30-minute diagnosis period and that the required time to perform the action is 26 minutes, while the time available is 300 minutes, which provides a 244-minute margin.

3.4.5 Conclusion

Given the limited amount of combustible materials, ignition sources, and the volume of the space, it is unlikely that a fire would occur and go undetected or unsuppressed by the smoke detection or Halon system noted above, or personnel, and damage the safe shutdown equipment. The low likelihood of damage to safe shutdown equipment due to a fire in this area, combined with the ability of OMA #18 to manipulate the plant in the event of a fire that damages safe shutdown equipment, provides adequate assurance that safe shutdown capability is maintained.

3.5 OB–FZ–8A Office Bldg. Reactor Recirculation MG Set Room & OB–FZ–8B Mechanical Equipment Room Elev. 23′-6″ & 35′-0″

3.5.1 Fire Prevention

Fire Zones OB–FZ–8A and 8B are evaluated together for the combustible loading and fire safe shutdown analysis. The licensee stated that the fire loading in this zone is low and that there is an administrative controls program in place to limit additional combustible materials and sources of ignition. The licensee also stated that there are minimal combustibles in Fire Zone OB–FZ–8B. The major combustibles in Fire Zone OB–FZ–8A are lubricating oil (approximately 83% of loading) and cable insulation (approximately 13% of loading).

3.5.2 Detection, Control, and Extinguishment

The licensee stated that OB–FZ–8A has a partial wet-pipe sprinkler system with a flow alarm that notifies the control room and that the area does not have a smoke detection system however, a duct smoke detector is located in the exhaust duct of fan EF–1–20. Since operation of the sprinkler system will alarm in the control room, prompt notification of and response by, the fire brigade for any required manual fire fighting activities is expected.

3.5.3 Preservation of Safe Shutdown Capability

The licensee stated that OB–FZ–8A has a ceiling height of approximately 10′-10″ and an approximate floor area of 2128 square feet and OB–FZ–8B has a ceiling height of approximately 11′-0″ and an approximate floor area of 479 square feet so it is unlikely that smoke and heat would accumulate at the height of the safe shutdown equipment and cause a failure due to fire damage.

3.5.4 OMAs Credited for a Fire in This Area

3.5.4.1 OMA #17—Provide Makeup Air to Isolation Condenser Valve V–11–34 Accumulator

In order for OMA #17 to be necessary, a loss of instrument air to the isolation condenser valve V–11–34 would have to occur due to fire damage. The licensee stated that they conservatively assume that instrument air is lost for all Appendix R fires based on the fact that instrument air lines run throughout many areas of the plant. The licensee's analysis assumes that the air line could potentially fail in approximately 45 minutes when exposed to the postulated fire.

The licensee also stated that OMA #17 connects a high pressure air cylinder to the accumulator of Condensate Transfer System valve V–11–34 and that these air-operated valves are used to control makeup to the isolation condensers. Each valve is provided with an air accumulator that provides a minimum of six full cycles. As a result, this OMA is only necessary to ensure long-term operation of these valves and makeup to the isolation condensers. Further, this OMA would only be necessary if the plant had to remain in hot shutdown for an extended time. This scenario is unlikely for this particular area since the plant would likely reach cold shutdown before the action is required.

In addition, the licensee stated that they maintain a fire support procedure (ABN–35, "Loss of Instrument Air") that provides guidance to perform this OMA if instrument air is lost and indicates that there are four annunciator alarm windows that monitor instrument air pressure, plus a pressure gauge on a panel in the control room for instrument air pressure. If all of these instruments are not available, then ABN–35 further indicates that the control rods will start to drift into the core and the MSIVs will close, as well as multiple air-operated valves changing state. Additionally, RPV level indication will not be compromised by a fire in any zone or area. All of these indications would help the operator diagnose the loss of instrument air and initiate mitigating procedures.

In the unlikely event that a fire does occur and causes a loss of instrument air to the air-operated valves, OMA #17 is available to provide makeup control air to the accumulator for V–11–34 for the isolation condenser makeup line due to the loss of instrument air. If OMA #17

becomes necessary, the licensee stated that they have assumed a 30-minute diagnosis period and that the required time to perform the action is 26 minutes, while the time available is 300 minutes, which provides a 244-minute margin.

3.5.5 Conclusion

Given the limited amount of combustible materials, ignition sources, and the large volume of the space, it is unlikely that a fire would occur and go undetected or unsuppressed by the smoke detection or sprinkler systems noted above, or personnel, and damage the safe shutdown equipment. The low likelihood of damage to safe shutdown equipment in this zone, combined with the ability of OMA #17 to manipulate the plant in the event of a fire that damages safe shutdown equipment, provides adequate assurance that safe shutdown capability is maintained.

3.6 OB–FZ–8C Office Bldg. A/B Battery Room, Tunnel and Electrical Tray Room Elev. 35′-0″

3.6.1 Fire Prevention

The licensee stated that the fire loading in this zone is low and that there is an administrative controls program in place to limit additional combustible materials and sources of ignition. The licensee also stated that the major combustibles in Fire Zone OB–FZ–8C are electrolyte-filled plastic battery cases and racks (approximately 56% of loading) and cable insulation (approximately 39% of loading).

3.6.2 Detection, Control, and Extinguishment

The licensee stated that OB–FZ–8C has a fixed, total-flooding, Halon 1301 extinguishing system, area-wide smoke detection that is installed at the ceiling level and cross-zoned to sound a local alarm, and an alarm in the control room upon actuation of one detector. Actuation of a second detector will sound a local alarm, discharge the Halon system, trip supply and exhaust fans, and close dampers.

3.6.3 Preservation of Safe Shutdown Capability

The licensee stated that OB–FZ–8C has a ceiling height of approximately 11′-0″ and an approximate floor area of 1292 square feet so it is unlikely that smoke and heat would accumulate at the height of the safe shutdown equipment and cause a failure due to fire damage.

3.6.4 OMAs Credited for a Fire in This Zone

3.6.4.1 OMA #17—Provide Makeup Air to Isolation Condenser Valve V–11–34 Accumulator

In order for OMA #17 to be necessary, a loss of instrument air to the isolation condenser valve V–11–34 would have to occur due to fire damage. The licensee stated that they conservatively assume that instrument air is lost for all Appendix R fires based on the fact that instrument air lines run throughout many areas of the plant. The licensee's analysis assumes that the air line could potentially fail in approximately 45 minutes when exposed to the postulated fire.

The licensee also stated that OMA #17 connects a high pressure air cylinder to the accumulator of Condensate Transfer System valve V–11–34 and that these air-operated valves are used to control makeup to the isolation condensers. Each valve is provided with an air accumulator that provides a minimum of six full cycles. As a result, this OMA is only necessary to ensure long-term operation of these valves and makeup to the isolation condensers. Further, this OMA would only be necessary if the plant had to remain in hot shutdown for an extended time. This scenario is unlikely for this particular area since the plant would likely reach cold shutdown before the action is required.

In addition, the licensee stated that they maintain a fire support procedure (ABN–35, "Loss of Instrument Air") that provides guidance to perform this OMA if instrument air is lost and indicates that there are four annunciator alarm windows that monitor instrument air pressure, plus a pressure gauge on a panel in the control room for instrument air pressure. If all of these instruments are not available, then ABN–35 further indicates that the control rods will start to drift into the core and the MSIVs will close, as well as multiple air-operated valves changing state. Additionally, RPV level indication will not be compromised by a fire in any zone or area. All of these indications would help the operator diagnose the loss of instrument air and initiate mitigating procedures.

In the unlikely event that a fire does occur and causes a loss of instrument air to the air-operated valves, OMA #17 is available to provide makeup control air to the accumulator for V–11–34 for the isolation condenser makeup line due to the loss of instrument air. If OMA #17 becomes necessary, the licensee stated that they have assumed a 30-minute diagnosis period and that the required time to perform the action is 26 minutes, while the time available is 300 minutes, which provides a 244-minute margin.

3.6.5 Conclusion

Given the limited amount of combustible materials, ignition sources, and the large volume of the space, it is unlikely that a fire would occur and go undetected or unsuppressed by the smoke detection or Halon systems noted above, or personnel, and damage the safe shutdown equipment. The low likelihood of damage to safe shutdown equipment due to a fire in this zone, combined with the ability of OMA #17 to manipulate the plant in the event of a fire that damages safe shutdown equipment, provides adequate assurance that safe shutdown capability is maintained.

3.7 OB–FZ–10A Office Bldg. Monitor and Change Room and Operations Support Area Elev. 35′-0″ & 46′-6″

3.7.1 Fire Prevention

The licensee stated that the fire loading in this zone is low and that there is an administrative controls program in place to limit additional combustible materials and sources of ignition. The licensee also stated that the major combustibles in this area are cable insulation (approximate 27% of loading), rubber flooring (approximately 31% of loading), miscellaneous plastics (approximately 17% of loading) and protective clothing supplies (approximately 20% of loading). However, since the protective clothing have been placed in metal cans with self-closing lids they are no longer considered a contribution to the combustibles in this area.

3.7.2 Detection, Control, and Extinguishment

The licensee stated that OB–FZ–10A has an area-wide smoke detection system and a wet-pipe automatic sprinkler system installed throughout the area. In addition, a hose station located nearby, outside the control room, provides manual suppression capability.

3.7.3 Preservation of Safe Shutdown Capability

The licensee stated that OB–FZ–10A has a ceiling height of approximately 13′-0″ and an approximate floor area of 2019 square feet so it is unlikely that smoke and heat would accumulate at the height of the safe shutdown equipment and cause a failure due to fire damage.

3.7.4 OMAs Credited for a Fire in This Area

3.7.4.1 OMA #18—Provide Makeup Air to Isolation Condenser Valve V–11–36 Accumulator

In order for OMA #18 to be necessary, a loss of instrument air to the isolation condenser valve V–11–36 would have to occur due to fire damage. The licensee stated that they conservatively assume that instrument air is lost for all Appendix R fires based on the fact that instrument air lines run throughout many areas of the plant. The licensee's analysis assumes that the air line could potentially fail in approximately 45 minutes when exposed to the postulated fire.

The licensee also stated that OMA #18 connects a high pressure air cylinder to the accumulator of Condensate Transfer System valve V–11–36 and that these air-operated valves are used to control makeup to the isolation condensers. Each valve is provided with an air accumulator that provides a minimum of six full cycles. As a result, this OMA is only necessary to ensure long-term operation of these valves and makeup to the isolation condensers. Further, this OMA would only be necessary if the plant had to remain in hot shutdown for an extended time. This scenario is unlikely for this particular area since the plant would likely reach cold shutdown before the action is required.

In addition, the licensee stated that they maintain a fire support procedure (ABN–35, "Loss of Instrument Air") that provides guidance to perform this OMA if instrument air is lost and indicates that there are four annunciator alarm windows that monitor instrument air pressure, plus a pressure gauge on a panel in the control room for instrument air pressure. If all of these instruments are not available, then ABN–35 further indicates that the control rods will start to drift into the core and the MSIVs will close, as well as multiple air-operated valves changing state. Additionally, RPV level indication will not be compromised by a fire in any zone or area. All of these indications would help the operator diagnose the loss of instrument air and initiate mitigating procedures.

In the unlikely event that a fire does occur and causes a loss of instrument air to the air-operated valves, OMA #18 is available to provide makeup control air to the accumulator for V–11–36 for the isolation condenser makeup line due to the loss of instrument air. If OMA #18 becomes necessary, the licensee stated that they have assumed a 30-minute diagnosis period and that the required time to perform the action is 29 minutes, while the time available is 300 minutes, which provides a 241-minute margin.

3.7.5 Conclusion

Given the limited amount of combustible materials, ignition sources, and the large volume of the space, it is unlikely that a fire would occur and go undetected or unsuppressed by the smoke detection or sprinkler systems noted above, or personnel, and damage the safe shutdown equipment. The low likelihood of damage to safe shutdown equipment due to a fire in this zone, combined with the ability of OMA #18 to manipulate the plant in the event of a fire that damages safe shutdown equipment, provides adequate assurance that safe shutdown capability is maintained.

3.8 RB–FZ–1D Reactor Bldg. Elev. 51′-3″

3.8.1 Fire Prevention

The licensee stated that the fire loading in this zone is low and that there is an administrative controls program in place to limit additional combustible materials and sources of ignition. The licensee also stated that the main combustible in this area is attributed to cable insulation (approximately 84% of loading).

3.8.2 Detection, Control, and Extinguishment

The licensee stated that RB–FZ–1D has an area-wide smoke detection system and an automatic fixed deluge water spray system installed over cable trays and open hatches. The deluge suppression system protecting safety related cable trays is automatically activated by a cross-zoned detection system consisting of linear heat detection wire located on top of the cables in each original safety related cable tray and smoke detectors are located in each beam pocket at the ceiling.

3.8.3 Preservation of Safe Shutdown Capability

The licensee stated that RB–FZ–1D has a ceiling height of approximately 21′-0″ and an approximate floor area of 9,100 square feet so it is unlikely that smoke and heat would accumulate at the height of the safe shutdown equipment and cause a failure due to fire damage.

3.8.4 OMAs Credited for a Fire in This Area

3.8.4.1 OMA #17—Provide Makeup Air to Isolation Condenser Valve V–11–34 Accumulator

In order for OMA #17 to be necessary, a loss of instrument air to the isolation condenser valve V–11–34 would have to occur due to fire damage. The licensee stated that they conservatively assume that instrument air is lost for all Appendix R fires based on the fact that instrument air lines run throughout many areas of the plant. The licensee's analysis assumes that the air line could potentially fail in approximately 45 minutes when exposed to the postulated fire.

The licensee also stated that OMA #17 connects a high pressure air cylinder to the accumulator of Condensate Transfer System valve V–11–34 and that these air-operated valves are used to control makeup to the isolation condensers. Each valve is provided with an air accumulator that provides a minimum of six full cycles. As a result, this OMA is only necessary to ensure long-term operation of these valves and makeup to the isolation condensers. Further, this OMA would only be necessary if the plant had to remain in hot shutdown for an extended time.

In addition, the licensee stated that they maintain a fire support procedure (ABN–35, "Loss of Instrument Air") that provides guidance to perform this OMA if instrument air is lost and indicates that there are four annunciator alarm windows that monitor instrument air pressure, plus a pressure gauge on a panel in the control room for instrument air pressure. If all of these instruments are not available, then ABN–35 further indicates that the control rods will start to drift into the core and the MSIVs will close, as well as multiple air-operated valves changing state. Additionally, RPV level indication will not be compromised by a fire in any zone or area. All of these indications would help the operator diagnose the loss of instrument air and initiate mitigating procedures.

In the unlikely event that a fire does occur and causes a loss of instrument air to the air-operated valves, OMA #17 is available to provide makeup control air to the accumulator for V–11–34 for the isolation condenser makeup line due to the loss of instrument air. If OMA #17 becomes necessary, the licensee stated that they have assumed a 30-minute diagnosis period and that the required time to perform the action is 26 minutes, while the time available is 300 minutes, which provides a 244-minute margin.

3.8.5 Conclusion

Given the limited amount of combustible materials, ignition sources, and the large volume of the space, it is unlikely that a fire would occur and go undetected or unsuppressed by the smoke detection or localized water deluge systems noted above, or personnel, and damage the safe shutdown equipment. The low likelihood of damage to safe shutdown equipment due to a fire in this area, combined with the ability of OMA #17 to manipulate the plant in the event of a fire that damages safe shutdown equipment, provides adequate assurance that safe shutdown capability is maintained.

3.9 RB–FZ–1E Reactor Bldg. Elev. 51′-3″

3.9.1 Fire Prevention

The licensee stated that the fire loading in this zone is low and that there is an administrative controls program in place to limit additional combustible materials and sources of ignition. The licensee also stated that the main combustible in this area is attributed to cable insulation (approximately 84% of loading).

3.9.2 Detection, Control, and Extinguishment

The licensee stated that RB–FZ–1E has an area-wide smoke detection system and an automatic fixed deluge water spray system installed over cable trays and open hatches. The deluge suppression system protecting safety related cable trays is automatically activated by a cross-zoned detection system consisting of linear heat detection wire located on top of the cables in each original safety related cable tray and smoke detectors are located in each beam pocket at the ceiling.

3.9.3 Preservation of Safe Shutdown Capability

The licensee stated that RB–FZ–1E has a ceiling height of approximately 26′-9″ and an approximate floor area of 12,140 square feet so it is unlikely that smoke and heat would accumulate at the height of the safe shutdown equipment and cause a failure due to fire damage.

3.9.4 OMAs Credited for a Fire in This Zone

3.9.4.1 OMA #17—Provide Makeup Air to Isolation Condenser Valve V–11–34 Accumulator

In order for OMA #17 to be necessary, a loss of instrument air to the isolation condenser valve V–11–34 would have to occur due to fire damage. The licensee stated that they conservatively assume that instrument air is lost for all Appendix R fires based on the fact that instrument air lines run throughout many areas of the plant. The licensee's analysis assumes that the air line could potentially fail in approximately 45 minutes when exposed to the postulated fire.

The licensee also stated that OMA #17 connects a high pressure air cylinder to the accumulator of Condensate Transfer System valve V–11–34 and that these air-operated valves are used to control makeup to the isolation condensers. Each valve is provided with an air accumulator that provides a minimum of six full cycles. As a result, this OMA is only necessary to ensure long-term operation of these valves and makeup to the isolation condensers. Further, this OMA would only be necessary if the plant had to remain in hot shutdown for an extended time.

In addition, the licensee stated that they maintain a fire support procedure (ABN–35, "Loss of Instrument Air") that provides guidance to perform this OMA if instrument air is lost and indicates that there are four annunciator alarm windows that monitor instrument air pressure, plus a pressure gauge on a panel in the control room for instrument air pressure. If all of these instruments are not available, then ABN–35 further indicates that the control rods will start to drift into the core and the MSIVs will close, as well as multiple air-operated valves changing state. Additionally, RPV level indication will not be compromised by a fire in any zone or area. All of these indications would help the operator diagnose the loss of instrument air and initiate mitigating procedures.

In the unlikely event that a fire does occur and causes a loss of instrument air to the air-operated valves, OMA #17 is available to provide makeup control air to the accumulator for V–11–34 for the isolation condenser makeup line due to the loss of instrument air. If OMA #17 becomes necessary, the licensee stated that they have assumed a 30-minute diagnosis period and that the required time to perform the action is 26 minutes, while the time available is 300 minutes, which provides a 244-minute margin.

3.9.5 Conclusion

Given the limited amount of combustible materials, ignition sources, and the large volume of the space, it is unlikely that a fire would occur and go undetected or unsuppressed by the smoke detection or localized water deluge systems noted above, or personnel, and damage the safe shutdown equipment. The low likelihood of damage to safe shutdown equipment due to a fire in this zone, combined with the ability of OMA #17 to manipulate the plant in the event of a fire that damages safe shutdown equipment, provides adequate assurance that safe shutdown capability is maintained.

3.10 RB–FZ–1F3 Reactor Bldg. Northwest Corner Elev. -19′-6″

3.10.1 Fire Prevention

The licensee stated that the fire loading in this zone is low and that there is an administrative controls program in place to limit additional combustible materials and sources of ignition. The licensee also stated that the major combustibles in this area are cable insulation (approximately 58% of loading), ladders (approximately 16% of loading) and lubricating oil in pumps (approximately 16% of loading).

3.10.2 Detection, Control, and Extinguishment

The licensee stated that RB–FZ–1F3 has smoke detectors which alarm locally and in the control room installed over hazards rather than mounted at the ceiling. Fire extinguishers are also provided for manual fire fighting backup. Hose lines are available from outside hydrants and hose houses.

3.10.3 Preservation of Safe Shutdown Capability

The licensee stated that RB–FZ–1F3 has a ceiling height of approximately 41′-6″ and an approximate floor area of 560 square feet so it is unlikely that smoke and heat would accumulate at the height of the safe shutdown equipment and cause a failure due to fire damage.

3.10.4 OMAs Credited for a Fire in This Zone

3.10.4.1 OMA #17—Provide Makeup Air to Isolation Condenser Valve V–11–34 Accumulator

In order for OMA #17 to be necessary, a loss of instrument air to the isolation condenser valve V–11–34 would have to occur due to fire damage. The licensee stated that they conservatively assume that instrument air is lost for all Appendix R fires based on the fact that instrument air lines run throughout many areas of the plant. The licensee's analysis assumes that the air line could potentially fail in approximately 45 minutes when exposed to the postulated fire.

The licensee also stated that OMA #17 connects a high pressure air cylinder to

the accumulator of Condensate Transfer System valve V–11–34 and that these air-operated valves are used to control makeup to the isolation condensers. Each valve is provided with an air accumulator that provides a minimum of six full cycles. As a result, this OMA is only necessary to ensure long-term operation of these valves and makeup to the isolation condensers. Further, this OMA would only be necessary if the plant had to remain in hot shutdown for an extended time. This scenario is unlikely for this particular area since the plant would likely reach cold shutdown before the action is required.

In addition, the licensee stated that they maintain a fire support procedure (ABN–35, "Loss of Instrument Air") that provides guidance to perform this OMA if instrument air is lost and indicates that there are four annunciator alarm windows that monitor instrument air pressure, plus a pressure gauge on a panel in the control room for instrument air pressure. If all of these instruments are not available, then ABN–35 further indicates that the control rods will start to drift into the core and the MSIVs will close, as well as multiple air-operated valves changing state. Additionally, RPV level indication will not be compromised by a fire in any zone or area. All of these indications would help the operator diagnose the loss of instrument air and initiate mitigating procedures.

In the unlikely event that a fire does occur and causes a loss of instrument air to the air-operated valves, OMA #17 is available to provide makeup control air to the accumulator for V–11–34 for the isolation condenser makeup line due to the loss of instrument air. If OMA #17 becomes necessary, the licensee stated that they have assumed a 30-minute diagnosis period and that the required time to perform the action is 26 minutes, while the time available is 300 minutes, which provides a 244-minute margin.

3.10.5 Conclusion

Given the limited amount of combustible materials, ignition sources, and large volume of the space, it is unlikely that a fire would occur and go undetected or unsuppressed by the smoke detection system or personnel and damage the safe shutdown equipment. The low likelihood of damage to safe shutdown equipment due to a fire in this area, combined with the ability of OMA #17 to manipulate the plant in the event of a fire that damages safe shutdown equipment, provides adequate assurance that safe shutdown capability is maintained.

3.11 RB–FZ–1F5 Reactor Bldg. Torus Room Elev. -19′-6″

3.11.1 Fire Prevention

The licensee stated that the fire loading in this zone is low and that there is an administrative controls program in place to limit additional combustible materials and sources of ignition. The licensee also stated that the major combustibles in this area are cable insulation (approximately 19% of loading) and gratings (approximately 76% of loading). The grating, which is the largest plastic material in this area, has a low flame spread rating (less than 25).

3.11.2 Detection, Control, and Extinguishment

The licensee stated that RB–FZ–1F5 does not have detection or suppression systems. However, due to the limited combustible loading and the nature of the combustibles, a fire in this zone is not expected to be of significant size or duration.

3.11.3 Preservation of Safe Shutdown Capability

The licensee stated that RB–FZ–1F5 is a voluminous area with an approximate floor area of 11,450 square feet and a ceiling height of approximately 41′-6″ therefore, it is unlikely that smoke and heat from a fire in the area would accumulate at the location of the instrument air line and cause a loss of instrument air.

3.11.4 OMAs Credited for a Fire in This Zone

3.11.4.1 OMA #17—Provide Makeup Air to Isolation Condenser Valve V–11–34 Accumulator

In order for OMA #17 to be necessary, a loss of instrument air to the isolation condenser valve V–11–34 would have to occur due to fire damage. The licensee stated that they conservatively assume that instrument air is lost for all Appendix R fires based on the fact that instrument air lines run throughout many areas of the plant. The licensee's analysis assumes that the air line could potentially fail in approximately 45 minutes when exposed to the postulated fire.

The licensee also stated that OMA #17 connects a high pressure air cylinder to the accumulator of Condensate Transfer System valve V–11–34 and that these air-operated valves are used to control makeup to the isolation condensers. Each valve is provided with an air accumulator that provides a minimum of six full cycles. As a result, this OMA is only necessary to ensure long-term operation of these valves and makeup to the isolation condensers. Further, this OMA would only be necessary if the plant had to remain in hot shutdown for an extended time. This scenario is unlikely for this particular area since the plant would likely reach cold shutdown before the action is required.

In addition, the licensee stated that they maintain a fire support procedure (ABN–35, "Loss of Instrument Air") that provides guidance to perform this OMA if instrument air is lost and indicates that there are four annunciator alarm windows that monitor instrument air pressure, plus a pressure gauge on a panel in the control room for instrument air pressure. If all of these instruments are not available, then ABN–35 further indicates that the control rods will start to drift into the core and the MSIVs will close, as well as multiple air-operated valves changing state. Additionally, RPV level indication will not be compromised by a fire in any zone or area. All of these indications would help the operator diagnose the loss of instrument air and initiate mitigating procedures.

In the unlikely event that a fire does occur and causes a loss of instrument air to the air-operated valves, OMA #17 is available to provide makeup control air to the accumulator for V–11–34 for the isolation condenser makeup line due to the loss of instrument air. If OMA #17 becomes necessary, the licensee stated that they have assumed a 30-minute diagnosis period and that the required time to perform the action is 26 minutes, while the time available is 300 minutes, which provides a 244-minute margin.

3.11.5 Conclusion

Given the limited amount of combustible materials, ignition sources, and the large volume of the area, it is unlikely that a fire would occur and go undetected or unsuppressed by personnel, and damage the safe shutdown equipment. The low likelihood of damage to safe shutdown equipment due to a fire in this area, combined with the ability of OMA #17 to manipulate the plant in the event of a fire that damages safe shutdown equipment, provides adequate assurance that safe shutdown capability is maintained.

3.12 RB–FZ–1G Reactor Bldg. Shutdown Cooling Room Elev. 38′-0″ & 51′-3″

3.12.1 Fire Prevention

The licensee stated that the fire loading in this zone is low and that there is an administrative controls program in place to limit additional

combustible materials and sources of ignition. The licensee also stated that the main combustibles in this area are cable insulation (approximately 12% of loading), plastic (approximately 57% of loading) and Class A combustibles (approximately 14% of loading). The grating, which is the majority of the plastic material in this area, has a low flame spread rating (less than 25).

3.12.2 Detection, Control, and Extinguishment

The licensee stated that RB–FZ–1G is provided with a smoke detection system that alarms locally and in the control room to provide prompt notification of a potential fire event.

3.12.3 Preservation of Safe Shutdown Capability

The licensee stated that RB–FZ–1G has a ceiling height of approximately 21′, measured from the 51′-3″ elevation, and an approximate floor area of 1,609 square feet so it is unlikely that smoke and heat would accumulate at the height of the safe shutdown equipment and cause a failure due to fire damage.

3.12.4 OMAs Credited for a Fire in This Area

3.12.4.1 OMA #17—Provide Makeup Air to Isolation Condenser Valve V–11–34 Accumulator

In order for OMA #17 to be necessary, a loss of instrument air to the isolation condenser valve V–11–34 would have to occur due to fire damage. The licensee stated that they conservatively assume that instrument air is lost for all Appendix R fires based on the fact that instrument air lines run throughout many areas of the plant. The licensee's analysis assumes that the air line could potentially fail in approximately 45 minutes when exposed to the postulated fire.

The licensee also stated that OMA #17 connects a high pressure air cylinder to the accumulator of Condensate Transfer System valve V–11–34 and that these air-operated valves are used to control makeup to the isolation condensers. Each valve is provided with an air accumulator that provides a minimum of six full cycles. As a result, this OMA is only necessary to ensure long-term operation of these valves and makeup to the isolation condensers. Further, this OMA would only be necessary if the plant had to remain in hot shutdown for an extended time. This scenario is unlikely for this particular area since the plant would likely reach cold shutdown before the action is required.

In addition, the licensee stated that they maintain a fire support procedure (ABN–35, "Loss of Instrument Air") that provides guidance to perform this OMA if instrument air is lost and indicates that there are four annunciator alarm windows that monitor instrument air pressure, plus a pressure gauge on a panel in the control room for instrument air pressure. If all of these instruments are not available, then ABN–35 further indicates that the control rods will start to drift into the core and the MSIVs will close, as well as multiple air-operated valves changing state. Additionally, RPV level indication will not be compromised by a fire in any zone or area. All of these indications would help the operator diagnose the loss of instrument air and initiate mitigating procedures.

In the unlikely event that a fire does occur and causes a loss of instrument air to the air-operated valves, OMA #17 is available to provide makeup control air to the accumulator for V–11–34 for the isolation condenser makeup line due to the loss of instrument air. If OMA #17 becomes necessary, the licensee stated that they have assumed a 30-minute diagnosis period and that the required time to perform the action is 26 minutes, while the time available is 300 minutes, which provides a 244-minute margin.

3.12.5 Conclusion

Given the limited amount of combustible materials, ignition sources, and large volume of the space, it is unlikely that a fire would occur and go undetected or unsuppressed by the smoke detection system or personnel and damage the safe shutdown equipment. The low likelihood of damage to safe shutdown equipment due to a fire in this area, combined with the ability of OMA #17 to manipulate the plant in the event of a fire that damages safe shutdown equipment, provides adequate assurance that safe shutdown capability is maintained.

3.13 TB–FA–3A Turbine Bldg. 4160V Emergency Switchgear Vault 1C Elev. 23′-6″

3.13.1 Fire Prevention

The licensee stated that the fire loading in this area is low and that there is an administrative controls program in place to limit additional combustible materials and sources of ignition. The licensee also stated that there are minimal amounts of cable insulation (approximately 5% of loading) miscellaneous plastic (approximately 73% of loading) and class A combustibles such as paper for procedures (approximately 20% of loading) in this area.

3.13.2 Detection, Control, and Extinguishment

The licensee stated that TB–FA–3A is provided with an area-wide smoke detection system and a total-flooding, manually actuated CO2 system.

3.13.3 Preservation of Safe Shutdown Capability

The licensee stated that TB–FA–3A has a ceiling height of approximately 21′ and an approximate floor area of 336 square feet so it is unlikely that smoke and heat would accumulate at the height of the safe shutdown equipment and cause a failure due to fire damage.

3.13.4 OMAs Credited for a Fire in This Area

3.13.4.1 OMA #17—Provide Makeup Air to Isolation Condenser Valve V–11–34 Accumulator

In order for OMA #17 to be necessary, a loss of instrument air to the isolation condenser valve V–11–34 would have to occur due to fire damage. The licensee stated that they conservatively assume that instrument air is lost for all Appendix R fires based on the fact that instrument air lines run throughout many areas of the plant. The licensee's analysis assumes that the air line could potentially fail in approximately 45 minutes when exposed to the postulated fire.

The licensee also stated that OMA #17 connects a high pressure air cylinder to the accumulator of Condensate Transfer System valve V–11–34 and that these air-operated valves are used to control makeup to the isolation condensers. Each valve is provided with an air accumulator that provides a minimum of six full cycles. As a result, this OMA is only necessary to ensure long-term operation of these valves and makeup to the isolation condensers. Further, this OMA would only be necessary if the plant had to remain in hot shutdown for an extended time. This scenario is unlikely for this particular area since the plant would likely reach cold shutdown before the action is required.

In addition, the licensee stated that they maintain a fire support procedure (ABN–35, "Loss of Instrument Air") that provides guidance to perform this OMA if instrument air is lost and indicates that there are four annunciator alarm windows that monitor instrument air pressure, plus a pressure gauge on a panel in the control room for instrument air pressure. If all of these instruments are not available, then ABN–35 further indicates that the control rods will start to drift into the core and the MSIVs will close, as well as multiple air-operated valves changing state. Additionally,

RPV level indication will not be compromised by a fire in any zone or area. All of these indications would help the operator diagnose the loss of instrument air and initiate mitigating procedures.

In the unlikely event that a fire does occur and causes a loss of instrument air to the air-operated valves, OMA #17 is available to provide makeup control air to the accumulator for V–11–34 for the isolation condenser makeup line due to the loss of instrument air. If OMA #17 becomes necessary, the licensee stated that they have assumed a 30-minute diagnosis period and that the required time to perform the action is 26 minutes, while the time available is 300 minutes, which provides a 244-minute margin.

3.13.5 Conclusion

Given the limited amount of combustible materials, ignition sources, and large volume of the space, it is unlikely that a fire would occur and go undetected or unsuppressed by the smoke detection or CO2 systems, or personnel, and damage the safe shutdown equipment. The low likelihood of damage to safe shutdown equipment due to a fire in this area, combined with the ability of OMA #17 to manipulate the plant in the event of a fire that damages safe shutdown equipment, provides adequate assurance that safe shutdown capability is maintained.

3.14 TB–FA–26 Turbine Bldg. 125V DC Battery Room C Elev. 23′-6″

3.14.1 Fire Prevention

The licensee stated that the fire loading in this area is moderate and that there is an administrative controls program in place to limit additional combustible materials and sources of ignition. The licensee also stated that the major combustibles in this area are plastic, which is contributed by the battery cases (approximately 92% of loading) and cable insulation (approximately 6% of loading).

3.14.2 Detection, Control, and Extinguishment

The licensee stated that TB–FA–26 has an area-wide automatic pre-action sprinkler system and an area-wide smoke detection system installed.

3.14.3 Preservation of Safe Shutdown Capability

The licensee stated that there are no specific cables in this fire area associated with the OMAs identified for Fire Area TB–FA–26 and that the only fire safe shutdown component and cable located in this fire area is associated with the "C" battery.

3.14.4 OMAs Credited for a Fire in This Area

The licensee stated that this fire area is wholly contained within Fire Zone TB–FZ–11C (A and B 4160V Room) and that all cables to TB–FA–26 must traverse TB–FZ–11C. Therefore, TB–FA–26 and TB–FZ–11C were analyzed together for safe shutdown purposes and the OMAs are duplicated for these two plant areas. Refer to Section 3.16 below for the discussion of OMAs #1, #2, #3, #7, #8, and #18.

3.14.5 Conclusion

Given the limited amount of combustible materials, ignition sources, and lack of multiple safe shutdown trains in this area, it is unlikely that a fire would occur and go undetected or unsuppressed by the smoke detection or sprinkler systems, or personnel, and damage the safe shutdown equipment. The low likelihood of damage to safe shutdown equipment due to a fire in this area, combined with the ability of OMAs #1, #2, #3, #7, #8, and #18 to manipulate the plant in the event of a fire that damages safe shutdown equipment, provides adequate assurance that safe shutdown capability is maintained.

3.15 TB–FZ–11B Turbine Bldg. Lube Oil Storage, Purification and Pumping Area Elev. 0′-0″, 27′-0″, and 36′-0″

3.15.1 Fire Prevention

The licensee stated that the fire loading in this zone is high and that there is an administrative controls program in place to limit additional combustible materials and sources of ignition. The licensee also stated that the major combustibles in this area are lubricating oil (approximately 99% of loading) and cable insulation (approximately 0.3% of loading).

3.15.2 Detection, Control, and Extinguishment

The licensee stated that TB–FZ–11B has automatic suppression systems installed over principal combustibles and a rate of rise/fixed temperature fire detection system installed at the lube oil tank. A closed head automatic sprinkler system protects cable trays and open head water spray deluge system protects oil handling equipment and the oil storage tank. Thermal detectors are located in close proximity to the lube oil tank so that a lube oil fire would be quickly detected, which in turn would activate the deluge system for extinguishment. Additionally, the licensee stated that there are fire extinguishers provided throughout the zone and that aqueous film-forming foam (AFFF) is staged in the Fire Brigade van for use if necessary.

3.15.3 Preservation of Safe Shutdown Capability

The licensee stated that the ceiling heights in the area are approximately 9′-0″ in the basement hallway, approximately 19′-0″ in the basement stairs, approximately 26′-0″ on the first floor of the area, and approximately 42′-0″ on the second floor of the area. Additionally, the licensee stated that the floor area, measured at the 0′-0″ elevation is approximately 3175 square feet.

3.15.4 OMAs Credited for a Fire in This Zone

3.15.4.1 OMA #3—Manually Control 480V USS 1B2 Breakers for CRD Pump at Remote Shutdown Panel

In order for OMA #3 to be necessary, the credited and redundant cables would have to be damaged due to a fire. The licensee stated that these cables are located in the same tray with additional cables and are generally located approximately 14 feet above the floor. The licensee also stated that the cables pass over the top of potential ignition sources MCC 1A12 and MCC 1B12 and that the cables are located approximately 6 feet above these ignition sources. Additionally, the lube oil tanks are located below the cables, although not directly below, with a distance of approximately 26 feet separating the cables and the tanks. The cables are also located approximately 20 feet from ignition sources MCC 1A12A and 1B12A.

In the unlikely event that a fire does occur and damages the credited and redundant cables, OMA #3 is available to manually control the 480V USS 1B2 Breakers for CRD Pump NC08B and 1B2M from the Remote Shutdown Panel due to control circuit damage. The licensee also stated that they have assumed a 30-minute diagnosis period and that the required time to perform the action is 8 minutes while the time available is 180 minutes, which provides a 142-minute margin.

3.15.4.2 OMA #18—Provide Makeup Air to Isolation Condenser Valve V–11–36 Accumulator

In order for OMA #18 to be necessary, a loss of instrument air to the isolation condenser valve V–11–36 would have to occur due to fire damage. The licensee stated that they conservatively assume that instrument air is lost for all Appendix R fires based on the fact that instrument air lines run throughout

many areas of the plant. The licensee's analysis assumes that the air line could potentially fail in approximately 45 minutes when exposed to the postulated fire.

The licensee also stated that OMA #18 connects a high pressure air cylinder to the accumulator of Condensate Transfer System valve V–11–36 and that these air-operated valves are used to control makeup to the isolation condensers. Each valve is provided with an air accumulator that provides a minimum of six full cycles. As a result, this OMA is only necessary to ensure long-term operation of these valves and makeup to the isolation condensers. Further, this OMA would only be necessary if the plant had to remain in hot shutdown for an extended time. This scenario is unlikely for this particular area since the plant would likely reach cold shutdown before the action is required.

In addition, the licensee stated that they maintain a fire support procedure (ABN–35, "Loss of Instrument Air") that provides guidance to perform this OMA if instrument air is lost and indicates that there are four annunciator alarm windows that monitor instrument air pressure, plus a pressure gauge on a panel in the control room for instrument air pressure. If all of these instruments are not available, then ABN–35 further indicates that the control rods will start to drift into the core and the MSIVs will close, as well as multiple air-operated valves changing state. Additionally, RPV level indication will not be compromised by a fire in any zone or area. All of these indications would help the operator diagnose the loss of instrument air and initiate mitigating procedures.

In the unlikely event that a fire does occur and causes a loss of instrument air to the air-operated valves, OMA #18 is available to provide makeup control air to the accumulator for V–11–36 for the isolation condenser makeup line due to the loss of instrument air. If OMA #18 becomes necessary, the licensee stated that they have assumed a 30-minute diagnosis period and that the required time to perform the action is 26 minutes, while the time available is 300 minutes, which provides a 244-minute margin.

3.15.5 Conclusion

Although the fire loading is high, the limited ignition sources, large volume of the space, and the detection and suppression system make it unlikely that a fire would occur and go undetected or unsuppressed and damage the safe shutdown equipment. Additionally, the availability of fire extinguishers and AFFF, which is effective against oil based fires, provides an augmented ability to suppress a fire prior to damaging safe shutdown equipment. The low likelihood of damage to safe shutdown equipment due to a fire in this zone, combined with the ability of OMAs #3 and #18 to manipulate the plant in the event of a fire that damages safe shutdown equipment, provides adequate assurance that safe shutdown capability is maintained.

3.16 TB–FZ–11C Turbine Bldg. 4160V SWGR Room 1A and 1B Elev. 23′-6″

3.16.1 Fire Prevention

The licensee stated that the fire loading in this zone is low and that there is an administrative controls program in place to limit additional combustible materials and sources of ignition. The licensee also stated that the main combustible loading is attributed to cable insulation (approximately 73% of loading) and plastic (approximately 17% of loading).

3.16.2 Detection, Control, and Extinguishment

The licensee stated that TB–FZ–11C has an area-wide smoke detection system and an area-wide automatic fixed pre-action sprinkler system (except in the small caged area located to the east of Fire Area TB–FA–3A) installed.

3.16.3 Preservation of Safe Shutdown Capability

The licensee stated that TB–FZ–11C has a ceiling height of approximately 21′-8″ and an approximate floor area of 2666 square feet so it is unlikely that smoke and heat would accumulate at the height of the safe shutdown equipment and cause a failure due to fire damage.

3.16.4 OMAs Credited for a Fire in This Area

3.16.4.1 OMA #1—Trip Field Breakers for Recirculation Pumps MG Set

In order for OMA #1 to be necessary, damage to the 1A and 1B 4160V Switchgear Cabinets and the "C" Battery distribution panel, or the associated control wiring, would have to occur due to a fire and prevent tripping of the 4160V motor-generator set breakers. The licensee stated that these cables are located in the same tray with additional cables and are generally located at least 17 feet above the floor. The licensee also stated that the tray passes over the top of potential ignition source "B" 4160V switchgear and that the cables are located approximately 9 feet above this ignition source and 3 feet above the iso-phase bus duct at their closest point.

In the unlikely event that a fire does occur and damages the credited and redundant equipment, OMA #1 is available to trip the field breakers for the recirculation pumps motor-generator set so that the Fuel Zone Level Indicators can be used. The licensee also stated that they have assumed a 10-minute diagnosis period and that the required time to perform the action is 8 minutes while the time available is 30 minutes, which provides a 12-minute margin.

3.16.4.2 OMA #2—Align Fire Water to Isolation Condenser

In order for OMA #2 to be necessary, loss of the "B" train of power would have to occur due to a fire causing a loss of both condensate transfer pumps. The licensee stated that this OMA is dependent on the LSP–1D OMA, which was included in the licensee's Phase 1 request, and would not be required unless the OMA at the LSP–1D is required and access is not immediately available. As such, this OMA is considered a contingency action. The licensee also stated that these cables are located in the same tray with additional cables and are generally located at least 17 feet above the floor and that the tray passes over the top of potential ignition source "B" 4160V switchgear and that the cables are located approximately 9 feet above this ignition source and 3 feet above the iso-phase bus duct at their closest point.

In the unlikely event that a fire does occur and damages the credited and redundant cables, OMA #2 is available to provide fire water to the isolation condenser shell by operating valves V–9–2099, V–11–49, V–11–63, and V–11–41 due to loss of power. The licensee also stated that they have assumed a 10-minute diagnosis period and that the required time to perform the action is 13 minutes while the time available is 45 minutes, which provides a 22-minute margin.

3.16.4.3 OMA #3—Manually Control 480V USS 1B2 Breakers for CRD Pump at Remote Shutdown Panel

In order for OMA #3 to be necessary, the credited and redundant cables would have to be damaged due to a fire. The licensee stated that these cables are located in the same tray with additional cables and are generally located at least 17 feet above the floor. The licensee also stated that the tray passes over the top of potential ignition source "B" 4160V switchgear and that the cables are located approximately 9 feet above this

ignition source and 3 feet above the iso-phase bus duct at their closest point.

In the unlikely event that a fire does occur and damages the credited and redundant cables, OMA #3 is available to manually control the 480V USS 1B2 Breakers for CRD Pump NC08B and 1B2M from the Remote Shutdown Panel due to control circuit damage. The licensee also stated that they have assumed a 30-minute diagnosis period and that the required time to perform the action is 8 minutes while the time available is 180 minutes, which provides a 142-minute margin.

3.16.4.4 OMA #7—Provide Makeup to Isolation Condenser via V–11–36

In order for OMA #7 to be necessary, loss of the "B" train of power would have to occur due to a fire causing a loss of both condensate transfer pumps. The licensee stated that this OMA is dependent on the LSP–1D OMA, which was included in the licensee's Phase 1 request, and would not be required unless the OMA at the LSP–1D is required and access is not immediately available. As such, this OMA is considered a contingency action. The licensee also stated that these cables are located in the same tray with additional cables and are generally located at least 17 feet above the floor and that the tray passes over the top of potential ignition source "B" 4160V switchgear and that the cables are located approximately 9 feet above this ignition source and 3 feet above the iso-phase bus duct at their closest point.

In the unlikely event that a fire does occur and damages the credited and redundant cables, OMA #7 is available to manually open V–11–36 to provide makeup to Isolation Condenser due to loss of power. The licensee also stated that they have assumed a 10-minute diagnosis period and that the required time to perform the action is 16 minutes while the time available is 45 minutes, which provides a 19-minute margin.

3.16.4.5 OMA #8—Locally Check Isolation Condenser Shell Level

In order for OMA #8 to be necessary, loss of the "B" train of power would have to occur due to a fire causing a loss of both condensate transfer pumps. The licensee stated that this OMA is dependent on the LSP–1D OMA, which was included in the licensee's Phase 1 request, and would not be required unless the OMA at the LSP–1D is required and access is not immediately available. As such, this OMA is considered a contingency action. The licensee also stated that these cables are located in the same tray with additional cables and are generally located at least 17 feet above the floor and that the tray passes over the top of potential ignition source "B" 4160V switchgear and that the cables are located approximately 9 feet above this ignition source and 3 feet above the iso-phase bus duct at their closest point.

In the unlikely event that a fire does occur and damages the credited and redundant cables, OMA #8 is available to check the isolation condenser shell level locally due to loss of power. The licensee also stated that they have assumed a 10-minute diagnosis period and that the required time to perform the action is 16 minutes while the time available is 45 minutes, which provides a 19-minute margin.

3.16.4.6 OMA #18—Provide Makeup Air to Isolation Condenser Valve V–11–36 Accumulator

In order for OMA #18 to be necessary, a loss of instrument air to the isolation condenser valve V–11–36 would have to occur due to fire damage. The licensee stated that they conservatively assume that instrument air is lost for all Appendix R fires based on the fact that instrument air lines run throughout many areas of the plant. The licensee's analysis assumes that the air line could potentially fail in approximately 45 minutes when exposed to the postulated fire.

The licensee also stated that OMA #18 connects a high pressure air cylinder to the accumulator of Condensate Transfer System valve V–11–36 and that these air-operated valves are used to control makeup to the isolation condensers. Each valve is provided with an air accumulator that provides a minimum of six full cycles. As a result, this OMA is only necessary to ensure long-term operation of these valves and makeup to the isolation condensers. Further, this OMA would only be necessary if the plant had to remain in hot shutdown for an extended time. This scenario is unlikely for this particular area since the plant would likely reach cold shutdown before the action is required.

In addition, the licensee stated that they maintain a fire support procedure (ABN–35, "Loss of Instrument Air") that provides guidance to perform this OMA if instrument air is lost and indicates that there are four annunciator alarm windows that monitor instrument air pressure, plus a pressure gauge on a panel in the control room for instrument air pressure. If all of these instruments are not available, then ABN–35 further indicates that the control rods will start to drift into the core and the main MSIVs will close, as well as multiple air-operated valves changing state. Additionally, RPV level indication will not be compromised by a fire in any zone or area. All of these indications would help the operator diagnose the loss of instrument air and initiate mitigating procedures.

In the unlikely event that a fire does occur and causes a loss of instrument air to the air-operated valves, OMA #18 is available to provide makeup control air to the accumulator for V–11–36 for the isolation condenser makeup line due to the loss of instrument air. If OMA #18 becomes necessary, the licensee stated that they have assumed a 30-minute diagnosis period and that the required time to perform the action is 26 minutes, while the time available is 300 minutes, which provides a 244-minute margin.

3.16.5 Conclusion

Given the limited amount of combustible materials, ignition sources, and large volume of the space, it is unlikely that a fire would occur and go undetected or unsuppressed by the smoke detection or sprinkler systems noted above, or personnel, and damage the safe shutdown equipment. The low likelihood of damage to safe shutdown equipment due to a fire in this area, combined with the ability of OMAs #1, #2, #3, #7, #8, and #18 to manipulate the plant in the event of a fire that damages safe shutdown equipment, provide adequate assurance that safe shutdown capability is maintained.

3.17 TB–FZ–11D Turbine Bldg. Basement Floor South End Elev. 3′-6″

3.17.1 Fire Prevention

The licensee stated that the fire loading in this zone is low and that there is an administrative controls program in place to limit additional combustible materials and sources of ignition. The licensee also stated that the major combustibles in this area are cable insulation (approximately 29% of loading), Dow Corning 561 Silicon transformer liquid (approximately 15% of loading) and lubricating oil (approximately 40% of loading).

3.17.2 Detection, Control, and Extinguishment

The licensee stated that an automatic wet-pipe sprinkler system and an automatic water spray system located at the hydrogen seal oil unit are installed in the area.

3.17.3 Preservation of Safe Shutdown Capability

The licensee stated that TB–FZ–11D has a ceiling height of approximately 19′ and an approximate floor area of 9668 square feet so it is unlikely that smoke and heat would accumulate at the

height of the safe shutdown equipment and cause a failure due to fire damage.

3.17.4 OMAs Credited for a Fire in This Zone

3.17.4.1 OMA #1—Trip Field Breakers for Recirculation Pumps MG Set

In order for OMA #1 to be necessary, damage to the 1A and 1B 4160V Switchgear Cabinets and the "C" Battery distribution panel, or the associated control wiring, would have to occur due to a fire and prevent tripping of the 4160V MG set breakers. The licensee stated that these cables are located in the same tray with additional cables and are generally located at least 15 feet above the floor. The primary combustible fuel load in the area is the cables themselves and storage of transient combustibles is limited due to a sump and abandoned acid/caustic tanks located in the area.

The licensee also stated that the primary ignition sources in the area near the cable trays are the Turbine Building Closed Cooling Water Pumps and USS 1A1 and its associated transformer (4160V to 480V transformer). However, the Turbine Building Closed Cooling Water Pumps contain less than 5 gallons of oil and are enclosed in metal casings and the cable tray containing the cables is approximately 13 feet from the top of the pumps/motors. The top of USS 1A1 and its associated transformer are located approximately 30 feet diagonally from the credited cables and approximately 15 feet diagonally from the redundant cables. Additionally, there is a concrete ceiling beam, with a water curtain sprinkler system attached, which would provide some shielding for the cables from potential products of combustion generated by this ignition source. Sprinkler heads are also located in a ceiling pocket between the concrete ceiling beam and the USS 1A1 and transformer.

In the unlikely event that a fire does occur and damages the credited and redundant equipment, OMA #1 is available to trip the field breakers for the recirculation pumps MG Set so that the fuel zone level indicators can be used. The licensee also stated that they have assumed a 10-minute diagnosis period and that the required time to perform the action is 8 minutes while the time available is 30 minutes, which provides a 12-minute margin.

3.17.4.2 OMA #2—Align Fire Water to Isolation Condenser

In order for OMA #2 to be necessary, loss of the "B" train of power would have to occur due to a fire causing a loss of both condensate transfer pumps. The licensee stated that this OMA is dependent on the LSP–1D OMA, which was included in the licensee's Phase 1 request, and would not be required unless the OMA at the LSP–1D is required and access is not immediately available. As such, this OMA is considered a contingency action. In addition, the licensee stated that these cables are located in the same tray with additional cables and are generally located at least 15 feet above the floor. The primary combustible fuel load in the area is the cables themselves and storage of transient combustibles is limited due to a sump and abandoned acid/caustic tanks located in the area.

The licensee also stated that the primary ignition sources in the area near the cable trays are the Turbine Building Closed Cooling Water Pumps and USS 1A1 and its associated transformer (4160V to 480V transformer). However, the Turbine Building Closed Cooling Water Pumps contain less than 5 gallons of oil and are enclosed in metal casings and the cable tray containing the cables is approximately 13 feet from the top of the pumps/motors. The top of USS 1A1 and its associated transformer are located approximately 30 feet diagonally from the credited cables and approximately 15 feet diagonally from the redundant cables. Additionally, there is a concrete ceiling beam, with a water curtain sprinkler system attached, which would provide some shielding for the cables from potential products of combustion generated by this ignition source. Sprinkler heads are also located in a ceiling pocket between the concrete ceiling beam and the USS 1A1 and transformer.

In the unlikely event that a fire does occur and damages the credited and redundant cables, OMA #2 is available to provide fire water to the isolation condenser shell by operating valves V–9–2099, V–11–49, V–11–63, and V–11–41 due to loss of power. The licensee also stated that they have assumed a 10-minute diagnosis period and that the required time to perform the action is 13 minutes while the time available is 45 minutes, which provides a 22-minute margin.

3.17.4.3 OMA #3—Manually Control 480V USS 1B2 Breakers for CRD Pump at Remote Shutdown Panel

In order for OMA #3 to be necessary, the credited and redundant cables would have to be damaged due to a fire. The licensee stated that these cables are located in the same tray with additional cables and are generally located at least 15 feet above the floor. The primary combustible fuel load in the area is the cables themselves and storage of transient combustibles is limited due to a sump and abandoned acid/caustic tanks located in the area.

The licensee also stated that the primary ignition sources in the area near the cable trays are the Turbine Building Closed Cooling Water Pumps and USS 1A1 and its associated transformer (4160V to 480V transformer). However, the Turbine Building Closed Cooling Water Pumps contain less than 5 gallons of oil and are enclosed in metal casings and the cable tray containing the cables is approximately 13 feet from the top of the pumps/motors. The top of USS 1A1 and its associated transformer are located approximately 30 feet diagonally from the credited cables and approximately 15 feet diagonally from the redundant cables. Additionally, there is a concrete ceiling beam, with a water curtain sprinkler system attached, which would provide some shielding for the cables from potential products of combustion generated by this ignition source. Sprinkler heads are also located in a ceiling pocket between the concrete ceiling beam and the USS 1A1 and transformer.

In the unlikely event that a fire does occur and damages the credited and redundant cables, OMA #3 is available to manually control the 480V USS 1B2 Breakers for CRD Pump NC08B and 1B2M from the Remote Shutdown Panel due to control circuit damage. The licensee also stated that they have assumed a 30-minute diagnosis period and that the required time to perform the action is 8 minutes while the time available is 180 minutes, which provides a 142-minute margin.

3.17.4.4 OMA #7—Provide Makeup to Isolation Condenser via V–11–36

In order for OMA #7 to be necessary, loss of the "B" train of power would have to occur due to a fire causing a loss of both condensate transfer pumps. The licensee stated that this OMA is dependent on the LSP–1D OMA, which was included in the licensee's Phase 1 request, and would not be required unless the OMA at the LSP–1D is required and access is not immediately available. As such, this OMA is considered a contingency action. In addition, the licensee stated that these cables are located in the same tray with additional cables and are generally located at least 15 feet above the floor. The primary combustible fuel load in the area is the cables themselves and storage of transient combustibles is limited due to a sump and abandoned acid/caustic tanks located in the area.

The licensee also stated that the primary ignition sources in the area near the cable trays are the Turbine Building

Closed Cooling Water Pumps and USS 1A1 and its associated transformer (4160V to 480V transformer). However, the Turbine Building Closed Cooling Water Pumps contain less than 5 gallons of oil and are enclosed in metal casings and the cable tray containing the cables is approximately 13 feet from the top of the pumps/motors. The top of USS 1A1 and its associated transformer are located approximately 30 feet diagonally from the credited cables and approximately 15 feet diagonally from the redundant cables. Additionally, there is a concrete ceiling beam, with a water curtain sprinkler system attached, which would provide some shielding for the cables from potential products of combustion generated by this ignition source. Sprinkler heads are also located in a ceiling pocket between the concrete ceiling beam and the USS 1A1 and transformer.

In the unlikely event that a fire does occur and damages the credited and redundant cables, OMA #7 is available to manually open V–11–36 to provide makeup to Isolation Condenser due to loss of power. The licensee also stated that they have assumed a 10-minute diagnosis period and that the required time to perform the action is 16 minutes while the time available is 45 minutes, which provides a 19-minute margin.

3.17.4.5 OMA #8—Locally Check Isolation Condenser Shell Level

In order for OMA #8 to be necessary, loss of the "B" train of power would have to occur due to a fire causing a loss of both condensate transfer pumps. The licensee stated that this OMA is dependent on the LSP–1D OMA, which was included in the licensee's Phase 1 request, and would not be required unless the OMA at the LSP–1D is required and access is not immediately available. As such, this OMA is considered a contingency action. In addition, the licensee stated that these cables are located in the same tray with additional cables and are generally located at least 15 feet above the floor. The primary combustible fuel load in the area is the cables themselves and storage of transient combustibles is limited due to a sump and abandoned acid/caustic tanks located in the area.

The licensee also stated that the primary ignition sources in the area near the cable trays are the Turbine Building Closed Cooling Water Pumps and USS 1A1 and its associated transformer (4160V to 480V transformer). However, the Turbine Building Closed Cooling Water Pumps contain less than 5 gallons of oil and are enclosed in metal casings and the cable tray containing the cables is approximately 13 feet from the top of the pumps/motors. The top of USS 1A1 and its associated transformer are located approximately 30 feet diagonally from the credited cables and approximately 15 feet diagonally from the redundant cables. Additionally, there is a concrete ceiling beam, with a water curtain sprinkler system attached, which would provide some shielding for the cables from potential products of combustion generated by this ignition source. Sprinkler heads are also located in a ceiling pocket between the concrete ceiling beam and the USS 1A1 and transformer.

In the unlikely event that a fire does occur and damages the credited and redundant cables, OMA #8 is available to check the isolation condenser shell level locally due to loss of power. The licensee also stated that they have assumed a 10-minute diagnosis period and that the required time to perform the action is 16 minutes while the time available is 45 minutes, which provides a 19-minute margin.

3.17.4.6 OMA #18—Provide Makeup Air to Isolation Condenser Valve V–11–36 Accumulator

In order for OMA #18 to be necessary, a loss of instrument air to the isolation condenser valve V–11–36 would have to occur due to fire damage. The licensee stated that they conservatively assume that instrument air is lost for all Appendix R fires based on the fact that instrument air lines run throughout many areas of the plant. The licensee's analysis assumes that the air line could potentially fail in approximately 45 minutes when exposed to the postulated fire.

The licensee also stated that OMA #18 connects a high pressure air cylinder to the accumulator of Condensate Transfer System valve V–11–36 and that these air-operated valves are used to control makeup to the isolation condensers. Each valve is provided with an air accumulator that provides a minimum of six full cycles. As a result, this OMA is only necessary to ensure long-term operation of these valves and makeup to the isolation condensers. Further, this OMA would only be necessary if the plant had to remain in hot shutdown for an extended time. This scenario is unlikely for this particular area since the plant would likely reach cold shutdown before the action is required.

In addition, the licensee stated that they maintain a fire support procedure (ABN–35, "Loss of Instrument Air") that provides guidance to perform this OMA if instrument air is lost and indicates that there are four annunciator alarm windows that monitor instrument air pressure, plus a pressure gauge on a panel in the control room for instrument air pressure. If all of these instruments are not available, then ABN–35 further indicates that the control rods will start to drift into the core and the MSIVs will close, as well as multiple air-operated valves changing state. Additionally, RPV level indication will not be compromised by a fire in any zone or area. All of these indications would help the operator diagnose the loss of instrument air and initiate mitigating procedures.

In the unlikely event that a fire does occur and causes a loss of instrument air to the air-operated valves, OMA #18 is available to provide makeup control air to the accumulator for V–11–36 for the isolation condenser makeup line due to the loss of instrument air. If OMA #18 becomes necessary, the licensee stated that they have assumed a 30-minute diagnosis period and that the required time to perform the action is 26 minutes, while the time available is 300 minutes, which provides a 244-minute margin.

3.17.5 Conclusion

Given the limited amount of combustible materials, ignition sources and the volume of the space, it is unlikely that a fire would occur and go undetected or unsuppressed by the suppression systems noted above, or personnel, and damage the safe shutdown equipment. The low likelihood of damage to safe shutdown equipment due to a fire in this zone, combined with the ability of OMAs #1, #2, #3, #7, #8, and #18 to manipulate the plant in the event of a fire that damages safe shutdown equipment, provides adequate assurance that safe shutdown capability is maintained.

3.18 TB–FZ–11E Turbine Bldg. Condenser Bay Area Elev. 0′-″0

3.18.1 Fire Prevention

The licensee stated that the fire loading in this zone is low and that there is an administrative controls program in place to limit additional combustible materials and sources of ignition. The licensee also stated that the major combustibles in this area are cable insulation (approximately 40% of loading) and plastic (approximately 59% of loading). The grating, which is the largest plastic material in this area, is dispersed throughout this fire zone (not concentrated) and has a low flame spread (less than 25). The licensee also stated that this Fire Zone is procedurally controlled as a transient combustible free area while the plant is operating and that this area is a high

radiation area during plant operation and is not normally accessed.

3.18.2 Detection, Control, and Extinguishment

The licensee stated that a closed head automatic sprinkler and spray systems protect the south end basement area and the hydrogen seal oil unit. An exemption was granted from the requirements of Appendix R Section III.G.2 in safety evaluations dated March 24, 1986, and June 25, 1990, for not having fixed fire detection in this area. The primary basis for this exemption was the presence of the automatic wet pipe sprinkler system and low fire loading. The Condenser Bay is procedurally controlled as a transient combustible free area in while the plant is operating. If a fire did occur, the flow alarm would notify the control room of any sprinkler system activation. Extinguishment of a fire can be accomplished by the automatic fixed suppression system and the plant fire brigade. A closed head automatic sprinkler system was recently expanded to provide fire suppression over the cables in cable trays in the northeast side of the condenser bay.

3.18.3 Preservation of Safe Shutdown Capability

The licensee stated that TB–FZ–11E has a ceiling height of at least 40′ and an approximate floor area of 26,427 square feet so it is unlikely that smoke and heat would accumulate at the height of the safe shutdown equipment and cause a failure due to fire damage.

3.18.4 OMAs Credited for a Fire in This Zone

3.18.4.1 OMA #3—Manually Control 480V USS 1B2 Breakers for CRD Pump at Remote Shutdown Panel

In order for OMA #3 to be necessary, the credited and redundant cables would have to be damaged due to a fire. The licensee stated that these cables are located in the same tray with additional cables and are generally located approximately 40 feet above the floor. With the exception of the cables themselves, there are no other ignition sources or combustibles located near the cables.

In the unlikely event that a fire does occur and damages the credited and redundant cables, OMA #3 is available to manually control the 480V USS 1B2 Breakers for CRD Pump NC08B and 1B2M from the Remote Shutdown Panel due to control circuit damage. The licensee also stated that they have assumed a 30-minute diagnosis period and that the required time to perform the action is 8 minutes while the time available is 180 minutes, which provides a 142-minute margin.

3.18.4.2 OMA #18—Provide Makeup Air to Isolation Condenser Valve V–11–36 Accumulator

In order for OMA #18 to be necessary, a loss of instrument air to the isolation condenser valve V–11–36 would have to occur due to fire damage. The licensee stated that they conservatively assume that instrument air is lost for all Appendix R fires based on the fact that instrument air lines run throughout many areas of the plant. The licensee's analysis assumes that the air line could potentially fail in approximately 45 minutes when exposed to the postulated fire.

The licensee also stated that OMA #18 connects a high pressure air cylinder to the accumulator of Condensate Transfer System valve V–11–36 and that these air-operated valves are used to control makeup to the isolation condensers. Each valve is provided with an air accumulator that provides a minimum of six full cycles. As a result, this OMA is only necessary to ensure long-term operation of these valves and makeup to the isolation condensers. Further, this OMA would only be necessary if the plant had to remain in hot shutdown for an extended time. This scenario is unlikely for this particular area since the plant would likely reach cold shutdown before the action is required.

In addition, the licensee stated that they maintain a fire support procedure (ABN–35, "Loss of Instrument Air") that provides guidance to perform this OMA if instrument air is lost and indicates that there are four annunciator alarm windows that monitor instrument air pressure, plus a pressure gauge on a panel in the control room for instrument air pressure. If all of these instruments are not available, then ABN–35 further indicates that the control rods will start to drift into the core and the MSIVs will close, as well as multiple air-operated valves changing state. Additionally, RPV level indication will not be compromised by a fire in any zone or area. All of these indications would help the operator diagnose the loss of instrument air and initiate mitigating procedures.

In the unlikely event that a fire does occur and causes a loss of instrument air to the air-operated valves, OMA #18 is available to provide makeup control air to the accumulator for V–11–36 for the isolation condenser makeup line due to the loss of instrument air. If OMA #18 becomes necessary, the licensee stated that they have assumed a 30-minute diagnosis period and that the required time to perform the action is 26 minutes, while the time available is 300 minutes, which provides a 244-minute margin.

3.18.5 Conclusion

Given the limited amount of combustible materials, ignition sources, and large volume of the space, it is unlikely that a fire would occur and go undetected or unsuppressed by the suppression system noted above or personnel, and damage the safe shutdown equipment. The low likelihood of damage to safe shutdown equipment due to a fire in this zone, combined with the ability of OMAs #3 and #18 to manipulate the plant in the event of a fire that damages safe shutdown equipment, provides adequate assurance that safe shutdown capability is maintained.

3.19 TB–FZ–11F Turbine Bldg. Feedwater Pump Room Elev. 0′-0″ & 3′-6″

3.19.1 Fire Prevention

The licensee stated that the fire loading in this zone is low and that there is an administrative controls program in place to limit additional combustible materials and sources of ignition. The licensee also stated that the major combustible load consists of cable insulation (approximately 15% of loading), lubricating oil (approximately 39% of loading), rubber (approximately 21% of loading) and plastics (approximately 17% of loading). The licensee states that the majority of the combustible loading attributed to rubber and plastic was due to the storage of hoses that are now no longer in the area.

3.19.2 Detection, Control, and Extinguishment

The licensee stated that TB–FZ–11F has an area-wide thermal fire detection system. Extinguishment of the fire will be accomplished by the plant fire brigade.

3.19.3 Preservation of Safe Shutdown Capability

The licensee stated that TB–FZ–11F has a ceiling height of approximately 16′ in approximately 70% of the area and approximately 19′-6″ in the remainder of the area. With an approximate floor area of 5650 square feet, it is unlikely that smoke and heat would accumulate at the height of the safe shutdown equipment and cause a failure due to fire damage.

3.19.4 OMAs Credited for a Fire in This Zone

3.19.4.1 OMA #18—Provide Makeup Air to Isolation Condenser Valve V–11–36 Accumulator

In order for OMA #18 to be necessary, a loss of instrument air to the isolation condenser valve V–11–36 would have to occur due to fire damage. The licensee stated that they conservatively assume that instrument air is lost for all Appendix R fires based on the fact that instrument air lines run throughout many areas of the plant. The licensee's analysis assumes that the air line could potentially fail in approximately 45 minutes when exposed to the postulated fire.

The licensee also stated that OMA #18 connects a high pressure air cylinder to the accumulator of Condensate Transfer System valve V–11–36 and that these air-operated valves are used to control makeup to the isolation condensers. Each valve is provided with an air accumulator that provides a minimum of six full cycles. As a result, this OMA is only necessary to ensure long-term operation of these valves and makeup to the isolation condensers. Further, this OMA would only be necessary if the plant had to remain in hot shutdown for an extended time. This scenario is unlikely for this particular area since the plant would likely reach cold shutdown before the action is required.

In addition, the licensee stated that they maintain a fire support procedure (ABN–35, "Loss of Instrument Air") that provides guidance to perform this OMA if instrument air is lost and indicates that there are four annunciator alarm windows that monitor instrument air pressure, plus a pressure gauge on a panel in the control room for instrument air pressure. If all of these instruments are not available, then ABN–35 further indicates that the control rods will start to drift into the core and the MSIVs will close, as well as multiple air-operated valves changing state. Additionally, RPV level indication will not be compromised by a fire in any zone or area. All of these indications would help the operator diagnose the loss of instrument air and initiate mitigating procedures.

In the unlikely event that a fire does occur and causes a loss of instrument air to the air-operated valves, OMA #18 is available to provide makeup control air to the accumulator for V–11–36 for the isolation condenser makeup line due to the loss of instrument air. If OMA #18 becomes necessary, the licensee stated that they have assumed a 30-minute diagnosis period and that the required time to perform the action is 26 minutes, while the time available is 300 minutes, which provides a 244-minute margin.

3.19.5 Conclusion

Given the limited amount of combustible materials, ignition sources, and large volume of the space, it is unlikely that a fire would occur and go undetected or unsuppressed by the thermal detection system noted above or personnel, and damage the safe shutdown equipment. The low likelihood of damage to safe shutdown equipment due to a fire in this zone, combined with the ability of OMA #18 to manipulate the plant in the event of a fire that damages safe shutdown equipment, provides adequate assurance that safe shutdown capability is maintained.

3.20 TB–FZ–11H Turbine Bldg. Demineralizer Tank and Steam Jet Air Ejector Area Elev. 3′-6″ & 23′-6″

3.20.1 Fire Prevention

The licensee stated that the fire loading in this zone is low and that there is an administrative controls program in place to limit additional combustible materials and sources of ignition. The licensee also stated that the major combustibles are cable insulation (approximately 23% of loading), ladders and other miscellaneous plastics (approximately 55% of loading) and miscellaneous ordinary combustibles.

3.20.2 Detection, Control, and Extinguishment

The licensee stated that TB–FZ–11H has a partial area thermal fire detector system. The system alarms locally and in the control room. Manual extinguishment of fire will be accomplished by the plant fire brigade.

3.20.3 Preservation of Safe Shutdown Capability

The licensee stated that TB–FZ–11H has a ceiling height of approximately 7′-0″, measured at the 3′-6″ elevation, and approximately 19′-0″, measured at the 23′-6″ elevation with an approximate floor area of 3,944 square feet and 4,366 square feet, respectively, so it is unlikely that smoke and heat would accumulate at the height of the safe shutdown equipment and cause a failure due to fire damage.

3.20.4 OMAs Credited for a Fire in This Area

3.20.4.1 OMA #18—Provide Makeup Air to Isolation Condenser Valve V–11–36 Accumulator

In order for OMA #18 to be necessary, a loss of instrument air to the isolation condenser valve V–11–36 would have to occur due to fire damage. The licensee stated that they conservatively assume that instrument air is lost for all Appendix R fires based on the fact that instrument air lines run throughout many areas of the plant. The licensee's analysis assumes that the air line could potentially fail in approximately 45 minutes when exposed to the postulated fire.

The licensee also stated that OMA #18 connects a high pressure air cylinder to the accumulator of Condensate Transfer System valve V–11–36 and that these air-operated valves are used to control makeup to the isolation condensers. Each valve is provided with an air accumulator that provides a minimum of six full cycles. As a result, this OMA is only necessary to ensure long-term operation of these valves and makeup to the isolation condensers. Further, this OMA would only be necessary if the plant had to remain in hot shutdown for an extended time. This scenario is unlikely for this particular area since the plant would likely reach cold shutdown before the action is required.

In addition, the licensee stated that they maintain a fire support procedure (ABN–35, "Loss of Instrument Air") that provides guidance to perform this OMA if instrument air is lost and indicates that there are four annunciator alarm windows that monitor instrument air pressure, plus a pressure gauge on a panel in the control room for instrument air pressure. If all of these instruments are not available, then ABN–35 further indicates that the control rods will start to drift into the core and the MSIVs will close, as well as multiple air-operated valves changing state. Additionally, RPV level indication will not be compromised by a fire in any zone or area. All of these indications would help the operator diagnose the loss of instrument air and initiate mitigating procedures.

In the unlikely event that a fire does occur and causes a loss of instrument air to the air-operated valves, OMA #18 is available to provide makeup control air to the accumulator for V–11–36 for the isolation condenser makeup line due to the loss of instrument air. If OMA #18 becomes necessary, the licensee stated that they have assumed a 30-minute diagnosis period and that the required time to perform the action is 26

minutes, while the time available is 300 minutes, which provides a 244-minute margin.

3.20.5 Conclusion

Given the limited amount of combustible materials, ignition sources, and large volume of the space, it is unlikely that a fire would occur and go undetected or unsuppressed by the thermal detection system noted above or personnel, and damage the safe shutdown equipment. The low likelihood of damage to safe shutdown equipment due to a fire in this zone, combined with the ability of OMA #18 to manipulate the plant in the event of a fire that damages safe shutdown equipment, provides adequate assurance that safe shutdown capability is maintained.

3.21 Yard

3.21.1 Fire Prevention

The licensee stated that no specific quantification of fire loading was considered necessary for the Yard area since it is an outdoor area with no ceiling or physical boundaries to contain heat and smoke from a fire event.

3.21.2 Detection, Control, and Extinguishment

The licensee stated that there is no fire detection or fixed fire suppression systems installed in this area but that manual suppression is provided by a hose station from the office building and by fire hydrants located throughout the Yard area.

3.21.3 Preservation of Safe Shutdown Capability

Since the Yard area is an outdoor space with no walls or ceiling, smoke and heat would not accumulate within the fire area to cause damage to components remote to the initiating fire or obstruct operator actions.

3.21.4 OMAs Credited for a Fire in This Area

3.21.4.1 OMA #12—Establish CRD Flow to Reactor

In order for OMA #12 to be necessary, a loss of instrument air to the CRD flow control valve would have to occur due to fire damage. The licensee stated that the normal CRD flow control valve is a single component without a redundant counterpart. Because of this, a manual bypass is provided to maintain flow around the CRD flow control valves that fail closed upon loss of instrument air or control cable damage.

In the unlikely event that a fire does occur and causes the normal flow control valve to be unavailable due to a loss of instrument air or cable damage, OMA #12 is available to manually open V–15–237, throttle V–15–30 while monitoring flow at FI–225–2, and close V–15–52 to establish CRD flow to the reactor. Furthermore, OMA #12 would only be necessary if the Isolation Condenser/CRD systems are utilized for hot shutdown. If OMA #12 becomes necessary, the licensee stated that they have assumed a 30-minute diagnosis period and that the required time to perform the action is 15 minutes, while the time available is 204 minutes, which provides a 159-minute margin.

3.21.4.2 OMA #17—Provide Makeup Air to Isolation Condenser Valve V–11–34 Accumulator

In order for OMA #17 to be necessary, a loss of instrument air to the isolation condenser valve V–11–34 would have to occur due to fire damage. The licensee stated that they conservatively assume that instrument air is lost for all Appendix R fires based on the fact that instrument air lines run throughout many areas of the plant. The licensee's analysis assumes that the air line could potentially fail in approximately 45 minutes when exposed to the postulated fire.

The licensee also stated that OMA #17 connects a high pressure air cylinder to the accumulator of Condensate Transfer System valve V–11–34 and that these air-operated valves are used to control makeup to the isolation condensers. Each valve is provided with an air accumulator that provides a minimum of six full cycles. As a result, this OMA is only necessary to ensure long-term operation of these valves and makeup to the isolation condensers. Further, this OMA would only be necessary if the plant had to remain in hot shutdown for an extended time. This scenario is unlikely for this particular area since the plant would likely reach cold shutdown before the action is required.

In addition, the licensee stated that they maintain a fire support procedure (ABN–35, "Loss of Instrument Air") that provides guidance to perform this OMA if instrument air is lost and indicates that there are four annunciator alarm windows that monitor instrument air pressure, plus a pressure gauge on a panel in the control room for instrument air pressure. If all of these instruments are not available, then ABN–35 further indicates that the control rods will start to drift into the core and the MSIVs will close, as well as multiple air-operated valves changing state. Additionally, RPV level indication will not be compromised by a fire in any zone or area. All of these indications would help the operator diagnose the loss of instrument air and initiate mitigating procedures.

In the unlikely event that a fire does occur and causes a loss of instrument air to the air-operated valves, OMA #17 is available to provide makeup control air to the accumulator for V–11–34 for the isolation condenser makeup line due to the loss of instrument air. If OMA #17 becomes necessary, the licensee stated that they have assumed a 30-minute diagnosis period and that the required time to perform the action is 26 minutes, while the time available is 300 minutes, which provides a 244-minute margin.

3.21.5 Conclusion

Given the limited amount of combustible materials, ignition sources, and large volume of the space, it is unlikely that a fire would occur and go undetected or unsuppressed by the thermal detection system noted above or personnel, and damage the safe shutdown equipment. The low likelihood of damage to safe shutdown equipment due to a fire in this area, combined with the ability of OMAs #12 and #17 to manipulate the plant in the event of a fire that damages safe shutdown equipment, provides adequate assurance that safe shutdown capability is maintained.

3.22 Feasibility and Reliability of the Operator Manual Actions

This analysis postulates that OMAs may be needed to assure safe shutdown capability in addition to the traditional fire protection features described above. NUREG–1852, "Demonstrating the Feasibility and Reliability of Operator Manual Actions in Response to Fire," provides criteria and associated technical bases for evaluating the feasibility and reliability of post-fire OMAs in nuclear power plants. The following provides the Oyster Creek analysis of these criteria for justifying the OMAs specified in this exemption.

3.22.1 Bases for Establishing Feasibility and Reliability

Using NUREG–1852, the NRC staff has evaluated the feasibility and reliability review provided by the licensee in the April 2, 2010, Response to Request for Additional Information. For an OMA to be considered feasible, the required actions must be proceduralized, any equipment that is needed to implement the OMA is available, the environments in which the OMA is to be performed must permit the action, and the time taken to diagnose the need for the OMA and implement it (time required) must be

less than the time in which the OMA must be completed (time available).

3.22.2 Feasibility

The feasibility review provided by the licensee documents that procedures are in place, in the form of fire response procedures, to ensure that clear and accessible instructions on how to perform the manual actions are available to the operators. All of the requested OMAs are directed by plant procedures, and the operators are trained in the use of the procedures. Specifically, the licensee stated that procedure ABN–29, Plant Fires, is entered whenever a fire or indication of a fire occurs on the main fire alarm panel in the control room or at any local fire alarm panel. In addition to dispatching a radio-equipped operator to the alarming location, ABN–29 also directs that the fire brigade be dispatched whenever a fire suppression system has actuated (sprinkler, deluge, Halon, or CO_2) or a fire is confirmed. In addition, the licensee stated that ABN–29 directs immediate entry into the Fire Support Procedure (FSP) for the affected fire area as soon as the existence of a fire is confirmed. The licensee states that the following indications or symptoms are considered examples of a confirmed fire:

- Fire detection alarm and equipment malfunction indication or alarms within the same area;
- Fire pump start and either sprinkler flow alarm or deluge flow alarm;
- Gaseous suppression system actuation;
- Report from the field of an actual smoke condition or actual fire condition; or
- Fire detection alarm with follow up confirmation by field operator.

Entering the FSP means that the operator will review the FSP, identify equipment that could be affected, identify equipment that will be available, monitor plant equipment from the control room and communicate with the fire brigade leader. Based on the symptoms received in the control room and the feedback from the fire brigade leader, the operator will decide using the procedure what mitigating actions are necessary. In the event that a plant shutdown has occurred before the FSP is entered, the operator will still enter the FSP based on the fire and initiate the OMAs as appropriate. OMAs that are considered "prompt" (i.e., those that must be done within 45 minutes or less) are identified in both ABN–29 and in the applicable FSPs as an item requiring immediate attention. The operators are trained to perform prompt actions first and prioritize them based upon existing plant conditions. The FSPs are based on the worst-case loss considerations by assuming all fire damage occurs instantaneously and thus all operator manual actions will be required. The use of the Emergency Operating Procedures in conjunction with the applicable FSPs will permit the use of any mitigating system available first, and if a desired system is not available, the FSP provides a contingency action to restore the system or provide another means to perform the function. Operator training, including simulator demonstrations and plant walk downs, has been performed to ensure consistency in operator and team response for each OMA.

The licensee evaluated several potential environmental concerns, such as radiation levels, temperature/humidity conditions and the ventilation configuration and fire effects that the operators may encounter during certain emergency scenarios. The licensee's feasibility review concluded that the operators performing the manual actions would not be exposed to adverse or untenable conditions during any particular operator manual action procedure or during the time to perform the procedure. The licensee stated that OMAs required for achieving and maintaining hot shutdown conditions are not impacted by environmental conditions associated with fires in the fire area identified in the request. Each of the safe shutdown calculations that provide the technical basis for the FSPs contains a timeline for operator actions for the specific fire area. In addition, the licensee stated that the equipment needed to implement OMAs remains available and the fire areas remain accessible during or following the event.

The licensee's analysis demonstrates that, for the expected scenarios, the OMAs can be diagnosed and executed within the amount of time available to complete them. The licensee's analysis also demonstrates that various factors, as discussed above, have been considered to address uncertainties in estimating the time available. Therefore, the OMAs included in this review are feasible because there is adequate time available for the operator to perform the required OMAs to achieve and maintain hot shutdown following a postulated fire event. Table 2 summarizes the "required" verses "available" times for each OMA. The licensee has included any diagnosis time as part of the required time for performing a particular action. Where an action has multiple times or contingencies associated with the "available" completion time, the lesser time is used. This is approach is considered to represent a conservative approach to analyzing the timelines associated with each of the OMAs with regard to the feasibility and reliability of the actions included in this exemption. The licensee provided a discussion of the times and circumstances associated with each of the actions in their March 3, 2009, and April 2, 2010, correspondence.

TABLE 2

OMA	Fire area/zone of fire origin	OMA location	Required time (min)	Available time (min)	Margin (min)
1	TB–FA–26, TB–FZ–11C, and TB–FZ–11D	OB–FZ–8A	18	30	12
2	TB–FA–26, TB–FZ–11C, and TB–FZ–11D	RB–FZ–1E	23	45	22
3	TB–FA–26, TB–FZ–11B, TB–FZ–11C, TB–FZ–11D, and TB–FZ–11E	OB–FZ–6B	38	180	142
7	TB–FA–26, TB–FZ–11C, and TB–FZ–11D	RB–FZ–1B	26	45	19
8	TB–FA–26, TB–FZ–11C, and TB–FZ–11D	DG–FA–17	26	45	19
9	Yard	RB–FZ–1E	45	204	159
17	CW–FA–14, OB–FZ–6A, OB–FZ–8A, OB–FZ–8B, OB–FZ–8C, OB–FA–9, RB–FZ–1D, RB–FZ–1E, RB–FZ–1F3, RB–FZ–1F5, RB–FZ–1G, TB–FA–3A, and Yard.	RB–FZ–1B	56	300	244
18	OB–FZ–6B, TB–FA–26, TB–FZ–11B, TB–FZ–11C, TB–FZ–11D, TB–FZ–11E, TB–FZ–11F, and TB–FZ–11H.	RB–FZ–1B	56	300	244
	OB–FZ–10A	.....	38	60	22

The NRC staff reviewed the required operator manual action completion time limits versus the time before the action becomes critical to safely shutting down the unit as presented in the feasibility analyses. The NRC staff recognizes that, in some cases the time required neared the time available for an OMA. The NRC staff, however, also recognizes that there are conservatisms built in to these time estimates such as adding in the entire time assumed to diagnose the need for an OMA where in reality, the actual time take would likely be less.

The NRC staff notes that, in one case, an OMA must be completed within 30 minutes (i.e., it is considered a prompt action). This action is identified as OMA #1 and requires an operator to trip the field breakers for the recirculation pumps MG set so that the Fuel Zone Level Indicators can be used. The action may be required as a result of fire in TB–FA–26, TB–FZ–11C, or TB–FZ–11D. The symptom for this action is the inability to trip the Recirculation Pumps from the control room and this is detected using the associated pump breaker indicating lights, alarms and flow indications. The Fire Support Procedures direct the operator to trip the pumps using the pump control switches or the Recirculation Pump Trip circuitry (two trip coils for pumps). If both of these methods fail on one or more pumps, the guidance is given to trip the pumps from the 4160V Switchgear 1A and 1B located outside the control room in Fire Area TB–FZ–11C. Only one operator would be required and it would take approximately 13 minutes for access to the area and to perform the action of tripping the breakers. Given the low complexity of this action, the NRC staff finds that there is a sufficient amount of time available to complete the proposed operator manual actions.

3.23 Reliability

The completion times noted in the table above provide reasonable assurance that the OMAs can reliably be performed under a wide range of conceivable conditions by different plant crews. This is because the time margins associated with each action and other installed fire protection features, account for sources of uncertainty such as variations in fire and plant conditions, factors unable to be recreated in demonstrations and human-centered factors. Therefore, the OMAs included in this review are reliable because there is adequate time available to account for uncertainties not only in estimates of the time available, but also in estimates of how long it takes to diagnose a fire and execute the OMAs. This is based, in part, on a plant demonstration of the actions under non-fire conditions.

3.24 Summary of Defense-in-Depth and Operator Manual Actions

In summary, the defense-in-depth concept for a fire in the fire areas discussed above provides a level of safety that limits the occurrence of fires and results in rapid detection, control and extinguishment of fires that do occur and the protection of structures, systems and components important to safety. It should be understood that the OMAs are a fall back in the unlikely event that the fire protection defense-in-depth features are insufficient. In most cases, there is no credible fire scenario that would necessitate the performance of these OMAs. As discussed above, the licensee has provided preventative and protective measures in addition to feasible and reliable OMAs that together demonstrate the licensee's ability to preserve or maintain safe shutdown capability in the event of a fire in the analyzed fire areas.

3.25 Authorized by Law

This exemption would allow Oyster Creek to rely on OMAs, in conjunction with the other installed fire protection features, to ensure that at least one means of achieving and maintaining hot shutdown remains available during and following a postulated fire event, as part of its fire protection program, in lieu of meeting the requirements specified in 10 CFR Part 50, Appendix R, Section III.G.2 for a fire in the analyzed fire areas. As stated above, 10 CFR 50.12 allows the NRC to grant exemptions from the requirements of 10 CFR Part 50. The NRC staff has determined that granting of this exemption will not result in a violation of the Atomic Energy Act of 1954, as amended, or the Commission's regulations. Therefore, the exemption is authorized by law.

3.26 No Undue Risk to Public Health and Safety

The underlying purpose of 10 CFR Part 50, Appendix R, Section III.G is to ensure that at least one means of achieving and maintaining hot shutdown remains available during and following a postulated fire event. Based on the above evaluation, the NRC staff finds that the plant features, as described in the March 3, 2009, submittal, as supplemented by letter dated April 2, 2010, should limit the occurrence and impacts of any fire that may occur. This, combined with the ability of the OMAs to place and maintain the plant in a safe condition in the event of a fire that does damage safe shutdown equipment, provides adequate protection of public health and safety. Therefore, there is no undue risk to public health and safety.

3.27 Consistent With Common Defense and Security

This exemption would allow Oyster Creek to credit the use of the specific OMAs, in conjunction with the other installed fire protection features, in response to a fire in the analyzed fire areas, discussed above, in lieu of meeting the requirements specified in III.G.2. This change, to the operation of the plant, has no relation to security issues nor does it diminish the level of safety from what was intended by the requirements of III.G.2. Therefore, the common defense and security is not diminished by this exemption.

3.28 Special Circumstances

One of the special circumstances described in 10 CFR 50.12(a)(2)(ii) is that the application of the regulation is not necessary to achieve the underlying purpose of the rule. The underlying purpose of 10 CFR Part 50, Appendix R, Section III.G is to ensure that at least one means of achieving and maintaining hot shutdown remains available during and following a postulated fire event. While the licensee does not comply with the explicit requirements of III.G.2, specifically, they do meet the underlying purpose of 10 CFR Part 50, Appendix R, and Section III.G as a whole. Therefore, special circumstances exist that warrant the issuance of this exemption as required by 10 CFR 50.12(a)(2)(ii).

4.0 Conclusion

Accordingly, the Commission has determined that, pursuant to 10 CFR 50.12(a), the exemption is authorized by law, will not present an undue risk to the public health and safety, is consistent with the common defense and security and that special circumstances are present to warrant issuance of the exemption. Therefore, the Commission hereby grants Exelon an exemption from the requirements of Section III.G.2 of Appendix R of 10 CFR Part 50, to utilize the OMAs discussed above at Oyster Creek.

Pursuant to 10 CFR 51.32, the Commission has determined that the granting of this exemption will not have a significant effect on the quality of the human environment (75 FR 33656).

This exemption is effective upon issuance.

Dated at Rockville, Maryland, this 30th day of March 2011.

For the Nuclear Regulatory Commission.

Robert A. Nelson,

Acting Director, Division of Operating Reactor Licensing, Office of Nuclear Reactor Regulation.

[FR Doc. 2011–8318 Filed 4–6–11; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2011–0075]

Notice of Availability (NOA) of the Models For Plant-Specific Adoption of Technical Specifications Task Force (TSTF) Traveler TSTF–422, Revision 2, "Change In Technical Specifications End States (CE NPSD–1186)," For Combustion Engineering (CE) Pressurized Water Reactor (PWR) Plants Using the Consolidated Line Item Improvement Process (CLIIP)

AGENCY: U.S. Nuclear Regulatory Commission (NRC).

ACTION: Notice of Availability.

SUMMARY: The NRC is announcing the availability of the model application (with model no significant hazards consideration (NSHC) determination) and model safety evaluation (SE) for plant-specific adoption of TSTF Traveler TSTF–422, Revision 2, "Change in Technical Specifications End States (CE NPSD–1186)," for CE plants using the CLIIP. TSTF–422, Revision 2, is available in the Agencywide Documents Access and Management System (ADAMS) under Accession Number ML093570241. TSTF–422, Revision 2, modifies the Required Action with the preferred end state with the addition of a Note to prohibit the use of the provisions of Limiting Condition for Operation 3.0.4.a to enter the end state Mode within the Applicability during startup. The Bases of each Required Action is revised to describe the Note. This model SE will facilitate expedited approval of plant-specific adoption of TSTF–422, Revision 2. Please note, this NOA supersedes in its entirety the NOA for TSTF–422, Revision 1, published in the **Federal Register** on July 5, 2005 (70 FR 38729–38731, ADAMS Package Accession Number ML051650144).

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, Public File Area 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 the ADAMS, which provides text and image files of NRC's public documents. If you do not have access to the ADAMS, or if there are problems in accessing the documents located in the 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 model application (with model NSHC determination) and model SE for plant-specific adoption of TSTF–422, Revision 2, are available electronically under ADAMS Accession Number ML103270197. No comments were received to the Notice of Opportunity for Public Comment announced in the **Federal Register** on May 4, 2005 (70 FR 23238).

Federal Rulemaking Web site: Supporting materials related to this notice can be found at *http://www.regulations.gov* by searching on Docket ID: NRC–2011–0075.

FOR FURTHER INFORMATION CONTACT: Ravinder Grover, Technical Specifications Branch, Mail Stop: O–7 C2A, Division of Inspection and Regional Support, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; *telephone:* 301–415–2166 or e-mail; *Ravinder.Grover@nrc.gov* or Ms. Michelle C. Honcharik, Senior Project Manager, Licensing Processes Branch, Mail Stop: O–12 D1, Division of Policy and Rulemaking, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; *telephone:* 301–415–1774 or e-mail at: *Michelle.Honcharik@nrc.gov*.

SUPPLEMENTARY INFORMATION: TSTF–422, Revision 2, is applicable to all CE PWR plants. Licensees opting to apply for this TS change are responsible for reviewing the NRC staff's model SE, referencing the applicable technical justifications, and providing any necessary plant-specific information. The NRC will process each amendment application responding to this NOA according to applicable NRC rules and procedures.

The proposed models do not prevent licensees from requesting an alternate approach or proposing changes other than those proposed in TSTF–422, Revision 2. However, significant deviations from the approach recommended in this notice or the inclusion of additional changes to the license require additional NRC staff review. This may increase the time and resources needed for the review or result in NRC staff rejection of the license amendment request (LAR). Licensees desiring significant deviations or additional changes should instead submit an LAR that does not claim to adopt TSTF–422, Revision 2.

Dated at Rockville, Maryland, this 22nd day of March, 2011.

For the Nuclear Regulatory Commission.

John R. Jolicoeur,

Chief, Licensing Processes Branch, Division of Policy and Rulemaking, Office of Nuclear Reactor Regulation .

[FR Doc. 2011–8310 Filed 4–6–11; 8:45 am]

BILLING CODE 7590–01–P

PENSION BENEFIT GUARANTY CORPORATION

Proposed Submission of Information Collection for OMB Review; Comment Request; Disclosure of Termination Information

AGENCY: Pension Benefit Guaranty Corporation.

ACTION: Notice of intent to request extension of OMB approval.

SUMMARY: Pension Benefit Guaranty Corporation ("PBGC") intends to request that the Office of Management and Budget ("OMB") extend approval, under the Paperwork Reduction Act of 1995, of a collection of information on the disclosure of termination information under its regulations for distress terminations, 29 CFR part 4041, Subpart C, and for PBGC-initiated terminations under 29 CFR part 4042 (OMB control number 1212–0065; expires October 31, 2011). This notice informs the public of PBGC's intent and solicits public comment on the collection of information.

DATES: Comments should be submitted by June 6, 2011.

ADDRESSES: Comments may be submitted by any of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the Web site instructions for submitting comments.
- *E-mail: paperwork.comments@pbgc.gov.*
- *Fax:* 202–326–4224.
- *Mail or Hand Delivery:* Legislative and Regulatory Department, Pension Benefit Guaranty Corporation, 1200 K Street, NW., Washington, DC 20005–4026.

PBGC will make all comments available on its Web site at *http://www.pbgc.gov.*

Copies of the collection of information may be obtained without charge by writing to the Disclosure Division of the Office of the General Counsel of PBGC at the above address, visiting the Disclosure Division, faxing a request to 202–326–4042, or calling 202–326–4040 during normal business hours. (TTY and TDD users may call the Federal relay service toll-free at 1–800–877–8339 and ask to be connected to 202–326–4040.) The regulations and instructions relating to this collection of information are available on PBGC's Web site at *http://www.pbgc.gov.*

FOR FURTHER INFORMATION CONTACT: Jo Amato Burns, Attorney, or Catherine B. Klion, Manager, Legislative and Regulatory Department, Pension Benefit Guaranty Corporation, 1200 K Street, NW., Washington, DC 20005, 202–326–4024. (For TTY and TDD, call 800–877–8339 and ask to be connected to 202–326–4024.)

SUPPLEMENTARY INFORMATION: Sections 4041 and 4042 of the Employee Retirement Income Security Act of 1974, as amended ("ERISA"), 29 U.S.C. 1301–1461, govern the termination of single-employer defined benefit pension plans that are subject to Title IV of ERISA. A plan administrator may initiate a distress termination pursuant to section 4041(c), and PBGC may itself initiate proceedings to terminate a pension plan under section 4042 if PBGC determines that certain conditions are present. Section 506 of the Pension Protection Act of 2006 (Pub. L. 109–280) amended sections 4041 and 4042 of ERISA. These amendments require that, upon a request by an affected party, a plan administrator must disclose information it has submitted to PBGC in connection with a distress termination filing, and that a plan administrator or plan sponsor must disclose information it has submitted to PBGC in connection with a PBGC-initiated termination. The provisions also require PBGC to disclose the administrative record relating to a PBGC-initiated termination upon request by an affected party. The new provisions are applicable to terminations initiated on or after August 17, 2006. On November 18, 2008 (at 73 FR 68333, PBGC amended its regulations to implement the PPA 2006 provisions.

A description of the current disclosure provisions for distress terminations can be found on PBGC's Web site at *http://www.pbgc.gov/Documents/Disclosure_of_Distress_Termination_Information.pdf.* A description of the disclosure provisions for PBGC-initiated terminations is attached to each notice of determination that PBGC issues that a plan should be terminated under section 4042 of ERISA.

Based on its experience and information from practitioners, PBGC estimates that three participants or other affected parties will annually make requests for termination information. PBGC estimates that the total annual burden for the collection of information will be about 45 hours and $900 (15 hours and $300 per request).

PBGC is soliciting public comments to—

- Evaluate whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including 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.

Issued in Washington, DC, this 1st day of April, 2011.

John H. Hanley,

Director, Legislative and Regulatory Department, Pension Benefit Guaranty Corporation.

[FR Doc. 2011–8355 Filed 4–6–11; 8:45 am]

BILLING CODE 7709–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–64165; File No. SR–Phlx–2011–39]

Self-Regulatory Organizations; NASDAQ OMX PHLX LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change Relating to QQQQ

April 1, 2011.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act"),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on March 25, 2011, NASDAQ OMX PHLX LLC ("Phlx" or "Exchange") filed with the Securities and Exchange Commission ("SEC" or "Commission") the proposed rule change as described in Items I, II, and III, below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend Section I of the Exchange's Fee Schedule titled "Rebates and Fees for Adding and Removing Liquidity in Select Symbols," specifically to amend the trading symbol for the PowerShares QQQ Trust.[3]

The text of the proposed rule change is available on the Exchange's website at *http://nasdaqtrader.com/micro.aspx?id=PHLXfilings,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The purpose of the proposed rule change is to amend the list of Select Symbols[4] in Section I of the Exchange's Fee Schedule, titled "Rebates and Fees for Adding and Removing Liquidity in Select Symbols." Specifically, the Exchange proposes to amend the trading symbol "QQQQ." The Exchange proposes to change the symbol from "QQQQ" to "QQQ" to reflect the recent change in that exchange-traded fund's ticker symbol. "QQQQ" would continue to be subject to the Fees and Rebates for

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] PowerShares QQQQ, formerly known the "NASDAQ–100 Index Tracking Stock®", is based on the Nasdaq-100 Index®.

[4] The term "Select Symbols" refers to the symbols which are subject to the Rebates and Fees for Adding and Removing Liquidity in Section I of the Exchange's Fee Schedule.

Adding and Removing Liquidity in Section I of the Exchange's Fee Schedule. The Exchange is also proposing to make conforming amendments within Section I of the Fee Schedule to change "QQQQ" to "QQQ" in the remainder of that Section.

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act [5] in general, and furthers the objectives of Section 6(b)(5) of the Act [6] in particular, in that it is designed to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general to protect investors and the public interest. The Exchange believes that updating the Exchange's Fee Schedule to amend the "QQQQ" symbol to "QQQ" will provide its members clarity as to which symbols are subject to the Fees and Rebates for Adding and Removing Liquidity in Section I of the Exchange's Fee Schedule.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Pursuant to Section 19(b)(3)(A) of the Act [7] and Rule 19b–4(f)(1)[8] thereunder, the Exchange has designated this proposal as one that constitutes a stated policy, practice or interpretation with respect to the meaning, administration, or enforcement of an existing rule of the SRO, and therefore has become effective.

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an e-mail to *rule-comments@sec.gov.* Please include File Number SR–Phlx-2011–39 on the subject line.

Paper Comments

- Send paper comments in triplicate to Elizabeth M. Murphy, Secretary, Securities and Exchange Commission, 100 F Street, NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–Phlx-2011–39. 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 website 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–Phlx–2011–39 and should be submitted on or before April 28, 2011.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[9]

Cathy H. Ahn,

Deputy Secretary.

[FR Doc. 2011–8231 Filed 4–6–11; 8:45 am]

BILLING CODE 8011–01–P

[5] 15 U.S.C. 78f(b).

[6] 15 U.S.C. 78f(b)(5).

[7] 15 U.S.C. 78s(b)(3)(A).

[8] 17 CFR 240.19b–4(f)(1).

[9] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–64167; File No. SR–OCC–2011–03]

Self-Regulatory Organizations; The Options Clearing Corporation; Notice of Filing of Proposed Rule Change to Allow for an Expansion of OCC's Internal Cross-Margining Program to Include the Ability of a Pair of Affiliated Clearing Members to Establish an Internal Non-Proprietary Cross-Margining Account

April 1, 2011.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act") [1] and Rule 19b–4 thereunder [2] notice is hereby given that on March 17, 2011, The Options Clearing Corporation ("OCC") filed with the Securities and Exchange Commission ("Commission") the proposed rule change as described in Items I, II, and III below, which Items have been prepared primarily by OCC. 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 proposed rule change would expand OCC's internal cross-margining program to permit a pair of affiliated clearing members to establish a cross-margining account ("Internal Non-Proprietary Cross-Margining Account") in which securities and security futures that are cleared by OCC in its capacity as a securities clearing agency may be cross-margined with commodity futures and options on such futures that are cleared by OCC in its capacity as a derivatives clearing organization ("DCO") registered with the Commodity Futures Trading Commission ("CFTC") under the Commodity Exchange Act ("CEA").

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, OCC 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. OCC has prepared summaries, set forth in sections (A), (B), and (C) below, of the most significant aspects of these statements.[3]

(A) Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In 2004, the CFTC and the Commission[4] approved OCC's proposal to create an "internal cross-margining" program under which an OCC clearing member could elect to cross-margin a non-proprietary futures account of a "market professional" (as defined in OCC's By-Laws)[5] with a non-proprietary securities account containing positions of the same market professional. At OCC, the securities and futures positions of all market professionals with cross-margined accounts at the clearing member are combined in a single Internal Non-Proprietary Cross-Margining Account of the clearing member at OCC. The existing program, which has operated successfully since 2004, requires that the same clearing member clear the securities and futures positions. In contrast, the existing cross-margining programs between OCC and other DCOs such as the clearing division of the Chicago Mercantile Exchange ("CME") and ICE Clear U.S. permit cross-margining where the member of the futures clearing organization is a different entity from its affiliate that is an OCC clearing member. The purpose of this proposed rule change is to expand the existing internal cross-margining program in an analogous way so that it would permit an Internal Non-Proprietary Cross-Margining Account to be maintained at OCC jointly by a pair of affiliated clearing members that clear transactions in securities options and in futures products through two different entities. In order to participate, both OCC clearing members would have to be affiliates of one another and would have to be registered as both a futures commission merchant under the CEA and as a broker-dealer under the Act.

OCC's current internal cross-margining program does not provide for internal cross-margining accounts to be carried jointly by a pair of affiliated clearing members because OCC did not believe in 2004 that there was any clearing member demand for such a service. Recently, however, OCC has learned that there is demand for such a service. Under OCC's current proposal, two affiliated clearing members could jointly maintain an Internal Non-Proprietary Cross-Margining Account. The clearing member that normally clears transactions in securities options would submit transactions in eligible securities options to the account for clearance, and the clearing member that normally clears transactions in futures products would submit transactions in eligible futures products to the account for clearance.

OCC proposes to amend its current By-Laws and Rules governing internal cross-margining to create rules similar to the rules of the long-standing cross-margining program for affiliated clearing members between OCC and CME, for example. In the case of the cross-margining programs between OCC and other DCOs, there are two accounts at the clearing level—one at each of the participating clearing organizations. In the internal cross-margining program, there is no need for two separate accounts, which would in any event be margined together and for which the affiliated clearing members would in any event be jointly and severally liable as they are for the two accounts in the case of the OCC–CME program.

Article VI, Section 25(b) of OCC's By-Laws currently requires clearing members to obtain a "Market Professional's Agreement for Internal Cross-Margining" from each market professional whose positions are included in an Internal Non-Proprietary Cross-Margining Account. OCC proposes to use a modified form of this agreement for an account held jointly by a pair of affiliated clearing members. The proposed form of the agreement, titled "Market Professional's Agreement for Internal Cross-Margining (Affiliated Clearing Members)" is attached as Exhibit 5A to this proposed rule change filing. The existing "Market Professional's Agreement for Internal Cross-Margining" applicable to the internal cross-margining program for single clearing members has been retitled "Market Professional's Agreement for Internal Cross-Margining (Single Clearing Member)" and is attached as Exhibit 5B to this proposed rule change filing. In addition to modifying the title to the form of the agreement applicable to single clearing members, a sentence has been added at the end of paragraph seven of that agreement to conform it to the corresponding provision in the form of the agreement for affiliated clearing members. OCC does not intend to require current participants in the internal cross-margining program to obtain reexecuted agreements in updated form because the modifications are clarifications only and not substantive changes.

As in the case of the existing internal cross-margining program, the Internal Non-Proprietary Cross-Margining Account would be treated as a segregated futures account under Section 4d of the CEA and, in accordance with Appendix B to Part 190 of the CFTC's regulations, would be separately segregated from the regular segregated futures account that an OCC clearing member may maintain under Article VI, Section 3(f) of OCC's By-Laws. In order to expand the internal cross-margining program to include accounts carried by pairs of affiliated clearing members, OCC is requesting that the CFTC either issue a new or amended order under Section 4d of the CEA.

Since it granted approval of the first cross-margining program in 1988,[6] the Commission has found that cross-margining programs are consistent with clearing agency responsibilities under Section 17A of the Act[7] and highly beneficial to the clearing organization, its clearing members and the public. OCC believes that cross-margining programs enhance clearing member and systemic liquidity, resulting in lower initial margin deposits. They reduce the risk that a clearing member will become insolvent in a distressed market and the corresponding risk that one insolvency could lead to multiple insolvencies in a ripple effect, and they enhance the security of the clearing system.[8]

OCC would not implement the internal cross-margining program for affiliated clearing members until such time after the CFTC has issued an order

[3] The Commission has modified the text of the summaries prepared by OCC.

[4] Securities Exchange Act Release No. 34–50509 (October 8, 2004), 69 FR 61289 (October 15, 2004).

[5] A market professional could be a market-maker, specialist or person acting in a similar capacity on a securities exchange, or a member of a futures exchange trading for its own account. A non-proprietary market professional is any market professional that is required to be treated as a "customer" under the CEA, and therefore excludes any market professional that is affiliated with the carrying clearing member in a way that would cause its account to be treated as a "proprietary account" under Section 1.3(y) of the CFTC's regulations.

[6] Securities Exchange Act Release No. 34–26153 (October 3, 1988), 53 FR 39567 (October 7, 1988).

[7] 15 U.S.C. 78q–1.

[8] Securities Exchange Act Release No. 34–32708 (August 2, 1993), 58 FR 42586 (August 10, 1993).

or amended order under Section 4d of the CEA as discussed above.

(B) Self-Regulatory Organization's Statement on Burden on Competition

OCC does not believe that the proposed rule change would impose any burden on competition.

(C) Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received from Members, Participants or Others

Written comments relating to the proposed rule change have not been solicited or received. OCC will notify the Commission of any written comments received by OCC.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 45 days of the date of publication of this notice in the **Federal Register** or within such longer period up to 90 days (i) as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the self-regulatory organization consents, the Commission will: (A) By order approve or disapprove the proposed rule change or (B) institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

• Use the Commissions 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–OCC–2011–03 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–OCC–2011–03. This file number should be included on the subject line if e-mail is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Section, 100 F Street, NE., Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Copies of such filings will also be available for inspection and copying at the principal office of OCC and on OCC's Web site at *http://www.optionsclearing.com/components/docs/legal/rules_and_bylaws/sr_occ_11_03.pdf.*

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–OCC–2011–03 and should be submitted on or before April 28, 2011.

For the Commission by the Division of Trading and Markets, pursuant to delegated authority.[9]

Cathy H. Ahn,

Deputy Secretary.

[FR Doc. 2011–8235 Filed 4–6–11; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[File No. 500–1]

In the Matter of: Sabratek Corp., SAN Holdings, Inc., SBD International, Inc. (n/k/a Solargy Systems, Inc.), Scantek Medical, Inc., SciLabs Holdings, Inc., The SCO Group, Inc., Secure Technologies Group, Inc., Secured Digital Applications, Inc., Senco Sensors, Inc., Sentex Sensing Technology, Inc., Serefex Corp., SinoFresh HealthCare, Inc., Sonoma College, Inc., and Source Petroleum Inc.; Order of Suspension of Trading

April 5, 2011.

It appears to the Securities and Exchange Commission that there is a lack of current and accurate information concerning the securities of Sabratek Corp. because it has not filed any periodic reports since the period ended March 31, 1999.

It appears to the Securities and Exchange Commission that there is a lack of current and accurate information concerning the securities of SAN Holdings, Inc. because it has not filed any periodic reports since the period ended June 30, 2007.

It appears to the Securities and Exchange Commission that there is a lack of current and accurate information concerning the securities of SBD International, Inc. (n/k/a Solargy Systems, Inc.) because it has not filed any periodic reports since the period ended September 30, 2006.

It appears to the Securities and Exchange Commission that there is a lack of current and accurate information concerning the securities of Scantek Medical, Inc. because it has not filed any periodic reports since the period ended March 31, 2003.

It appears to the Securities and Exchange Commission that there is a lack of current and accurate information concerning the securities of SciLabs Holdings, Inc. because it has not filed any periodic reports since the period ended March 31, 2002.

It appears to the Securities and Exchange Commission that there is a lack of current and accurate information concerning the securities of The SCO Group, Inc. because it has not filed any periodic reports since the period ended January 31, 2009.

It appears to the Securities and Exchange Commission that there is a lack of current and accurate information concerning the securities of Secure Technologies Group, Inc. because it has not filed any periodic reports since the period ended December 31, 2004.

It appears to the Securities and Exchange Commission that there is a lack of current and accurate information concerning the securities of Secured Digital Applications, Inc. because it has not filed any periodic reports since the period ended September 30, 2008.

It appears to the Securities and Exchange Commission that there is a lack of current and accurate information concerning the securities of Senco Sensors, Inc. because it has not filed any periodic reports since the period ended November 30, 1999.

It appears to the Securities and Exchange Commission that there is a lack of current and accurate information concerning the securities of Sentex Sensing Technology, Inc. because it has not filed any periodic reports since the period ended August 31, 2007.

It appears to the Securities and Exchange Commission that there is a lack of current and accurate information

[9] 17 CFR 200.30–3(a)(12).

concerning the securities of Serefex Corp. because it has not filed any periodic reports since the period ended February 28, 2009.

It appears to the Securities and Exchange Commission that there is a lack of current and accurate information concerning the securities of SinoFresh HealthCare, Inc. because it has not filed any periodic reports since the period ended September 30, 2008.

It appears to the Securities and Exchange Commission that there is a lack of current and accurate information concerning the securities of Sonoma College, Inc. because it has not filed any periodic reports since the period ended September 30, 2006.

It appears to the Securities and Exchange Commission that there is a lack of current and accurate information concerning the securities of Source Petroleum Inc. because it has not filed any periodic reports since the period ended June 30, 2007.

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 April 5, 2011, through 11:59 p.m. EDT on April 18, 2011.

By the Commission.

Elizabeth M. Murphy,

Secretary.

[FR Doc. 2011–8390 Filed 4–5–11; 11:15 am]

BILLING CODE 8011–01–P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration # 12513]

California Disaster # CA–00170 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 State of California, dated 03/31/2011.

Incident: Salmon Fishery Closure 2010 Season.

Incident Period: 04/10/2010 through 09/30/2010.

Effective Date: 03/31/2011.

EIDL Loan Application Deadline Date: 01/03/2012.

ADDRESSES: Submit completed loan applications to: U.S. Small Business 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 Counties: Del Norte, Mendocino, San Luis Obispo, San Mateo, Santa Clara, Santa Cruz, Sonoma.

Contiguous Counties: California: Alameda, Glenn, Humboldt, Kern, Kings, Lake, Marin, Merced, Monterey, Napa, San Benito, San Francisco, Santa Barbara, Siskiyou, Solano, Stanislaus, Tehama, Trinity.

Oregon:

Curry, Josephine.

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 125130.

The States which received an EIDL Declaration # are California, Oregon.

(Catalog of Federal Domestic Assistance Number 59002)

Dated: March 31, 2011.

Karen G. Mills,

Administrator.

[FR Doc. 2011–8335 Filed 4–6–11; 8:45 am]

BILLING CODE 8025–01–P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #12517 and #12518]

Tennessee Disaster #TN–00050

AGENCY: U.S. Small Business Administration.

ACTION: Notice.

SUMMARY: This is a Notice of the Presidential declaration of a major disaster for Public Assistance Only for the State of Tennessee (FEMA–1965–DR), dated 04/01/2011.

Incident: Severe Storms, Tornadoes, and Flooding.

Incident Period: 02/28/2011 through 03/01/2011.

Effective Date: 04/01/2011.

Physical Loan Application Deadline Date: 05/31/2011.

Economic Injury (EIDL) Loan Application Deadline Date: 01/03/2012.

ADDRESSES: Submit completed loan applications to: U.S. Small Business 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 President's major disaster declaration on 04/01/2011, Private Non-Profit organizations that provide essential services of governmental nature may file disaster loan applications at the address listed above or other locally announced locations.

The following areas have been determined to be adversely affected by the disaster:

Primary Counties:

Fentress, Franklin, Grainger, Hamilton, Houston, Humphreys, Jackson, Jefferson, Moore, Morgan, Pickett, Scott, Union.

The Interest Rates are:

	Percent
For Physical Damage:	
Non-Profit Organizations With Credit Available Elsewhere	3.250
Non-Profit Organizations Without Credit Available Elsewhere	3.000
For Economic Injury:	
Non-Profit Organizations Without Credit Available Elsewhere	3.000

The number assigned to this disaster for physical damage is 12517B and for economic injury is 12518B.

(Catalog of Federal Domestic Assistance Numbers 59002 and 59008)

James E. Rivera,

Associate Administrator for Disaster Assistance.

[FR Doc. 2011–8336 Filed 4–6–11; 8:45 am]

BILLING CODE 8025–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Public Notice for a Change in Use of Aeronautical Property at Bradford Regional Airport (BFD), Bradford, PA

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Request for public comment.

SUMMARY: The Federal Aviation Administration is requesting public comment on the Bradford Regional Airport Authority's request to change 35.46 acres of airport property from aeronautical use to non-aeronautical use.

The parcel is located at Bradford Regional Airport (BFD) in Lafayette Township, McKean County, PA. The property is currently depicted on the Airport Layout Plan of record as airport property and consists mostly of wooded undeveloped land bound by State Highway Rt. 59 and the Airport Access Road. More specifically, the 35.46 Acre tract is positioned east of the airport access road and north of State Highway Rt. 59 at their intersection. The airport is proposing redesignating this area as available for non-aeronautical use. The requested change is for the anticipated purpose of permitting the Airport Owner to lease commercial space to tenants for commercial and light industrial development that is compatible with airport operations.

This action will allow the redesignation of the 35.46 area as land available for non-aeronautical use on the Airport Layout Plan (ALP). Documents reflecting the Sponsor's request are available, by appointment only, for inspection at the Bradford Airport Manager's office and the FAA Harrisburg Airport District Office.

DATES: Comments must be received on or before May 9, 2011.

ADDRESSES: Documents are available for review at the Airport Manager's office: Thomas C. Frungillo, Airport Director, Bradford Regional Airport, 212 Airport Drive, Lewis Run, PA 16738. 814–368–5928 and at the FAA Harrisburg Airports District Office: Oscar D. Sanchez, Program Manager, Harrisburg Airports District Office, 3905 Hartzdale Dr., Suite 508, Camp Hill, PA 17011. (717) 730–2830.

FOR FURTHER INFORMATION CONTACT: Oscar D. Sanchez, Program Manager, Harrisburg Airports District Office (location listed above).

SUPPLEMENTARY INFORMATION: The FAA invites public comment on the request to re-designate current aeronautical property at the Bradford Regional Airport as available for non-aeronautical use under the provisions of Section 47125(a) of Title 49 U.S.C.

The following is a brief overview of the request:

The Bradford Regional Airport (BFD) has requested the designation of a 35.46 acre parcel located on airport property, in proximity to State Rt. 59 and east of the Airport Access Road, as available for non-aeronautical development. This land was acquired by The City of Bradford and McKean County in October of 1941, as part of a 600 acre plot composed of properties acquired from Bingham Petroleum Co., Anna Gates, Mt. Jewett Catholic Church, South Penn Oil Co., Sylvania Corporation, Erie Railroad, F.W. Paul Estate and Byron W. Pierce. There are no known adverse impacts to the operation of the airport and the 35.46 acre parcel of land is not needed for future aeronautical development as indicated on the approved Bradford Airport Layout Plan (ALP). There is to be no sale or transfer of property rights in connection with this Airport Layout Plan change. Any proceeds from the lease of the future tenant space or other future non-aeronautical development, are to remain on the airport for capital development and to cover the operating costs of the Airport.

Any person may inspect the request by appointment at the FAA office address listed above.

Interested persons are invited to comment on the proposed change in use of the property. All comments will be considered by the FAA to the extent practicable.

Issued in Camp Hill, Pennsylvania, April 1, 2011.

Lori K. Pagnanelli,

Manager, Harrisburg Airports District Office.

[FR Doc. 2011–8267 Filed 4–6–11; 8:45 am]

BILLING CODE P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Public Meeting/Notice of Availability, Review, and Comment on Preliminary Alternatives for the Development of an Air Tour Management Plan for Hawaii Volcanoes National Park, HI

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of public meeting, request for comments, and availability of preliminary alternatives, correction.

SUMMARY: This action corrects an error in the notice of public meeting, request for comments, and availability of preliminary alternatives published in the **Federal Register** on Tuesday, March 29, 2011, announcing the availability of preliminary air tour alternatives and announcing meetings hosted by the National Park Service, Hawaii Volcanoes National Park and the FAA's Air Tour Management Program. This document corrects two Web sites for public comments.

DATES: Comment Period: Comments must be received on or before June 6, 2011.

Meetings: The meetings will be held at the following locations, dates, and times:

Volcano, Hawaii, Monday, April 18, 2011, 5:30–7:30 p.m., Hawai'i Volcanoes National Park, Kīlauea Visitor Center, 1 Crater Rim Drive.

Pāhoa, Hawaii, Tuesday, April 19, 2011, 5–7 p.m., Pāhoa Community Center, 15–2910 Puna Rd.

Nā'ālehu, Hawaii, Wednesday, April 20, 2011, 5:00–7:00 p.m., Nā'ālehu Community Center, 95–5635 Mamalahoa Highway.

FOR FURTHER INFORMATION CONTACT: Ms. Vicki McCusker, National Park Service, Natural Resource Program Center, Natural Sounds and Night Skies Division, 1201 Oakridge Drive, Suite 100, Fort Collins, CO 80525; telephone: (970) 267–2117 or Mr. Larry Tonish, Federal Aviation Administration, Air Tour Management Program, AWP–1SP, 15000 Aviation Blvd., Hawthorne, CA 90250; telephone: (310) 725–3817.

SUPPLEMENTARY INFORMATION:

History

On Tuesday, March 29, 2011, a notice of public meeting, request for comments, and availability of preliminary alternatives was published in the Federal Register concerning proposed alternatives available to the public which contain routes and altitudes used by air tour operators when providing air tours of the Hawaii Volcanoes National Park. A couple of web sites for the public to submit comments were incorrect. This action provides the correct information.

Correction

1. In the Notice document FR Doc. 2011–7310, as published on March 29, 2011 (76 FR 17472) on page 17473 column one, at the end of the first full paragraph, make the following correction:

Remove the Web site *http://parkplanning.nps.gov/documentsAndLinks.cfm?projectID=29122* and in it's place add: *http://parkplanning.nps.gov/projectHome.cfm?projectID=36002*.

2. In the Notice document FR Doc. 2011–7310, as published on March 29, 2011 (76 FR 17472) on page 17473 column one, at the end of the fourth full paragraph, that begins with NPS Planning, Environment and Public Comment Web site, make the following correction:

Remove the Web site *http://parkplanning.nps.gov/documentsAndLinks.cfm?projectID=29122* and in it's place add *http://parkplanning.nps.gov/projectHome.cfm?projectID=36002*.

Issued in Hawthorne, California on March 31, 2011.

Larry Tonish,

Program Manager, Air Tour Management Program.

[FR Doc. 2011–8282 Filed 4–6–11; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[Docket No. FAA–2011–0248]

Orders Limiting Scheduled Operations at John F. Kennedy International Airport, LaGuardia Airport, and Newark Liberty International Airport; High Density Rule at Reagan National Airport

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of FAA Decision on Request for Waiver of the Slot Usage Requirement.

SUMMARY: This action denies a request by the Air Transport Association of America (ATA) for a waiver of the requirements to use slots at Washington's Reagan National Airport (DCA) and Operating Authorizations (slots) at John F. Kennedy International Airport (JFK), LaGuardia Airport (LGA), and Newark Liberty International Airport (EWR).

DATES: Effective upon publication.

FOR FURTHER INFORMATION CONTACT: Robert Hawks, Office of the Chief Counsel, Federal Aviation Administration, 800 Independence Avenue, SW., Washington, DC 20591; telephone: (202) 267–7143; e-mail: *rob.hawks@faa.gov*.

SUPPLEMENTARY INFORMATION:

Background

By letter posted in Docket Number FAA–2011–0248 on March 15, 2011, ATA requested the FAA grant a limited waiver of the minimum slot usage requirements for DCA, JFK, EWR, and LGA for January 7 through 18, 2011, and January 26 through February 4, 2011, due to intense snowfalls in the northeastern and mid-Atlantic United States that seriously disrupted air carrier operations at those airports. In support of its request, ATA referenced a waiver granted by the FAA in February 2010 due to multiple snowstorms that severely disrupted aviation and other modes of transportation.[1]

ATA also stated the National Oceanic and Atmospheric Administration reported New York City and Newark, New Jersey, experienced the snowiest month of January on record. New York City recorded 36 inches of snow that month, surpassing the previous record of 27.4 inches; Newark recorded 37.4 inches, surpassing its previous January record of 31.6 inches. ATA highlights three major snowstorms in the regions occurring from January 9 through 13; from January 25 through 27, which also affected the D.C. metro area; and from February 1 through 3.

ATA asserts the effects of the weather events at DCA, JFK, EWR, and LGA were dramatic and lingering, disrupting operations during January and into early February. Twelve U.S. air carriers reported cancellations totaling 10,944 flights at the airports in the January 7 through 12, January 18, January 26 through 27, and February 1 through 4 periods. ATA also states that major snowstorms in the Midwest and New England further disrupted operations at DCA, JFK, EWR, and LGA because of network-wide weather disruptions and corresponding recovery programs.

By e-mail dated March 15, 2011, AirTran Airways stated its support for the ATA request for waiver.

FAA Analysis

Under the FAA's High Density Rule and Orders limiting scheduled operations at LGA, JFK, and EWR, slots must be used at least 80 percent of the time. These rules are expected to accommodate routine weather and other cancellations under all but the most unusual circumstances. Slots not meeting the minimum usage rules will be withdrawn or not receive historic precedence for the following scheduling season, depending on the airport.[2] The FAA may grant a waiver from the minimum usage requirements in highly unusual and unpredictable conditions that are beyond the control of the carrier and affect carrier operations for a period of five or more consecutive days. However, the FAA does not routinely grant general waivers to the usage requirements except under the most unusual circumstances.

The FAA is sympathetic to the disruptions created by winter weather. In February 2010, the FAA granted a general waiver because unusual snowstorms closed slot-controlled airports for multiple days and also caused mass cancellations resulting from reduced airport capacity. FAA air traffic records for the 2011 snowstorms do not demonstrate the same magnitude of either airport closures or cancellations over an extended period. Although there were multiple snowstorms, operations do not appear to have been impacted for any period lasting five or more consecutive days as required by the rules, and there were at least several days of recovery between the snowstorms. Accordingly, the FAA has determined ATA's request is too broad and may afford a benefit to some carriers that did not experience actual hardships.

Moreover, in recent years, the FAA has noticed a pattern that indicates some carriers may be meeting the usage requirements without planning a scheduled flight for each allocated slot. By underutilizing allocated slots, and using a portion of the 20 percent allowable non-use of slots to cover planned cancellations or underscheduling, carriers have a reduced ability to meet the usage requirements when weather events force additional cancellations. The FAA intends allocated slots be used for actual operations because slots are scarce resources at each of these airports. Although existing rules do not require each slot to directly correspond to a scheduled flight, the FAA is not required to use its waiver authority to endorse underutilization of allocated slots.

Although the FAA has determined that a general waiver of the usage requirements is inappropriate, it acknowledges that nationwide weather during this period may have created a unique hardship for some carriers. To assess that hardship and determine whether relief is warranted, the FAA requests that affected carriers submit an individual request for limited waiver. The FAA will consider the periods of January 7 through February 4, 2011, but will make a waiver determination on an individual-day basis. A waiver request should indicate the individual days of significant cancellations, a detail of the allocated slots on those days, a detail of the scheduled flights for those days, and a detail of the flights cancelled due to weather on those days. A carrier should also identify the specific slot or slots for which it is requesting a waiver and the utilization of the slot(s) for the reporting period. The FAA acknowledges weather in carriers' non-slot-controlled hub airports may have forced additional cancellations because there were several unusual storms throughout the nation

[1] 75 FR 9017 (Feb. 26, 2010).

[2] 14 CFR 93.227 (DCA); 74 FR 51648 (Oct. 7, 2009) (EWR); 74 FR 51650 (Oct. 7, 2009) (JFK); 74 FR 51653 (Oct. 7, 2009) (LGA).

during this period. In making a waiver determination, the FAA will consider a significant number of cancellations during those periods because of weather at a destination airport.

FAA Decision

In consideration of the foregoing, ATA's request for a grant of waiver is DENIED. Carriers who were uniquely affected by winter weather during January and February 2011 may request a limited grant of waiver. However, any request must detail the hardship caused by the snowstorms and demonstrate that hardship was not caused or exacerbated by underutilization of allocated slots. The FAA will carefully consider these individual requests for waiver.

Issued in Washington, DC on March 28, 2011.

J. David Grizzle,

Chief Counsel.

[FR Doc. 2011–8281 Filed 4–6–11; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Notice of Intent to Rule on Request To Release Airport Property at the Northeast Philadelphia Airport (PNE), Philadelphia, PA

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of request to release airport property.

SUMMARY: The FAA proposes to rule and invite public comment on the release of land at the Northeast Philadelphia Airport, Philadelphia, Pennsylvania under the provisions of Section 47125(a) of Title 49 United States Code (U.S.C.).

DATES: Comments must be received on or before May 9, 2011.

ADDRESSES: Comments on this application may be mailed or delivered to the following address: Joseph F. Messina, Divisional Deputy City Solicitor, City of Philadelphia Law Department, Transportation Division, One Parkway, 1515 Arch Street, Philadelphia, PA 19102–1595 and at the FAA Harrisburg Airports District Office: Lori K. Pagnanelli, Manager, Harrisburg Airports District Office, 3905 Hartzdale Dr., Suite 508, Camp Hill, PA 17011.

FOR FURTHER INFORMATION CONTACT: Lori Ledebohm, Community Planner, Harrisburg Airports District Office location listed above.

The request to release property may be reviewed in person at this same location.

SUPPLEMENTARY INFORMATION: The FAA invites public comment on the request to release property at the Northeast Philadelphia Airport under the provisions of Section 47125(a) of Title 49 U.S.C. On March 28, 2011, the FAA determined that the request to release property at the Northeast Philadelphia Airport submitted by the City of Philadelphia (City) met the procedural requirements.

The following is a brief overview of the request:

The City requests the release of real property, totaling 3.5 acres, of aeronautical airport property, to Biagio DeSimone. The land was originally purchased with City funds in 1945. The purpose of the release is to sell the land that was airport property to Biagio DeSimone, the current tenant. The property is located at 11295 E. Roosevelt Boulevard. The Parcel is currently leased to a tenant operating as a dealership and is improved with a 6,225 square foot building being used by the tenant in the operation of its automobile dealership and a gravel parking lot for customers of the dealership. The Parcel is not contiguous to the area being operated as the Northeast Philadelphia Airport. The subject land does not serve an aeronautical purpose and is not needed for airport development, as shown on the Airport Layout Plan. All proceeds from the sale of property are to be used for the capital development of the airport. Fair Market Value (FMV) will be obtained from the land sale and reinvested back in the airport.

Any person may inspect the request by appointment at the FAA office address listed above. Interested persons are invited to comment on the proposed release from obligations. All comments will be considered by the FAA to the extent practicable.

Issued in Camp Hill, Pennsylvania, April 1, 2011.

Lori K. Pagnanelli,

Manager, Harrisburg Airports District Office.

[FR Doc. 2011–8268 Filed 4–6–11; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

Safety Advisory 2011–01

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

ACTION: Notice of Safety Advisory; equipment fouling adjacent tracks.

SUMMARY: FRA is issuing Safety Advisory 2011–01 to remind each railroad and railroad employees of the importance of compliance with Federal regulations and railroad operating rules regarding rolling equipment being left in a location that is clear of any adjacent tracks. This safety advisory contains various recommendations to railroads to ensure that this issue is addressed by appropriate policies and procedures, and receives employee compliance.

FOR FURTHER INFORMATION CONTACT: Ron Hynes, Director, Office of Safety Assurance and Compliance, Office of Railroad Safety, FRA, 1200 New Jersey Avenue, SE., Washington, DC 20590, telephone (202) 493–6404; or Joseph St. Peter, Trial Attorney, Office of Chief Counsel, FRA, 1200 New Jersey Avenue, SE., Washington, DC 20590, telephone (202) 493–6047.

SUPPLEMENTARY INFORMATION: The overall safety of railroad operations in the area of equipment securement and protection has improved in recent years. However, two recent fatal incidents highlight the need to review and adhere to existing Federal regulations and railroad operating rules pertaining to rolling equipment being left in a location that is clear of any adjacent tracks.

On May 18, 2005, the Railroad Safety Advisory Committee (RSAC) authorized the RSAC Operating Rules Working Group to address eight human factors (HF) train accident report cause codes that were attributed to nearly half (47 percent) of all HF-caused train accidents nationwide. On February 13, 2008, FRA published a final rule addressing those HF causes, which was codified at Title 49 Code of Federal Regulations (CFR) Part 218, Subpart F (Subpart F). Two of those eight HF cause codes, H301 and H302, were designated for rolling equipment left out to foul. From 2005 to 2010, HF-caused train accidents, attributed to these two cause codes, were reduced by 66 percent. Unfortunately, despite that overall improvement, the rail industry experienced two recent railroad employee fatalities that appear to have been related to equipment being left in a location where it fouled an adjacent track.

Recent Incidents

The following is a discussion of the circumstances surrounding two recent fatal incidents, and is based only on FRA's preliminary investigations. The incidents are still under investigation by FRA. The causes and contributing factors, if any, have not yet been established. Therefore, nothing in this safety advisory is intended to attribute a cause to the incidents or place

responsibility for the incidents on the acts or omissions of any person or entity.

Two railroad employees, while each riding the side of rolling equipment to protect a shoving movement, were fatally injured (in separate incidents) when the equipment they were riding struck other equipment that was left out to foul. A common factor in both accidents was that the equipment was left in a location where it fouled an adjacent track by the very employees who were involved in the incidents.

The first incident occurred on September 2, 2010, in Bridgeport, New Jersey, when a conventional two-person switching crew was shoving rolling equipment into an industrial facility. The locomotive engineer was in the locomotive control compartment and the conductor was positioned on the leading end of a tank car directing the shoving move. The conductor had one foot on the end platform and the other on the side ladder tread as he began to pass a tank car that he had spotted at that location the previous day. Unfortunately, the car had been left in the foul of the adjacent track and the cars struck each other; the conductor sustained fatal injuries.

The second incident occurred on February 8, 2011, in Kankakee, Illinois. A conventional switching crew that consisted of a conductor, engineer, and a conductor-in-training was switching cars on a switching lead track and using various other yard tracks. The crew had left a car on one of the yard tracks in a location where it was in the foul of an adjacent track. Shortly thereafter, the conductor and conductor-in-training boarded opposite sides of the leading end of a gondola car and began a shoving movement. Subsequently, the side of the gondola on which the conductor was riding struck the car that was previously left in the foul of the adjacent track. The conductor was crushed between the two cars and sustained fatal injuries.

Although the preponderance of incidents involving equipment that is left in the foul of an adjacent track fortunately only result in railroad property damage, the potential for injury or death in such instances is always present. By issuing this safety advisory, FRA is reminding all stakeholders of the importance of situational awareness and compliance with all applicable operating and safety rules, particularly those related to leaving rolling equipment in a location that is clear of adjacent tracks.

FRA Action: Despite the significant reduction in train accidents caused by equipment being left in the foul of an adjacent track, a review of FRA's inspection data relative to 49 CFR 218.101 indicates a disturbing trend. From calendar year (CY) 2009 to CY 2010, violations of 49 CFR 218.101 recommended for prosecution by FRA inspectors increased 124 percent. Based on the results of inspection data for the first 2 months of 2011, if trends continue, violations recommended for prosecution in 2011 versus 2010 would increase by an additional 81 percent. Whether the increase in violations is due to greater vigilance by FRA or is due to an actual increase in the number of instances where equipment is being left in such locations, FRA intends to ensure that railroads take necessary steps to prevent and reduce the potential trend indicated by the statistics noted above.

Over the next several months, FRA intends to increase its inspection activity to focus on compliance with railroad operating rules that address all of the requirements contained in Subpart F. Particular emphasis will be placed on the requirements contained in 49 CFR 218.101. FRA will also focus its inspection efforts on railroad operational testing activity, particularly as it relates to Subpart F. FRA strongly encourages railroad industry members to reemphasize the importance of leaving equipment in the clear as frequently as possible, and to take such other actions as may help ensure safety on the Nation's railroads.

Recommended Railroad Action: In light of the recent accidents discussed above, and in an effort to maintain the safety of railroad employees on the Nation's rail system, FRA recommends that railroads:

(1) Review with employees the circumstances of the two most recent fatal incidents;

(2) Reinstruct supervisors and employees on the operating and safety rules applicable to leaving rolling equipment in a location that is clear of adjacent tracks. Particular emphasis should be placed on the procedures that enable employees to identify clearance points and the means to identify locations where clearance points will not permit a person to safely ride on the side of a car;

(3) Increase operational testing on those operating and safety rules that pertain to leaving rolling equipment in a location that is clear of adjacent tracks; and

(4) Review current job briefing procedures among coworkers and determine if the procedures are sufficient to encourage more effective communication regarding switching activities, specifically as the procedures relate to the positioning of rolling equipment so that the equipment is in a location that is clear of adjacent tracks.

FRA encourages railroad industry members to take action that is consistent with the preceding recommendations and to take other actions to help ensure the safety of the Nation's railroad employees. FRA may modify this Safety Advisory 2011–01, issue additional safety advisories, or take other appropriate action necessary to ensure the highest level of safety on the Nation's railroads, including pursing other corrective measures under its rail safety authority.

Issued in Washington, DC, on April 1, 2011.

Jo Strang,

Associate Administrator for Railroad Safety/ Chief Safety Officer.

[FR Doc. 2011–8232 Filed 4–6–11; 8:45 am]

BILLING CODE 4910–06–P

DEPARTMENT OF TRANSPORTATION

Federal Transit Administration

Intent To Prepare an Environmental Impact Statement for the Downtown San Francisco Ferry Terminal Expansion Project in the City and County of San Francisco, CA

AGENCY: Federal Transit Administration (FTA), DOT.

ACTION: Notice of intent to prepare an environmental impact statement (EIS).

SUMMARY: The FTA, as the lead Federal agency, and the San Francisco Bay Area Water Emergency Transportation Authority (WETA) are planning to prepare an EIS for the proposed expansion and improvements to the Downtown San Francisco Ferry Terminal at the Port of San Francisco Ferry Building. The proposed project would serve commuters, visitors, and recreational users desiring an alternative way to cross San Francisco Bay, and reach nearby employment, entertainment, and recreational destinations in San Francisco. The project expands the number of ferry gates and improves ferry patron circulation, boarding, and wayfinding in and around the Ferry Building. In addition, the project enhances emergency response capabilities to evacuate people from San Francisco and/or mobilize first responders to San Francisco via ferries if a catastrophic event occurs. The EIS will be prepared in accordance with Section 102(2)C of the National Environmental Policy Act of 1969 (NEPA) and pursuant to the Council on the Environmental Quality's

regulations (40 Code of Federal Regulations [CFR] parts 1500–08) as well as provisions of the recently enacted Safe, Accountable, Flexible Efficient Transportation Equity Act: A Legacy for Users (SAFETEA–LU). The purpose of this notice is to alert interested parties regarding the intent to prepare an EIS; provide information on the proposed transit project; invite participation in the EIS process, including comments on the scope of the EIS proposed in this notice; and announce when the public scoping meeting will be conducted.

DATES: Written comments on the scope of the EIS should be sent to Mike Gougherty, WETA Project Manager, by May 16, 2011. A public scoping meeting to accept comments on the scope of the EIS will be held on the following date:

• April 26, 2011, from 5:30 p.m. to 7:30 p.m., at Pier 1, Bayside Conference Room, San Francisco, California.

An interagency scoping meeting for agencies with interest in the project will be held on the following date:

• April 26, 2011 from 2 p.m. to 4 p.m. at the Pier 1, Bayside Conference Room, San Francisco, California.

The meeting will be accessible to persons with disabilities. If special translation or signing services or other special accommodations are needed, please contact Mike Gougherty at (415) 364–3189 at least 48 hours before the meeting. A scoping information packet is available on the WETA Web site at *http://www.watertransit.org* or by calling Mike Gougherty at (415) 364–3189. Copies will also be available at the scoping meeting.

ADDRESSES: Comments on the scope of the EIS will be accepted at the public scoping meeting, or written comments should be sent to Mike Gougherty, WETA Project Manager, San Francisco Bay Water Emergency Transportation Authority, Pier 9, Suite 111, The Embarcadero, San Francisco, CA, 94111.

FOR FURTHER INFORMATION CONTACT: Debra Jones, Environmental Protection Specialist, FTA, San Francisco Regional Office at (415) 744–3133.

SUPPLEMENTARY INFORMATION:

Scoping

The FTA and WETA invite all interested individuals and organizations, public agencies, and Native American Tribes to comment on the scope of the EIS, including the project's purpose and need, the alternatives to be studied, the impacts to be evaluated, and the evaluation methods to be used. Comments should address (1) feasible alternatives that may better achieve the project's need and purposes with fewer adverse impacts, and (2) any significant environmental impacts relating to the alternatives.

NEPA "scoping" (Title 40 of the CFR 1501.7) has specific and fairly limited objectives, one of which is to identify the significant issues associated with alternatives that will be examined in detail in the document, while simultaneously limiting consideration and development of issues that are not truly significant. It is in the NEPA scoping process that potentially significant environmental impacts—those that give rise to the need to prepare an environmental impact statement—should be identified; impacts that are deemed not to be significant need not be developed extensively in the context of the impact statement, thereby keeping the statement focused on impacts of consequence consistent with the ultimate objectives of the NEPA implementing regulations—"to make the environmental impact statement process more useful to decision makers and the public; and to reduce paperwork and the accumulation of extraneous background data, in order to emphasize the need to focus on real environmental issues and alternatives… [by requiring] impact statements to be concise, clear, and to the point, and supported by evidence that agencies have made the necessary environmental analyses." Executive Order 11991, of May 24, 1977.

Once the scope of the environmental study, including significant environmental issues to be addressed, is settled, a scoping report will be prepared that: (1) Documents the results of the scoping process; (2) contributes to the transparency of the process; and (3) provides a clear roadmap for concise development of the environmental document.

Purpose and Need for the Project

The purpose of the Downtown San Francisco Ferry Terminal Expansion Project is to support and expand ferry service on San Francisco Bay, as established by WETA in its Implementation and Operations Plan (IOP), and in accordance with city and regional policies to encourage transit use. Furthermore, the project will address deficiencies in the transportation network that impede ferry operation and ferry patron access and circulation at the Downtown San Francisco Ferry Terminal. The project objectives include:

• Accommodate WETA's projected increase in ferry ridership and related ferry arrivals and departures from the Downtown San Francisco Ferry Terminal;

• Provide a viable alternative mode of transportation that accommodates projected increases in transbay trips, and helps alleviates congestion over the Bay Bridge and through the Bay Area Rapid Transit (BART) Transbay Tube;

• Address WETA's and the Port of San Francisco's (Port) emergency response needs;

• Establish a circulation plan and improved signage that provides clear pedestrian routes for ferry to bus and ferry to rail transfers, as well as safe routes for bikes, emergency vehicles, and delivery trucks to enter, park and exit the area;

• Provide necessary landside improvements, such as designated weather-protected areas for waiting and queuing, ticket machines and fare collection equipment, improved lighting, and improved boarding and arrival/departure information to serve ferry patrons and to enhance the Ferry Building as the central point of embarkation for ferries on San Francisco Bay; and

• Enhance the area's public access and open space with design features that create attractive, safe daytime and nighttime public spaces for both ferry patrons and other users of the Ferry Building area;

• Recognize the Port's land use planning and development proposals in and around the Ferry Building so as not to preclude, conflict with, or inhibit proposed development plans in the project vicinity.

WETA recognizes and supports the Port of San Francisco's land use planning and development proposals in and around the Ferry Building, including the historic renovation of the Agricultural Building and enhancements to the Ferry Plaza area. These Port initiatives are being planned and funded independent of the WETA project and, as a result, are not included as project elements. WETA will stage construction and manage and operate ferry services so they do not preclude, conflict with, or inhibit the Port's proposed development plans in the project vicinity.

Project Location and Environmental Setting

The project is located in the northeastern section of San Francisco, California, at the San Francisco Ferry Building, situated at the foot of Market Street. The study area encompasses Port of San Francisco property between Pier 1 on the north and Pier 14 on the south, and includes the Ferry Building, ferry gates, and the Ferry Plaza.

Possible Alternatives

A study of potential ferry terminal improvements at the San Francisco Ferry Building was completed by the Port in 1994. The planning process, summarized in the Downtown San Francisco Ferry Terminal Project, Concept Design—Stage 1 Final Report, addressed deficiencies in the circulation of pedestrians across the Embarcadero and through the Ferry Building; constraints imposed by previous design modifications of the Ferry Building that obscured wayfinding to the ferry gates; limited opportunities for public gathering and access to the Bay; and restricted commercial development within the building. A variety of design, configuration, and circulation improvements were considered. The Port selected those improvements that best met its long-term public service and facility objectives, and completed those projects, including construction of Gates B and E and the south basin breakwater at Pier 14, as Phase 1 of the Downtown San Francisco Ferry Terminal Project in 2003. This project builds on the previous improvements, described under the Action Alternative below. In addition to the Action Alternative, WETA considers the effects of doing nothing, identified as the No Action Alternative. Both the Action and No Action Alternatives are being considered in the EIS, as described below.

No Action Alternative. Six ferry routes currently serve the Downtown San Francisco Ferry Terminal. Today, the Downtown San Francisco Ferry Terminal has approximately 130 ferry arrivals and departures daily, serving more than 10,000 daily ferry patrons.

The existing Ferry Terminal gate configuration serves current ferry operations and provides the circulation areas to access these gates. The No Action Alternative maintains the existing ferry services, gate configuration, and circulation areas, including the function, uses, and design of the Ferry Building, which also serves as an important public space in San Francisco. No new gates or additional boarding capacity to accommodate new ferry services would occur as part of the No Action Alternative. Similarly, circulation and boarding improvements to respond to emergency planning requirements would not be implemented.

The No Action Alternative retains vehicle circulation and drop-off areas near the Ferry Building as well as the current circulation patterns for ferry patrons to access the ferry boarding areas. Pedestrian pathways to boarding locations for San Francisco Municipal Railway (Muni) bus and streetcar lines and the Amtrak bus would remain unchanged. Programmed Transbay bus and rail transit improvements identified in the Regional Transportation Plan would be implemented as part of the No Action Alternative. This alternative serves as the baseline against which the environmental effects of the other alternatives are measured.

Action Alternative. The Action Alternative incorporates modifications and improvements to the Ferry Terminal gates and ferry boarding areas to accommodate future WETA service and increased ferry patronage. Current estimates for 2025 projected daily ridership at the Ferry Terminal are approximately 35,000 passengers. The ridership projections account for existing service, plus new ferry services from downtown San Francisco to Berkeley, Treasure Island, Hercules, Richmond, Redwood City, Martinez, and Antioch to be initiated between 2014 and 2030. Service frequencies during the day and evenings would reflect the travel demand for commute and non-commute periods. Existing services operated by others (*i.e.,* Sausalito, Larkspur, and Tiburon), and existing services operated by WETA (*i.e.,* Vallejo, Alameda/Oakland, and Alameda Harbor Bay) would remain, but the access and boarding environments for these services would be improved by the project.

In addition, landside improvements to allow staging and circulation for possible emergency evacuation at the Ferry Building are included in the Action Alternative. The modifications and improvements are the responsibility of WETA in cooperation with the Port of San Francisco, with funding coming from Regional Measure 2, State Proposition 1B, and FTA.

The WETA-sponsored improvements represent sequential construction phases (Phase 2 and Phase 3). As noted previously, the Phase 2 and Phase 3 improvements build on those elements already completed by the Port in 2003 during Phase 1. Phase 2, which is expected to be completed by 2017, will include:

- Demolition and removal of Pier ½ and Pier 2;
- Construction of Gate A in the north basin, and Gates F and G in the south basin;
- Installation of boarding area amenities such as weather-protected areas for queuing, ticket machines and fare collection equipment, improved lighting, and ferry boarding and arrival/departure information signs;
- Widening of ferry access pathways along existing pedestrian promenades, and separation of ferry patron queuing from other pedestrian and vehicular movements where possible;
- Improved wayfinding signage in the vicinity of the Ferry Building, which will indicate ferry boarding areas and transit connections; and
- Filling in the lagoon to prepare for and accommodate staging and circulation of evacuees following a catastrophic event.

As new ferry gates are constructed, existing ferry services would relocate to new gates. Pier demolition and construction activities would be staged and sequenced to allow continuity of existing ferry services during construction. Demolition of Pier ½ would precede construction of Gate A. Similarly, demolition of Pier 2 would precede construction of Gate F. Gate G, which is designated for ferry services not expected to operate until 2020 or later, would serve as a vessel layover location, temporary storage area, and emergency boarding location in the interim. WETA's capital improvement plan synchronizes the purchase or leasing of vessels to meet future service and emergency response requirements.

Phase 3 is contingent on the implementation of the Treasure Island Redevelopment Plan. At full build-out, expected to occur sometime between 2020 and 2030, new commercial, recreational, and residential facilities on Treasure Island would require additional ferry capacity to serve substantial numbers of visitors and residents. The additional capacity would be provided by larger, bow-loading vessels purchased by the Treasure Island developer, and operated by WETA. The bow-loading vessels would necessitate the redesign of Gate E to accommodate the larger ferries.

Possible Effects

The purpose of this EIS process is to study, in a public setting, the potentially significant effects of the proposed project on the quality of the human environment. Primary areas of investigation for this project include, but are not limited to: land use, development potential, displacements, historic resources, visual and aesthetic qualities, air quality, noise and vibration, dredging and bay fill requirements, hazardous materials resulting from demolition and construction activities, traffic circulation and transportation linkages, pedestrian circulation, safety, security, and emergency response, bay habitat, and cumulative impacts. The environmental analysis may reveal that

the proposed project will not affect, or affect substantially, many of those areas. However, if any adverse impacts are identified, measures to avoid, minimize, or mitigate those adverse impacts will be proposed.

FTA Procedures

Regulations implementing NEPA, as well as provisions of the Safe, Accountable, Flexible, Efficient Transportation Equity Act: A Legacy for Users (SAFETEA–LU), call for public involvement in the EIS process. Section 6002 of SAFETEA–LU (23 U.S.C. 139) requires that FTA and WETA do the following: (1) Extend an invitation to other Federal and non-Federal agencies and Native American Tribes that may have an interest in the proposed project to become "participating agencies;" (2) provide an opportunity for involvement by participating agencies and the public to help define the purpose and need for a proposed project, as well as the range of alternatives for consideration in the EIS; and (3) establish a plan for coordinating public and agency participation in, and comment on, the environmental review process. An invitation to become a participating or cooperating agency, with scoping materials appended, will be extended to other Federal and non-Federal agencies and Native American Tribes that may have an interest in the proposed project. It is possible that FTA and WETA will not be able to identify all Federal and non-Federal agencies and Native American Tribes that may have such an interest. Any Federal or non-Federal agency or Native American Tribe interested in the proposed project that does not receive an invitation to become a participating agency should notify at the earliest opportunity the Project Manager identified above under **ADDRESSES**.

A comprehensive public involvement program for public and interagency involvement will be developed for the project and posted on WETA's Web site: *http://www.watertransit.org.* The public involvement program includes a full range of activities including maintaining the project Web page on the WETA Web site and outreach to local officials, community and civic groups, and the public.

Paperwork Reduction

The Paperwork Reduction Act seeks, in part, to minimize the cost to the taxpayer of the creation, collection, maintenance, use, dissemination, and disposition of information. Consistent with this goal and with principles of economy and efficiency in government, it is FTA policy to limit insofar as possible distribution of complete printed sets of environmental documents. Accordingly, unless a specific request for a complete printed set of environmental documents is received (preferably in advance of printing), FTA and its grantees will distribute only the executive summary of the environmental document together with a compact disc of the complete environmental document. A complete printed set of the environmental document will be available for review at the grantee's offices and elsewhere; an electronic copy of the complete environmental document will also be available on the grantee's Web site.

Other

The EIS will be prepared in accordance with NEPA and its implementing regulations issued by the Council on Environmental Quality (40 CFR parts 1500–1508), and with the FTA/Federal Highway Administration regulations "Environmental Impact and Related Procedures" (23 CFR part 771).

Issued on: March 31, 2011.

Leslie T. Rogers,

Regional Administrator, FTA, Region 9.

[FR Doc. 2011–8227 Filed 4–6–11; 8:45 am]

BILLING CODE 4910–57–P

DEPARTMENT OF TRANSPORTATION

Federal Transit Administration

Notice of Limitation on Claims Against Proposed Public Transportation Projects

AGENCY: Federal Transit Administration (FTA), DOT.

ACTION: Notice of limitation on claims.

SUMMARY: This notice announces final environmental actions taken by the Federal Transit Administration (FTA) for the following projects: (1) Hatcher Pass Recreational Area Access, Trails, and Transit Facilities Project, Matanuska-Susitna Borough, Hatcher Pass, AK; (2) Bus Rapid Transit Project, Roaring Fork Transportation Authority, Pitkin, Eagle, and Garfield Counties, CO; (3) Second Avenue Subway Project, Metropolitan Transportation Authority, New York, NY; and (4) Sugar House Streetcar Project, Utah Transit Authority, South Salt Lake and Salt Lake City, Salt Lake County, UT. The purpose of this notice is to announce publicly the environmental decisions by FTA on the subject projects and to activate the limitation on any claims that may challenge these final environmental actions.

DATES: By this notice, FTA is advising the public of final agency actions subject to Section 139(l) of Title 23, United States Code (U.S.C.). A claim seeking judicial review of the FTA actions announced herein for the listed public transportation projects will be barred unless the claim is filed on or before September 30, 2011.

FOR FURTHER INFORMATION CONTACT: Katie Grasty, Environmental Protection Specialist, Office of Planning and Environment, 202–366–9139, or Christopher Van Wyk, Attorney-Advisor, Office of Chief Counsel, 202–366–1733. FTA is located at 1200 New Jersey Avenue, SE., Washington, DC 20590. Office hours are from 9 a.m. to 5:30 p.m., EST, Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION: Notice is hereby given that FTA has taken final agency actions by issuing certain approvals for the public transportation projects listed below. The actions on these projects, as well as the laws under which such actions were taken, are described in the documentation issued in connection with each project to comply with the National Environmental Policy Act (NEPA) and in other documents in the FTA administrative record for the project. Interested parties may contact either the project sponsor or the relevant FTA Regional Office for more information on these projects. Contact information for FTA's Regional Offices may be found at *http://www.fta.dot.gov.*

This notice applies to all FTA decisions on the listed projects as of the issuance date of this notice and all laws under which such actions were taken, including, but not limited to, NEPA [42 U.S.C. 4321–4375], Section 4(f) of the Department of Transportation Act of 1966 [49 U.S.C. 303], Section 106 of the National Historic Preservation Act [16 U.S.C. 470f], and the Clean Air Act [42 U.S.C. 7401–7671q]. This notice does not, however, alter or extend the limitation period of 180 days for challenges of project decisions subject to previous notices published in the **Federal Register**. For example, this notice does not extend the limitation on claims announced for earlier decisions on the Second Avenue Subway project.

The projects and actions that are the subject of this notice are:

1. *Project name and location:* Hatcher Pass Recreational Area Access, Trails, and Transit Facilities Project, Hatcher Pass, AK. *Project sponsor:* Matanuska-Susitna Borough. *Project description:* The project consists of the development of transportation access and transit-related infrastructure to improve access

to the Government Peak Subunit of Hatcher Pass. The proposed actions include the construction of access roads, parking lots, and enclosed transit facilities. *Final agency actions:* Section 106 finding of no historic properties affected; Section 4(f) determination; and a Record of Decision dated January 2011. *Supporting documentation:* Final Environmental Impact Statement dated November 2010.

2. *Project name and location:* Bus Rapid Transit Project, Pitkin, Eagle, and Garfield Counties, CO. *Project sponsor:* Roaring Fork Transportation Authority. *Project description:* The project consists of a Bus Rapid Transit project with service along approximately 40 miles of Colorado State Highway 82 from Glenwood Springs to Aspen, CO. The project includes 18 buses, nine stations, and five park and ride lots. *Final agency actions:* Section 106 finding of no historic properties affected; no use of Section 4(f) properties; project-level air quality conformity; and a Finding of No Significant Impact (FONSI) dated November 2010. *Supporting documentation:* Environmental Assessment dated August 2010.

3. *Project name and location:* Second Avenue Subway, New York, NY. *Project sponsor:* Metropolitan Transportation Authority. *Project description:* The Second Avenue Subway project is the phased construction of a new 8.5-mile subway line under Second Avenue in Manhattan from 125th Street to Hanover Square in Lower Manhattan. It includes sixteen new stations which will be accessible by persons with disabilities. FTA has agreed to partially fund the first phase of the project which will run between 105th Street and 62nd Street and will connect to the existing F line at 63rd Street, so that Phase 1 can be operated before the other phases are built. Various changes to Phase 1 have been evaluated in a number of technical memorandums. *Final agency actions:* FTA determination that neither a supplemental environmental impact statement nor a supplemental environmental assessment is necessary. *Supporting documentation:* Technical Memorandum No. 8 assessing design changes for the 86th Street Station Ancillary Facility #2 dated January 2011.

4. *Project name and location:* Sugar House Streetcar Project, South Salt Lake and Salt Lake City, Salt Lake County, UT. *Project sponsor:* Utah Transit Authority. *Project description:* The project is a 2-mile streetcar line on an existing railroad right-of-way between 1700 South and Interstate 80 in Salt Lake County, UT. The streetcar will connect a commercial center to the existing TRAX light rail system. *Final agency actions:* Section 4(f) determination; Section 106 finding of no adverse effect; project-level air quality conformity; and a Finding of No Significant Impact (FONSI) signed February 2011. *Supporting documentation:* Environmental Assessment dated November 2010.

Issued on: April 1, 2011.

Elizabeth S. Riklin,

Deputy Associate Administrator for Planning and Environment, Washington, DC.

[FR Doc. 2011–8225 Filed 4–6–11; 8:45 am]

BILLING CODE 4910–57–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket Number MARAD 2010 0115]

Finding of No Significant Impact (FONSI) for the Beaumont Layberth Facility

AGENCY: U.S. Department of Transportation, Maritime Administration.

ACTION: Notice of Availability of Finding of No Significant Impact.

SUMMARY: Notice is hereby given that the Maritime Administration, of the U.S. Department Transportation (US DOT) has made available to interested parties the Finding of No Significant Impact (FONSI) for the Beaumont Layberth Facility. An environmental assessment (EA) and FONSI have been prepared pursuant to the National Environmental Policy Act (NEPA) (42 U.S.C. 4321 *et seq.*) in accordance with the Council on Environmental Quality (CEQ) regulations for implementing the procedural provisions of NEPA (40 CFR 1500–1508).

The purpose of the EA is to evaluate the potential environmental impacts from the construction of a Layberth facility that can accommodate eight Large Medium Speed Roll-on/Roll-off sized vessels at the Beaumont National Defense Reserve Fleet anchorage. A preliminary cost feasibility assessment determined that building a permanent Layberth facility would be more cost-effective over the long term than using commercial Layberth facilities.

FOR FURTHER INFORMATION CONTACT: Kris Gilson 1200 New Jersey Ave., SE., Washington, DC 20590; phone (202) 366–1939; or e-mail *Kristine.gilson@dot.gov.* Persons who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 to contact the above individuals during business hours. The FIRS is available twenty-four hours a day, seven days a week, to leave a message or question with the above individuals. You will receive a reply during normal business hours. A copy of the Final EA and Finding of No Significant Impact can be obtained or viewed online at *http://www.regulations.gov.* The files are in a portable document format (pdf); in order to review or print the document, users need to obtain a free copy of Acrobat Reader. The Acrobat Reader can be obtained from *http://www.adobe.com/prodindes/acrobat/readstep.html.*

By Order of the Maritime Administrator. Dated: March 31, 2011.

Christine Gurland,

Secretary, Maritime Administration.

[FR Doc. 2011–8080 Filed 4–6–11; 8:45 am]

BILLING CODE P

DEPARTMENT OF TRANSPORTATION

Surface Transportation Board

[Docket No. AB 290 (Sub-No. 323X)]

The Alabama Great Southern Railroad Company—Abandonment Exemption—in Saint Bernard Parish, LA

The Alabama Great Southern Railroad Company (AGS),[1] filed a verified notice of exemption under 49 CFR part 1152 subpart F–*Exempt Abandonments* to abandon a 3.50-mile rail line between mileposts 1.00–PT and 4.50–PT, near Toca, in Saint Bernard Parish, La.[2] The line traverses United States Postal Service Zip Code 70085.

AGS has certified that: (1) No local traffic has moved over the line for at least 2 years; (2) no overhead traffic has moved over the line for at least 2 years, and that overhead traffic, if there were any, could be rerouted over other lines; (3) no formal complaint filed by a user of rail service on the line (or by a state or local government entity acting on behalf of such user) regarding cessation of service over the line either is pending with the Surface Transportation Board (Board) or with any U.S. District Court or has been decided in favor of complainant within the 2-year period; and (4) the requirements at 49 CFR 1105.7(c) (environmental report), 49 CFR 1105.11 (transmittal letter), 49 CFR

[1] AGS is a wholly-owned subsidiary of Norfolk Southern Railway Company.

[2] Service on the line (plus an additional segment between mileposts 0.00–PT and 1.00–PT) was discontinued in 2006 pursuant to Board authorization in *Alabama Great Southern Railroad—Discontinuance of Service Exemption—in Saint Bernard Parish, La.,* Docket No. AB 290 (Sub-No. 273X) (served July 18, 2006).

1105.12 (newspaper publication), and 49 CFR 1152.50(d)(1) (notice to governmental agencies) have been met.

As a condition to this exemption, any employee adversely affected by the abandonment shall be protected under *Oregon Short Line Railroad—Abandonment Portion Goshen Branch Between Firth & Ammon, in Bingham & Bonneville Counties, Idaho,* 360 I.C.C. 91 (1979). To address whether this condition adequately protects affected employees, a petition for partial revocation under 49 U.S.C. 10502(d) must be filed.

Provided no formal expression of intent to file an offer of financial assistance (OFA) has been received, this exemption will be effective on May 7, 2011, unless stayed pending reconsideration. Petitions to stay that do not involve environmental issues,[3] formal expressions of intent to file an OFA under 49 CFR 1152.27(c)(2),[4] and trail use/rail banking requests under 49 CFR 1152.29 must be filed by April 18, 2011. Petitions to reopen or requests for public use conditions under 49 CFR 1152.28 must be filed by April 27, 2011, with the Surface Transportation Board, 395 E Street, SW., Washington, DC 20423–0001.

A copy of any petition filed with the Board should be sent to AGS's representative: Greg E. Summy, Three Commercial Place, Norfolk, VA 23510.

If the verified notice contains false or misleading information, the exemption is void *ab initio.*

AGS has filed a combined environmental and historic report which addresses the effects, if any, of the abandonment on the environment and historic resources. OEA will issue an environmental assessment (EA) by April 12, 2011. Interested persons may obtain a copy of the EA by writing to OEA (Room 1100, Surface Transportation Board, Washington, DC 20423–0001) or by calling OEA, at (202) 245–0305. Assistance for the hearing impaired is available through the Federal Information Relay Service (FIRS) at 1 800–877–8339. Comments on environmental and historic preservation matters must be filed within 15 days after the EA becomes available to the public.

Environmental, historic preservation, public use, or trail use/rail banking conditions will be imposed, where appropriate, in a subsequent decision.

Pursuant to the provisions of 49 CFR 1152.29(e)(2), AGS shall file a notice of consummation with the Board to signify that it has exercised the authority granted and fully abandoned the line. If consummation has not been effected by AGS's filing of a notice of consummation by April 7, 2012, and there are no legal or regulatory barriers to consummation, the authority to abandon will automatically expire.

Board decisions and notices are available on our Web site at *http://www.stb.dot.gov.*

Decided: April 1, 2011.

By the Board, Rachel D. Campbell, Director, Office of Proceedings.

Jeffrey Herzig,

Clearance Clerk.

[FR Doc. 2011–8170 Filed 4–6–11; 8:45 am]

BILLING CODE 4915–01–P

[3] The Board will grant a stay if an informed decision on environmental issues (whether raised by a party or by the Board's Office of Environmental Analysis (OEA) in its independent investigation) cannot be made before the exemption's effective date. *See Exemption of Out-of-Serv. Rail Lines,* 5 I.C.C.2d 377 (1989). Any request for a stay should be filed as soon as possible so that the Board may take appropriate action before the exemption's effective date.

[4] Each OFA must be accompanied by the filing fee, which is currently set at $1,500. *See* 49 CFR 1002.2(f)(25).

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Publication of Inflation Adjustment Factor, Nonconventional Source Fuel Credit, and Reference Price for Calendar Year 2010

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice.

SUMMARY: Publication of the inflation adjustment factor, nonconventional source fuel credit, and reference price for calendar year 2010 as required by section 45K of the Internal Revenue Code (26 U.S.C. 45K). The inflation adjustment factor and reference price are used to determine the credit allowable under section 45K for coke or coke gas (other than from petroleum based products) for calendar year 2010.

DATES: The 2010 inflation adjustment factor, nonconventional source fuel credit, and reference price apply to coke or coke gas (other than from petroleum based products) sold during calendar year 2010.

Inflation Adjustment Factor: The inflation adjustment factor for coke or coke gas for calendar year 2010 is 1.1435.

Credit: The nonconventional source fuel credit for coke or coke gas for calendar year 2010 is $3.43 per barrel-of-oil equivalent of qualified fuels.

Reference Price: The reference price for calendar year 2010 is $74.71. The phase-out of the credit does not apply to coke or coke gas.

FOR FURTHER INFORMATION CONTACT:

For questions about how the inflation adjustment factor is calculated—

Wu-Lang Lee, RAS:R:TSBR, Internal Revenue Service, 1111 Constitution Avenue, NW., Washington, DC 20224, Telephone Number (202) 874–0531 (not a toll-free number).

For all other questions about the credit or the reference price—

Martha McRee, CC:PSI:6, Internal Revenue Service, 1111 Constitution Avenue, NW., Washington, DC 20224, Telephone Number (202) 622–3110 (not a toll-free number).

Dated: March 31, 2011.

Curt G. Wilson,

Associate Chief Counsel, Passthroughs and Special Industries.

[FR Doc. 2011–8230 Filed 4–6–11; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF VETERANS AFFAIRS

Privacy Act of 1974; Deletion of System of Records

AGENCY: Department of Veterans Affairs.

ACTION: Notice.

Notice is hereby given that the Department of Veterans Affairs (VA) is deleting a system of records entitled "PROS/KEYS User Permissions Database-VA" (67VA30), which was first published FR Vol. 52, No 155 dated August 12, 1987. The system of records known as "PROS/KEYS User Permissions Database-VA" is obsolete. The information was initially developed as a means to grant individuals access permissions to the resources of the Austin Data Processing Center. The requirement for VA to maintain this system of records no longer exists because the PROS/KEYS Database was replaced by 87VA045, "Automated Customer Registration System (ACRS)-VA", which was published in FR Vol. 60, No 239 dated December 13, 1995. 87VA045 was subsequently amended, renamed, renumbered and republished in its entirety as 87VA0050P, "Customer User Provisioning System (CUPS)-VA", in FR Vol. 74, No 156 dated August 14, 2009.

A "Report of Intention to Publish a Federal Register Notice of Deletion of a System of Records" and an advance copy of the system notice have been provided to the appropriate congressional committees and to the Director, Office of Management and Budget (OMB), as required by 5 U.S.C.

552a(r) and guidelines issued by OMB (65 CFR 77677), dated December 12, 2000. This system deletion is effective April 7, 2011.

Approved: March 18, 2011.

John R. Gingrich,

Chief of Staff, Department of Veterans Affairs.

[FR Doc. 2011–8280 Filed 4–6–11; 8:45 am]

BILLING CODE P

FEDERAL REGISTER

Vol. 76 Thursday,
No. 67 April 7, 2011

Part II

Department of Health and Human Services

Centers for Medicare & Medicaid Services
Office of the Inspector General

42 CFR Part 425
Medicare Program; Medicare Shared Savings Program: Accountable Care Organizations and Medicare Program: Waiver Designs in Connection With the Medicare Shared Savings Program and the Innovation Center; Proposed Rule and Notice

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 425

[CMS–1345–P]

RIN 0938–AQ22

Medicare Program; Medicare Shared Savings Program: Accountable Care Organizations

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

ACTION: Proposed rule.

SUMMARY: This proposed rule would implement section 3022 of the Affordable Care Act which contains provisions relating to Medicare payments to providers of services and suppliers participating in Accountable Care Organizations (ACOs). Under these provisions, providers of services and suppliers can continue to receive traditional Medicare fee-for-service payments under Parts A and B, and be eligible for additional payments based on meeting specified quality and savings requirements.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on June 6, 2011.

ADDRESSES: In commenting, please refer to file code CMS–1345–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–1345–P, P.O. Box 8013, Baltimore, MD 21244–8013.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address only: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1345–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: Dr. Terri Postma (410)786–8084.

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.

Table of Contents

To assist readers in referencing sections contained in this preamble, we are providing a table of contents.

Acronyms

ACO Accountable Care Organizations
AHRQ Agency for Healthcare Research and Quality
BCBSMA Blue Cross Blue Shield of Massachusetts
BIPA Benefits Improvement and Protection Act
BQI Better Quality Information
CAD Coronary Artery Disease
CAHPS Consumer Assessment of Health Providers and Systems
CAHs Critical Access Hospitals
CAM Complementary and Alternative Services
CBIC Competitive Bidding Implementation Contractor
CCNC Community Care of North Carolina
CHCs Community Health Centers
CHIP Children's Health Insurance Program
CMMI Center for Medicare and Medicaid Innovation
CMP Civil Monetary Penalties
CMS Centers for Medicare and Medicaid Services
CNM Certified Nurse Midwife
CMS–HCC CMS Hierarchal Condition Category
COPD Chronic Obstructive Pulmonary Disease
CP Certified Psychologist
CSW Clinical Social Worker
CVE Chartered Value Exchange
CWF Common Working File
DHHS Department of Health and Human Services
DM Diabetes Mellitus
DOJ Department of Justice
DRA Deficit Reduction Act of 2005(Pub. L. 109–171)
DSH Disproportionate Share Hospital
DUA Data use Agreement
E&M Evaluation and Management
EDB Enrollment Database
EHR Electronic Health Record

ESRD End Stage Renal Disease
eRx Electronic Prescribing Incentive Program
FFS Fee For Service
FQHCs Federally Qualified Health Centers
FTC Federal Trade Commission
GAO Government Accountability Office
GPCI Geographic Practice Cost Index
GPRO Group Practice Reporting Option
HAC Hospital Acquired Conditions
HCAHPS Health Care Providers Systems and Surveys
HCC Hierarchal Condition Category
HCO Health Care Organizations
HCPCS Health Care Procedural Coding System
HHA Home Health Agencies
HICN Health Insurance Claim Number
HIPAA Heath Insurance Portability and Accountability Act of 1996
HIE Health Information Exchange
HIT Health Information Technology
HITECH Health Information Technology for Economic and Clinical Health
HMO Health Maintenance Organization
HRSA Health Resources Services Administration
HVBP Hospital Value Based Purchasing
IHIE Indiana Health Information Exchange
IME Indirect Medical Education
INPC Indiana Network for Patient Care
IOM Institute of Medicine
IPPS Inpatient Prospective Payment System
IQR Inpatient Quality Reporting
IRS Internal Revenue Services
LTCHs Long-Term Acute Care Hospitals
MA Medicare Advantage
MAeHC Massachusetts eHealth Collaborative
MDCs Major Diagnostic Categories
MedPAC Medicare Payment Advisory Commission
MHCQ Medicare Health Care Quality
MMA Medicare Prescription Drug, Improvement, and Modernization Act
MPFS Medicare Physician Fee Schedule
MS–DRGs Medicare Severity-Diagnosis Related Groups
MSP Minimum Savings Percentage
MSR Minimum Savings Rate
NC–CCN North Carolina Community Care Networks
NCH National Claims History
NCQA National Committee for Quality Assurance
NP Nurse Practitioner
NPI National Provider Identifier
NQF National Quality Forum
NYCLIX The New York Clinical Information Exchange
OIG Office of Inspector General
OMB Office of Management and Budget
PA Physician Assistant
PACE Program of All Inclusive Care for the Elderly
PACFs Post-Acute Care Facilities
PCMH Patient Centered Medical Home
PFS Physician Fee Schedule
PGP Physician Group Practice
PHI Protected health information
POS Point of Service
PPO Preferred provider organization
PPS Prospective Payment System
PQRI Physician Quality Reporting Initiative
PQRS Physician Quality Reporting System
PRA Paperwork Reduction Act
PSA Primary Service Areas
RFI Request for Information
RHCs Rural Health Centers
RHQDAPU Reporting Hospital Quality Data for Annual Payment Update
RIA Regulatory Impact Analysis
SNFs Skilled Nursing Facilities
SOR Privacy Act Systems of Record
SSA Social Security Administration
SSN Social Security Number
TIN Tax Identification Number

I. Background

A. Introduction and Overview of Value-Based Purchasing

On March 23, 2010, the Patient Protection and Affordable Care Act (Pub. L. 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. These public laws are collectively known as the Affordable Care Act. The Affordable Care Act includes a number of provisions designed to improve the quality of Medicare services, support innovation and the establishment of new payment models in the program, better align Medicare payments with provider costs, strengthen program integrity within Medicare, and put Medicare on a firmer financial footing.

With respect to quality improvement, the Affordable Care Act includes provisions to expand value-based purchasing, broaden quality reporting, improve the level of performance feedback available to suppliers, create incentives to enhance quality, improve beneficiary outcomes, and increase the value of care.

Value-based purchasing is a concept that links payment directly to the quality of care provided and is a strategy that can help transform the current payment system by rewarding providers for delivering high quality, efficient clinical care. We have significant experience in developing, refining, and expanding health care quality performance measures through our experience with value-based demonstration efforts, noting some of these efforts later in the document, and various Medicare payment systems. For example, since 2005, we have applied the Hospital Inpatient Quality Reporting (IQR) Program under the hospital inpatient prospective payment system. Hospital IQR provides differential payments to hospitals that meet certain requirements, including publicly reporting their performance on a defined set of inpatient care performance measures. Beginning in 2007, under the physician fee schedule, we have provided for quality measure reporting through the Physician Quality Reporting System, which includes incentive payments for eligible professionals who satisfactorily report data on quality measures for covered professional services furnished to Medicare beneficiaries. In 2009, Congress passed the Health Information and Technology for Economic and Clinical Health (HITECH) Act. As part of the Electronic Health Records (EHR) Incentive Program under HITECH, we have defined measures for the meaningful use of certified electronic health records technology and have developed incentive payment programs for both Medicare and Medicaid providers. We have extended similar efforts to additional payment systems, including the hospital outpatient prospective payment system and various post-acute care systems.

In addition to improving quality, value-based purchasing initiatives seek to reduce growth in health care expenditures. It is widely recognized that the trajectory for the nation's health care spending is unsustainable. Medicare beneficiaries share in the burden of rising costs, as they pay higher premiums, and larger cost-sharing obligations and out-of-pocket expenses. The Affordable Care Act includes a series of reforms expected to significantly slow growth in the Medicare spending rate while simultaneously strengthening the care provided to Medicare beneficiaries. These reforms build upon existing value-based purchasing efforts currently underway within CMS to find ways to better coordinate care and reduce unnecessary services to lower the growth in Medicare spending while improving the quality of care received by beneficiaries.

We view value-based purchasing as an important step to revamping how care and services are paid for, moving increasingly toward rewarding better value, outcomes, and innovations instead of merely volume. In implementing these value-based purchasing initiatives, we seek to meet certain common goals, as follows:

- Improving quality.

++ Value-based payment systems and public reporting should rely on a mix of standards, processes, outcomes, and patient experience measures, including measures of care transitions and changes in patient functional status. Across all programs, we seek to move as quickly as possible to the use of outcome and patient experience measures. To the extent practicable and appropriate, these outcome and patient experience measures should be adjusted

for risk or other appropriate patient, population, or provider characteristics.

++ To the extent possible, and recognizing differences in payment system readiness and statutory authorities, measures should be aligned across Medicare and Medicaid's public reporting and payment systems. We seek to evolve 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 and measures for that provider.

++ The collection of information should minimize the burden on providers to the extent possible. As part of that effort, we will continuously seek to align our measures with the adoption of meaningful use standards for health information technology (HIT), so the collection of performance information is part of care delivery.

++ To the extent practicable, the measures used by the Shared Savings Program should be nationally endorsed by a multistakeholder organization. We should align measures with best practices among other payers and the needs of the end users of the measures.

• Lowering growth in expenditures.

++ Providers should be accountable for the cost of care, and be rewarded for reducing unnecessary expenditures and be responsible for excess expenditures.

++ In reducing excess expenditures, providers should continually improve the quality of care they deliver and must honor their commitment to do no harm to beneficiaries.

++ To the extent possible, and recognizing differences in payers' value-based purchasing initiatives, providers should apply cost reducing and quality improving redesigned care processes to their entire patient population.

As noted previously, the Affordable Care Act includes provisions to expand value-based purchasing, broaden quality reporting, improve the level of performance feedback available to suppliers, create incentives to enhance quality, improve beneficiary outcomes, and increase the value of care. Among these provisions, section 3022 of the Affordable Care Act requires the Secretary to establish the Medicare Shared Savings Program (Shared Savings Program), intended to encourage the development of Accountable Care Organizations (ACOs) in Medicare. The Affordable Care Act intends the Medicare Shared Saving Program to be a program "that promotes accountability for a patient population and coordinates items and services under parts A and B, and encourages investment in infrastructure and redesigned care processes for high quality and efficient service delivery." The Shared Savings Program is a key Medicare delivery system reform initiatives that will be implemented under the Affordable Care Act and is a new approach to the delivery of health care aimed at: (1) Better care for individuals; (2) better health for populations; and (3) lower growth in expenditures. We refer to this approach throughout the document as the three-part aim.

B. Statutory Basis for the Medicare Shared Savings Program

Section 3022 of the Affordable Care Act amended Title XVIII of the Social Security Act (the Act) (42 U.S.C. 1395 *et seq.*) by adding new section 1899 to the Act to establish a Shared Savings Program that promotes accountability for a patient population, coordinates items and services under Parts A and B, and encourages investment in infrastructure and redesigned care processes for high quality and efficient service delivery. Section 1899(a)(1) of the Act requires the Secretary to establish this program no later than January 1, 2012. Section 1899(a)(1)(A) of the Act further provides that, "groups of providers of services and suppliers meeting criteria specified by the Secretary may work together to manage and coordinate care for Medicare fee-for-service beneficiaries through an [ACO]". Section 1899(a)(1)(B) of the Act also provides that ACOs that meet quality performance standards established by the Secretary are eligible to receive payments for "shared savings".

Section 1899(b)(1) of the Act establishes the types of groups of providers of services and suppliers, with established mechanisms for shared governance, that are eligible to participate as ACOs under the program, subject to the succeeding provisions of section 1899 of the Act, as determined appropriate by the Secretary. Specifically, sections 1899(b)(1)(A) through (E) of the Act provide, respectively, that the following groups of providers of services and suppliers are eligible to participate:

• ACO professionals in group practice arrangements.

• Networks of individual practices of ACO professionals.

• Partnerships or joint venture arrangements between hospitals and ACO professionals.

• Hospitals employing ACO professionals.

• Such other groups of providers of services and suppliers as the Secretary determines appropriate.

Section 1899(b)(2) of the Act establishes the requirements that such eligible groups must meet in order to participate in the program. Specifically, sections 1899(b)(2)(A) through (H) of the Act provide, respectively, that eligible groups of providers of services and suppliers must meet the following requirements to participate in the program as ACOs:

• The ACO shall be willing to become accountable for the quality, cost, and overall care of the Medicare fee-for-service (FFS) beneficiaries assigned to it.

• The ACO shall enter into an agreement with the Secretary to participate in the program for not less than a 3-year period.

• The ACO shall have a formal legal structure that would allow the organization to receive and distribute payments for shared savings to participating providers of services and suppliers.

• The ACO shall include primary care ACO professionals that are sufficient for the number of Medicare FFS beneficiaries assigned to the ACO. At a minimum, the ACO shall have at least 5,000 such beneficiaries assigned to it in order to be eligible to participate in the Shared Savings Program.

• The ACO shall provide the Secretary with such information regarding ACO professionals participating in the ACO as the Secretary determines necessary to support the assignment of Medicare fee-for-service beneficiaries to an ACO, the implementation of quality and other reporting requirements, and the determination of payments for shared savings.

• The ACO shall have in place a leadership and management structure that includes clinical and administrative systems.

• The ACO shall define processes to promote evidence-based medicine and patient engagement, report on quality and cost measures, and coordinate care, such as through the use of telehealth, remote patient monitoring, and other such enabling technologies.

• The ACO shall demonstrate to the Secretary that it meets patient-centeredness criteria specified by the Secretary, such as the use of patient and caregiver assessments or the use of individualized care plans.

Section 1899(b)(3) of the Act establishes the quality and other reporting requirements for the Shared Savings Program. For purposes of quality reporting, section 1899(b)(3)(A) of the Act provides that the Secretary shall determine appropriate measures to assess the quality of care furnished by the ACO, such as measures of clinical processes and outcomes, patient and,

where practicable, caregiver experience of care, and utilization (such as rates of hospital admissions for ambulatory care sensitive conditions). Section 1899(b)(3)(B) of the Act requires an ACO to submit data in a form and manner specified by the Secretary on measures the Secretary determines necessary for the ACO to report in order to evaluate the quality of care furnished by the ACO. This provision further states that such data may include care transitions across health care settings, including hospital discharge planning and post-hospital discharge follow-up by ACO professionals, as determined to be appropriate by the Secretary. Section 1899(b)(3)(C) of the Act requires the Secretary to establish quality performance standards to assess the quality of care furnished by ACOs. That section also requires that the Secretary shall seek to improve the quality of care furnished by ACOs over time by specifying higher standards, new measures, or both for purposes of assessing such quality of care. Finally, section 1899(b)(3)(D) of the Act provides that the Secretary may, as the Secretary determines appropriate, incorporate reporting requirements and incentive payments related to the Physician Quality Reporting System under section 1848 of the Act, including such requirements and such payments related to electronic prescribing, electronic health records, and other similar initiatives under section 1848 of the Act, and may use alternative criteria than would otherwise apply under such section for determining whether to make such payments. CMS should not take the incentive payments described in the preceding sentence into consideration when calculating any payments otherwise made under of section 1899(d) the Act.

Section 1899(b)(4) of the Act prohibits duplication in participation in other shared savings programs by participants in the Shared Savings Program. Specifically, a provider of services or supplier that participates in any of the following is not eligible to participate in an ACO under the Shared Savings Program: A model tested or expanded under section 1115A of the Act that involves shared savings under this title, any other program or demonstration project that involves such shared savings, or the Independence at Home Demonstration under section 1866E of the Act.

Section 1899(c) of the Act provides the Secretary with discretion to determine an appropriate method to assign Medicare FFS beneficiaries to an ACO participating in the Shared Savings Program. This discretion is limited, however, by the fact that under the Act, assignment must be based on beneficiaries' utilization of primary care services provided under Medicare by an ACO professional who is a physician as defined in section 1861(r)(1) of the Act.

Section 1899(d) of the Act establishes the principles and requirements for payments and treatment of savings under the Shared Savings Program. Specifically, section 1899(d)(1)(A) of the Act provides that, subject to the requirements concerning monitoring avoidance of at-risk patients, payments shall continue to be made to providers of services and suppliers participating in an ACO under the original Medicare FFS program under Parts A and B in the same manner as they would otherwise be made, except that a participating ACO is eligible to receive payment for shared savings if the following occur:

- The ACO meets quality performance standards established by the Secretary; and
- The ACO meets the requirements for realizing savings.

Section 1899(d)(1)(B) of the Act establishes the savings requirements and the method for establishing and updating the benchmark against which any savings would be determined. Specifically, section 1899(d)(1)(B)(i) of the Act establishes that, in each year of the agreement period, an ACO shall be eligible to receive payment for shared savings only if the estimated average per capita Medicare expenditures under the ACO for Medicare FFS beneficiaries for Parts A and B services, adjusted for beneficiary characteristics, is at least the percent specified by the Secretary below the applicable benchmark. The Secretary shall determine the appropriate percent of shared savings to account for normal variation in Medicare expenditures, based upon the number of Medicare FFS beneficiaries assigned to an ACO. Section 1899(d)(1)(B)(ii) of the Act, in turn, requires the Secretary to estimate a benchmark for each agreement period for each ACO using the most recent available 3 years of per beneficiary expenditures for Parts A and B services for Medicare FFS beneficiaries assigned to the ACO. This benchmark must be adjusted for beneficiary characteristics and such other factors as the Secretary determines appropriate and updated by the projected absolute amount of growth in national per capita expenditures for Parts A and B services under the original Medicare FFS program, as estimated by the Secretary. Furthermore, the benchmark must be reset at the start of each new agreement period.

Section 1899(d)(2) of the Act provides for the actual payments for shared savings under the Shared Savings Program. Specifically, if an ACO meets the quality performance standards established by the Secretary, and meets the savings requirements, a percent (as determined appropriate by the Secretary) of the difference between the estimated average per capita Medicare expenditures in the year, adjusted for beneficiary characteristics, and the benchmark for the ACO may be paid to the ACO as shared savings and the remainder of the difference shall be retained by the Medicare program. The Secretary is required to establish limits on the total amount of shared savings paid to an ACO.

Section 1899(d)(3) of the Act requires the Secretary to monitor ACOs for avoidance of at-risk patients. Specifically, if the Secretary determines that an ACO has taken steps to avoid patients at risk in order to reduce the likelihood of increasing costs to the ACO, the Secretary may impose an appropriate sanction on the ACO, including termination from the program. Section 1899(d)(4) of the Act, in turn, provides that the Secretary may terminate an agreement with an ACO if it does not meet the quality performance standards established by the Secretary. Section 1899(e) of the Act provides that chapter 35 of title 44 of the U.S. Code, which includes such provisions as the Paperwork Reduction Act (PRA), shall not apply to the Shared Savings Program. Section 1899(f) of the Act further provides the Secretary with the authority to waive such requirements of sections 1128A and 1128B of the Act and title XVIII of the Act as may be necessary to carry out the Shared Savings Program. Section 1899(g) of the Act establishes limitations on judicial and administrative review of the Shared Savings Program. This section provides that there shall be no administrative or judicial review under section 1869 of the Act, section 1878 of the Act, or otherwise of the following:

- The specification of criteria under 1899(a)(1)(B) of the Act.
- The assessment of the quality of care furnished by an ACO and the establishment of performance standards under 1899(b)(3) of the Act.
- The assignment of Medicare FFS beneficiaries to an ACO under 1899(c) of the Act.
- The determination of whether an ACO is eligible for shared savings under 1899(d)(2) of the Act and the amount of such shared savings, including the determination of the estimated average per capita Medicare expenditures under the ACO for Medicare FFS beneficiaries

assigned to the ACO and the average benchmark for the ACO under 1899(d)(1)(B) of the Act.

• The percent of shared savings specified by the Secretary under 1899(d)(2) of the Act and any limit on the total amount of shared savings established by the Secretary under such subsection.

• The termination of an ACO under 1899(d)(4) of the Act for failure to meet the quality performance standards.

Section 1899(h) of the Act defines some basic terminology that applies to the Shared Savings Program. Specifically, section 1899(h)(1) of the Act defines the term "ACO professional" as a physician (as defined in section 1861(r)(1) of the Act) or a practitioner described in section 1842(b)(18)(C)(i) of the Act (that is, a physician assistant, nurse practitioner or clinical nurse specialist (as defined in section 1861(aa)(5) of the Act)). Section 1899(h)(2) of the Act defines the term "hospital" as a hospital (as defined in section 1886(d)(1)(B) of the Act." (A "subsection (d) hospital" is a hospital located in one of the fifty States or the District of Columbia, excluding hospitals and hospital units that are not paid under the inpatient prospective payment system under section 1886(d)(1)(B) of the Act, such as psychiatric, rehabilitation, long term care, children's, and cancer hospitals.) Section 1899(h)(3) of the Act defines the term "Medicare fee-for-service beneficiary" as an individual who is enrolled in the original Medicare FFS program under Medicare Parts A and B and is not enrolled in a Medicare Advantage (MA) plan under Medicare Part C, an eligible organization under section 1876 of the Act, or a Program of All-Inclusive Care for the Elderly (PACE) under section 1894 of the Act.

Section 1899(i) of the Act provides that the Secretary may use either a partial capitation model or other payment model, rather than the payment model described in section 1899(d) of the Act, for making payments under the Shared Savings Program. Sections 1899(i)(2)(B) and 1899(i)(3)(B) of the Act require that any such model maintain budget neutrality. Specifically, these sections require that any such model adopted by the Secretary, "does not result in spending more for such ACO for such beneficiaries than would otherwise be expended for such ACO for such beneficiaries for such year if the model were not implemented, as estimated by the Secretary."

Finally, section 1899(k) of the Act provides for an extension to the Physician Group Practice (PGP) demonstration: "During the period beginning on the date of the enactment of this section and ending on the date the program is established, the Secretary may enter into an agreement with an ACO under the demonstration under section 1866A, subject to rebasing and other modifications deemed appropriate by the Secretary."

C. Overview and Intent of the Medicare Shared Savings Program

The intent of the Shared Savings Program is to promote accountability for a population of Medicare beneficiaries, improve the coordination of FFS items and services, encourage investment in infrastructure and redesigned care processes for high quality and efficient service delivery, and incent higher value care. As an incentive to ACOs that successfully meet quality and savings requirements, the Medicare Program can share a percentage of the achieved savings with the ACO. In order to meet the intent of the Shared Savings Program as established by the Affordable Care Act, we will focus on achieving, as our highest-level goal, the three-part aim, which consists of the following:

• Better care for individuals—as described by all six dimensions of quality in the Institute of Medicine report: Safety, effectiveness, patient-centeredness, timeliness, efficiency, and equity;

• Better health for populations with respect to educating beneficiaries about the upstream causes of ill health—like poor nutrition, physical inactivity, substance abuse, economic disparities—as well as the importance of preventive services such as annual physicals and flu shots; and

• Lower growth in expenditures by eliminating waste and inefficiencies while not withholding any needed care that helps beneficiaries.

Under the Shared Savings Program, ACOs will only share in savings if they first generate shareable savings and then meet the quality standards. In the spirit of the three-part aim and the vision of always keeping the beneficiary in the forefront of all decisions, we believe that an ACO should embrace the following goals:

• An ACO will put the beneficiary and family at the center of all its activities. It will honor individual preferences, values, backgrounds, resources, and skills, and it will thoroughly engage people in shared decision-making about diagnostic and therapeutic options.

• An ACO will ensure coordination of care for beneficiaries regardless of its time or place. In an ACO, people will find that they no longer carry the burden of ensuring that everyone caring for them has the information they need. Beneficiaries will see that organizational teamwork improves their health care.

• An ACO will attend carefully to care transitions, especially as beneficiaries journey from one part of the care system to another.

• An ACO will manage resources carefully and respectfully. It will ensure continual waste reduction, and that every step in care adds value to the beneficiary. An ACO will be able to make investments where investments count, and move resources to meet beneficiaries' needs. Because of its capabilities with respect to prevention and anticipation, especially for chronically ill people, an ACO will be able to continually reduce its dependence on inpatient care. Instead, its patients will more likely be able to be home, where they often want to be, and, during a hospital admission, they receive assurance that their discharges will be well coordinated, and that they will not return due to avoidable complications.

• An ACO will be proactive by reaching out to patients with reminders and advice that can help them stay healthy and let them know when it is time for a checkup or a test.

• An ACO will collect, evaluate, and use data on health care processes and outcomes sufficiently to measure what it achieves for beneficiaries and communities over time and use such data to improve care delivery and patient outcomes.

• An ACO will be innovative in the service of the three-part aim of better care for individuals, better health for populations, and lower growth in expenditures. It will draw upon the best, most advanced models of care, using modern technologies, including telehealth and electronic health records, and other tools to continually reinvent care in the modern age. It will monitor and compare its performance to other ACOs, identify and examine new processes for care improvement, and adopt those approaches that are demonstrated to be effective.

• An ACO will continually invest in the development and pride of its own workforce, including affiliated clinicians. It will maintain and execute plans for helping build skill, knowledge, and teamwork.

As proposed in this notice of proposed rulemaking (NPRM), the Shared Savings Program encourages providers of services and suppliers to form ACOs that seek to achieve a three-part aim of better care for individuals, better health for populations, and lower growth in expenditures. The proposed

rule establishes the requirements for ACOs to take responsibility for improving the quality of care they deliver to a group of Medicare FFS beneficiaries, while lowering the growth in costs, in return for a share of the resulting savings. In addition to establishing a shared savings model for rewarding quality and financial performance, the program also holds ACOs accountable for excess expenditures by establishing, as an option, a two-sided risk model which requires repayment of losses to us. This represents a new approach for the Medicare FFS program, under which providers have traditionally had little or no financial incentive to coordinate the care for their patients or to be accountable for the total costs and quality of the care provided.

Since there is little comparative experience with implementing a Shared Savings Program and alternative payment models at the national level, we sought input on the impact of this proposed program from a wide range of external experts, including credentialed actuaries, clinical managers, and academic researchers on the potential impact of the program through, for example, the White House meeting, multiple listening sessions, Special Open Door Forum on ACOs, Workshop Regarding ACOs with CMS, OIG, and the Antitrust Agencies, and a Request For Information. Incorporating their input, we estimate that up to 5 million Medicare beneficiaries will receive care from providers participating in ACOs, many of which are located in higher cost areas, and that the program can have a significant impact on lowering Medicare expenditure growth. Furthermore, projections on the initial impact of the program by the Congressional Budget Office also suggest the Shared Savings Program could result in significant savings to the Medicare program.

We also believe that the Shared Savings Program should provide an entry point for all willing organizations who wish to move in a direction of providing value-driven healthcare. Consequently, in accordance with the authority granted to the Secretary under section 1899(i) of the Act, we are proposing for comment creating and implementing both a shared savings model (one-sided model) and a shared savings/losses model (two-sided model). Under this proposal, balanced maximum sharing rates under the two options to provide greater reward for ACOs accepting risk while maintaining an incentive to encourage ACOs not immediately ready to accept risk to participate in the one-sided model. This approach provides an entry point for organizations with less experience managing care and accepting financial risk, such as physician-driven organizations or smaller ACOs, to gain experience with population management in the FFS setting before transitioning to more risk.

We believe that ACOs electing to initially enter the one-sided model automatically transition to a two-sided risk model during the final year of their initial agreement. We also believe that a two-sided model that builds off a one-sided model could be offered as an option at the beginning of the program. We would immediately reward ACOs electing to enter the two-sided model with higher sharing rates available under that model. This approach provides an opportunity for more experienced ACOs that are ready to accept risk to enter a sharing arrangement that provides greater reward for greater responsibility. For more detail on the two-sided risk model refer to section II.G. of this proposed rule.

In addition to the opportunity to implement alternative payment models such as partial capitation under 1899(i) of the Act, the Center for Medicare and Medicaid Innovation (Innovation Center), created by the Affordable Care Act also has authority to test innovative payment models. As we gain experience with the shared savings model and alternative payment models, we will continue to refine and improve the program over time to make it increasingly effective in achieving our three-part aim of better care for individuals, better health for populations, and lower growth in expenditures. Finally, in developing the Shared Savings Program, and in response to stakeholder suggestions, we have worked very closely with agencies across the Federal government to develop policies to encourage participation and to ensure a coordinated and aligned inter- and intra-agency effort in the implementation of the program. The result of this effort is the release of several notices with which potential participants are strongly encouraged to become familiar. Detailed descriptions of these notices appear in section II.I of this proposed rule, and include: (1) A joint CMS and DHHS OIG Medicare Program; Waiver Designs in Connection with the Medicare Shared Savings Program and the Innovation Center; (2) an Internal Revenue Service (IRS) notice soliciting comments regarding the need for additional tax guidance for tax-exempt organizations, including tax-exempt hospitals, participating in the Shared Savings Program; and (3) a proposed Antitrust Policy Statement issued by the FTC and DOJ (collectively, the Antitrust Agencies).

D. Related Affordable Care Act Provisions

The Affordable Care Act intends to improve quality and make health care more affordable through the Shared Savings Program as well as through other provisions. There are four programs authorized by the Affordable Care Act discussed later in the document which may affect Shared Savings Program policy or help to guide future Shared Savings Program policy, or may intersect with the Shared Savings Program in other ways.

1. Establishment of Center for Medicare and Medicaid Innovation (Innovation Center)

Section 1115A of the Act, as added by section 3021 of the Affordable Care Act, required the establishment of the new Innovation Center not later than January 1, 2011 to test innovative payment and service delivery models to reduce program expenditures under Medicare, Medicaid, and the Children's Health Insurance Program (CHIP) while preserving or enhancing the quality of care furnished to beneficiaries under these programs. In selecting such models for testing, the statute requires the Secretary to give preference to models that also improve the coordination, quality, and efficiency of health care services furnished under Medicare, Medicaid, and CHIP.

Section 1115A authorizes the Secretary to expand the duration and scope of a model being tested through rulemaking (including implementation on a nationwide basis) to the extent the Secretary—

- Determines expected expansion to reduce spending under the applicable title without reducing the quality of care or improve the quality of patient care without increasing spending;
- Obtains a certification from our Chief Actuary that such expansion would reduce (or would not result in any increase in) net program spending under applicable titles; and
- Determines that such expansion would not deny or limit the coverage or provision of benefits under Medicare, Medicaid, or CHIP.

Through the Innovation Center, we plan to explore alternative payment models for the Shared Savings Program. As we test and refine these models, gain operational experience, and put the necessary infrastructure in place to support program wide implementation, including critical monitoring and

patient protection infrastructure, we plan to make these options available under the Shared Savings Program in future rulemaking. Our intent is to move participants of the demonstration models that have a demonstrated track record of realizing shared savings and high quality performance into the Shared Savings Program in future agreement periods.

2. Independence at Home Medical Practices

Section 1866E of the Act, as added by section 3024 of the Affordable Care Act authorizes the Secretary to conduct a demonstration program to test a payment incentive and service delivery model that utilizes Independence at Home Medical Practices, which are comprised of physician and nurse practitioner directed home-based primary care teams, to provide services designed to reduce expenditures and improve health outcomes for certain Medicare beneficiaries.

Subject to performance on quality measures established for the demonstration, participating practices may be eligible to receive an incentive payment in the form of shared savings. In determining whether savings were generated, the Secretary shall establish an estimated annual spending target, for the amount the Secretary estimates would have been spent in absence of the demonstration, for items and services covered under Parts A and B furnished to applicable beneficiaries for each qualifying Independence at Home medical practice. A practice is eligible to receive an incentive payment if actual expenditures for the year for the applicable beneficiaries it enrolls are less than the estimated spending target established for the year. An incentive payment for each year shall be equal to a portion of the amount by which actual expenditures for applicable beneficiaries under Parts A and B for the year are estimated to be less than 5 percent less than the estimated spending target for the year.

3. State Option To Provide Health Homes

Section 1945 of the Act, as added by section 2703 of the Affordable Care Act authorizes a State option under Medicaid to provide a health home for individuals with chronic conditions. The definition of the term "health home" is defined as a designated provider (including a provider that operates in coordination with a team of health care professionals) or a health team selected by an eligible individual with chronic conditions to provide health home services. Health home services are defined as comprehensive and timely high-quality services, including comprehensive care management; care coordination and health promotion; comprehensive transitional care, including appropriate follow-up, from inpatient to other settings; patient and family support (including authorized representatives); referral to community and social support services, if relevant; and use of health information technology to link services, as feasible and appropriate.

Under section 1945 of the Act, States pay the designated provider, team of health care professionals operating with such a provider, or health team for the provision of health home services to each eligible individual with chronic conditions that selects them as their health home. A State specifies in their State plan amendment the methodology it will use to determine payment for health home services. The methodology may be tiered to reflect, with respect to each eligible individual with chronic conditions, the severity or number of such individual's chronic conditions or the specific capabilities of the provider, team of health care professionals, or health team. A time-limited higher Federal Medicaid matching payment is available for health home services.

4. Community Health Teams

Section 3502 of the Affordable Care Act requires the Secretary to establish a program to provide grants to or enter into contracts with eligible entities to establish community based interdisciplinary, inter-professional teams (referred to in the statute as "health teams") to support primary care practices, including obstetrics and gynecology practices, within the hospital service areas served by the eligible entities. These grants or contracts shall be used to establish health teams to provide support services to primary care providers and provide capitated payments to primary care providers as determined by the Secretary. For purposes of this section, primary care is the provision of integrated, accessible health care services by clinicians who are accountable for addressing a large majority of personal health care needs, developing a sustained partnership with patients, and practicing in the context of the family and community.

A health team established under a grant or contract must establish contractual agreements with primary care providers to provide support services. The team must support patient-centered medical homes, defined as a mode of care that includes—(1) Personal physicians; (2) whole person orientation; (3) coordinated and integrated care; (4) safe and high-quality care through evidence-informed medicine, appropriate use of health information technology, and continuous quality improvements; (5) expanded access to care; and (6) payment that recognizes added value from additional components of patient centered care.

Health teams must also collaborate with local primary care providers and existing State and community-based resources to coordinate—(1) disease prevention; (2) chronic disease management; (3) transitioning between health care providers and settings; and (4) case management for patients, including children, with priority given to those amenable to prevention and with chronic diseases or conditions identified by the Secretary. In collaboration with local health care providers, a health team must develop and implement interdisciplinary, interprofessional care plans that integrate clinical and community preventive and health promotion services for patients, including children, with a priority given to those amenable to prevention and with chronic diseases or conditions identified by the Secretary.

E. Related Ongoing CMS Efforts

1. Physician Group Practice Demonstration

We have previous experience developing and implementing shared savings models through demonstrations. First, under section 412 of the Medicare, Medicaid, and CHIP Benefits Improvement and Protection Act of 2000 (BIPA), we implemented the Physician Group Practice (PGP) Demonstration in April of 2005—our first attempt at establishing a Shared Savings ACO model. The PGP Demonstration offered a unique payment model by which PGP providers received their normal Parts A and B FFS payments for services rendered and offered an additional performance payment for demonstrating "value." The performance payments were tied directly to achieving targets for process and outcome quality measures as well as cost savings. The PGP Demonstration showed that physician-driven organizations are willing to engage in efforts to improve the overall quality and cost efficiency of care for the patient population they serve. Under the demonstration, the PGPs were accountable for a patient population to whom they provided the plurality of office-based evaluation and

management care. The assignment of patients to the PGP at the end of each performance year and data has shown that assigned patients had on average four or five visits at the PGP during the year. This provided the opportunity for the organizations to better coordinate services and improve the quality and efficiency of care provided to Medicare FFS patients. Medicare patients retained their entitlement to see any Medicare provider they chose and were not enrolled or required to only see PGP physicians under the demonstration.

Based on their experience with the PGP demonstration, participants identified several factors as critical to improving quality and the opportunity to share savings:

- An integrated organization with an environment that supports expending resources on multiple programs and initiatives to improve quality and reduce unnecessary services.
- Dedicated physician leadership with a proven ability to motivate physicians to participate in the development and implementation of quality improvement and other clinical programs and initiatives.
- Health information technology that facilitates the aggregation and analysis of data, allows patient-level feedback, and provides alerts and reminders at the point of care.
- Experience with non-Medicare payer initiatives, particularly through a managed care affiliate, to improve quality and reduce expenditure growth.

Under the demonstration, at the end of the third performance year, all 10 of the PGPs continued to improve the quality of care for patients with chronic illness or who required preventive care by achieving benchmark or target performance on at least 28 out of 32 quality markers for patients with diabetes, coronary artery disease, congestive heart failure, hypertension, and for cancer screening. Two of the PGPs achieved benchmark quality performance on all 32 quality measures. Over the course of the first three years, 6 of the 10 groups shared in approximately $46 million in savings.

2. Medicare Health Care Quality Demonstration

We have begun testing models under the Medicare Health Care Quality (MHCQ) Demonstration, created by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173). Section 1866C(b) of the Act, as added by section 646 of the MMA, required the Secretary to establish a 5-year demonstration program under which the Secretary was required to approve demonstration projects that examine health delivery factors that encourage the delivery of improved quality in patient care. Section 3021(c) of the Affordable Care Act amended section 1866C of the Act to allow the Secretary to expand, through rulemaking, the duration and scope of a demonstration the Secretary is conducting under that section to the extent determined appropriate by the Secretary if the demonstration meets certain criteria. The MHCQ Demonstration Projects design examine the extent to which major, multi-faceted changes to traditional Medicare's health delivery and financing systems lead to improvements in the quality of care provided to Medicare beneficiaries, without increasing total program expenditures. We approved one such program, the Indiana Health Information Exchange (IHIE).

Beginning July 1, 2009, we began the first MHQC project, the IHIE's implementation of a regional, multi-payer, pay-for-performance and quality reporting program, based (by-and-large) on a common set of quality measures. The expectation is such that the IHIE's interventions provide important empirical evidence on the effectiveness of pay-for-performance, health IT, and multipayer initiatives in improving the quality and efficiency of care provided to Medicare beneficiaries.

IHIE aggregates our claims and administrative data in the demonstration with other data processed in conjunction with its regional health information exchange (HIE). Data used from the various sources generate patient-level and provider level quality reports, alerts, and reminders for participating providers. By incorporating our data into IHIE's HIE and producing these quality reports, IHIE can provide participating physicians with a more complete picture of the care that is or is not being provided to their Medicare patients and give physicians the information they need to positively impact the quality and cost of care being provided.

During the demonstration, we review cost and quality data for Medicare FFS beneficiaries that have at least one office or other outpatient evaluation and management (E&M) visit with an IHIE participating physician. It is expected that an estimated 100,000 Medicare beneficiaries residing in the Indianapolis metropolitan area will meet this criterion in each year of the demonstration.

Quality of care is measured at the population-level (that is, performance measurement will focus on whether or not the site has achieved improvements in quality when looking at the entire group of treated patients) using a set of Medicare specific quality measures. Improvements in the quality of care provided to Medicare beneficiaries are determined on the extent to which IHIE participating physicians are able to reduce the gap between the maximum attainable level for a quality measure and the baseline performance for the quality measure. We used approximately 14 ambulatory care quality measures in the first year, growing to approximately 30 in the fifth year.

Quality-contingent shared savings are available with our calculating savings in the intervention population by comparing actual costs to expected costs for treated beneficiaries. Expected costs for the intervention group are projected using adjusted utilization trends from a comparison group. In general, calculated Medicare savings are the difference between the expected costs and actual costs for beneficiaries in the intervention group. At least 50 percent of shared savings that are available to be paid for payment to the site are contingent on quality of care results for the year. Only after quality of care performance results for a year are determined can the final amount of shared savings to be paid to the site be determined.

II. Provisions of the Proposed Rule

A. Organization of the Proposed Rule

The remainder of this document is organized as follows: In section II.A. of this proposed rule, we propose an operational definition of an ACO for purposes of the shared savings program. In section II.B. of this proposed rule, we put forth proposed eligibility requirements for an ACO to participate in this program. In section II.C. of this proposed rule, we propose requirements for an ACO to commit to a 3-year participation agreement under this program and present a proposal for data sharing with ACOs. In section II.D. of this proposed rule, we discuss our proposed methodology for assigning beneficiaries to an ACO. In section II.E. of this proposed rule, we present our proposals regarding quality measures and the methodology for measuring ACO performance under this program. In section II.F. of this proposed rule, we discuss our proposed shared savings payment methodology, including the establishment of an expenditure benchmark, performance target, minimum savings percentage, sharing rate, performance cap. In section II.G. of this proposed rule, we discuss our proposal for introducing risk into the

shared savings program, the two-sided model and differences from the one-sided model. In section II.H. of this proposed rule, we discuss our proposal for monitoring ACO performance and we propose grounds and procedures for terminating agreements. In section II.I. of this proposed rule, we discuss our efforts to coordinate the development of this proposed rule with other Federal agencies to ensure a coordinated and aligned inter- and intra-agency effort in the implementation of the program. In section II.J. of this proposed rule, we discuss overlap in Medicare programs and how this might affect Shared Savings Program participants. Finally, in section V. of this proposed rule, we present our Regulatory Impact Analysis, which sets forth an analysis of the impact of these proposals on affected entities and beneficiaries.

For purposes of this proposed rule, we propose definitions for the following terms:

- *Accountable care organization* (ACO) means a legal entity that is recognized and authorized under applicable State law, as identified by a Taxpayer Identification Number (TIN), and comprised of an eligible group (as discussed in section II.B. of this proposed rule) of ACO participants that work together to manage and coordinate care for Medicare FFS beneficiaries and have established a mechanism for shared governance that provides all ACO participants with an appropriate proportionate control over the ACO's decision making process,
- *ACO participant* means a Medicare-enrolled provider of services and/or a supplier (as discussed in section II.B. of this proposed rule, as identified by a TIN).
- *ACO provider/supplier* means a provider of services and/or a supplier (as discussed in section II.B. of this proposed rule) that bills for items and services it furnishes to Medicare beneficiaries under a Medicare billing number assigned to the TIN of an ACO participant in accordance with applicable Medicare rules and regulations.

B. Eligibility and Governance

1. Eligible Entities

Section 1899(b) of the Act establishes eligibility requirements for ACOs participating in the Shared Savings Program. Section 1899(b)(1) of the Act allows several designated groups of providers of services and suppliers to participate as an ACO under this program, "as determined appropriate by the Secretary," and under the condition that they have "established a mechanism for shared governance." The statute lists the following groups of providers of services and suppliers as eligible to participate as an ACO:

- ACO professionals in group practice arrangements.
- Networks of individual practices of ACO professionals.
- Partnerships or joint venture arrangements between hospitals and ACO professionals.
- Hospitals employing ACO professionals.
- Such other groups of providers of services and suppliers as the Secretary determines appropriate.

Section 1899(h)(1) of the Act defines an "ACO professional" as a physician (as defined in section 1861(r)(1) of the Act, which refers to a doctor of medicine or osteopathy), or a practitioner (as defined in section 1842(b)(18)(C)(i) of the Act, which includes physician assistants, nurse practitioners, and clinical nurse specialists). Section 1899(h)(2) of the Act also provides that, for purposes of the Shared Savings Program, the term "hospital" means a subsection (d) hospital as defined in section 1886(d)(1)(B) of the Act, thus limiting the definition to include only acute care hospitals paid under the hospital inpatient prospective payment system (IPPS). Other providers of services and suppliers that play a critical role in the nation's health care delivery system, such as Federally qualified health centers (FQHCs), rural health centers (RHCs), skilled nursing facilities (SNFs), nursing homes, long-term care hospitals (LTCHs) and critical access hospitals (CAHs), among others, are not specifically designated as eligible participants in the Shared Savings Program under section 1899(b)(1) of the Act. We note, however, that the statutorily defined groups of providers and suppliers that are eligible to participate in the Shared Savings Program as ACOs, would also have to meet the eligibility criteria discussed in detail later in this proposed rule in order to qualify for participation in the program. While the statute enumerates certain kinds of provider and supplier groups that are eligible to participate in this program, it also provides the Secretary with discretion to tailor eligibility in a way that narrows or expands the statutory list of eligible ACO participants. Therefore, we have considered whether it would be advisable, at least in the initial stage of the Shared Savings Program, to—(1) Permit participation in the program by only those ACO participants that are specifically identified in the statute; (2) restrict eligibility to those ACO participants that would most effectively advance the goals of the program; or (3) employ the discretion provided to the Secretary under section 1899(b)(1)(E) of the Act to expand the list of eligible groups to include other types of Medicare-enrolled providers and suppliers identified in the Act.

Some have argued that ACOs would be most effective if they include certain entities as ACO participants. For example, the Medicare Payment Advisory Commission (MedPAC) has noted that provider groups with hospitals in their systems may be most effective in generating savings. The MedPAC notes that hospitals working with physician teams can prevent further hospitalizations after discharge and provide ongoing services to keep the patient as healthy as possible. Also, the savings generated by ACOs, in many cases, are expected to result from reduced inpatient admissions. As a result, provider groups with hospitals may have a greater incentive to coordinate care to ensure that a portion of the revenue lost from decreased admissions is made up through shared savings. (To view the MedPAC discussion referenced previously go to: *http://www.medpac.gov/documents/jun09_entirereport.pdf*.)

Another option for limiting eligibility would be to restrict eligibility to only those ACO professionals providing primary care services. Primary care professionals may have the best opportunity to reduce unnecessary costs by ensuring care coordination for beneficiaries with multiple chronic conditions. By coordinating with specialists to whom the beneficiary has been referred, primary care providers can reduce unnecessary repetition of laboratory testing or imaging. By ensuring timely access to the outpatient services, primary care providers can also reduce the number of avoidable admissions. Limiting eligibility for the Shared Savings Program to primary care providers, therefore, may be desirable to emphasize the important role played by these professionals and ensure a primary care focus for the program. Adopting either of these approaches would require a narrower eligibility definition than is permitted (although not required) under the statute.

However, the benefits of limiting eligibility need to be balanced against the prospect that such limitations could compromise potential innovations and forfeit the opportunity to assess new models that could potentially transform health care in ways that improve quality and beneficiary satisfaction while better controlling costs. More importantly, defining eligibility narrowly also has the potential to impede development of

ACOs that include other provider and supplier types, especially those that provide services in rural and other underserved areas. For example, while section 1899(b)(1) of the Act does not mention certain entities such as critical access hospital (CAHs), federally qualified health centers (FQHCs), or rural health clinics (RHCs) in its listing of entities eligible to form an ACO under the Shared Savings Program these entities play a critical role in the nation's health care delivery system, serving as safety net providers of primary care and other health care and social services in rural and other underserved areas and for low-income beneficiaries, including those dually eligible for Medicare and Medicaid. Permitting participation by these groups of providers and suppliers has the potential to improve coordination and quality of care for a greater number of beneficiaries in more communities, while better controlling costs in more varied settings and across a broader array of providers and suppliers.

Since the statute requires that beneficiary assignment be determined on the basis of utilization of primary care services provided by ACO professionals that are physicians, we considered whether expansion of eligibility would allow additional Medicare enrolled providers and suppliers to form an ACO to participate in addition to the four groups specified in section 1899(b)(1)(A)–(D) of the Act. Specifically, we considered whether it would be feasible for CAHs, FQHCs, and RHCs to form an ACO or whether it would be necessary for these entities to join with the four groups specified in section 1899(b)(1)(A)–(D) of the Act in order to meet statutory criteria. We have especially considered the circumstances of CAHs, FQHCs, and RHCs because these entities play a critical role in the nation's health care delivery system, serving as safety net providers of primary care and other health care and social services. At the same time, the specific payment methodologies, claims billing systems, and data reporting requirements that apply to these entities pose some challenges in relation to their independent participation in the Shared Savings Program. In order for an entity to be able to form an ACO, it is necessary that we obtain sufficient data in order to carry out the necessary functions of the program, including assignment of beneficiaries, establishment and updating of benchmarks, and determination of shared savings, if any. As we discuss in section II.D of this proposed rule, consistent with section 1899(c) of the Act, which provides that beneficiaries shall be assigned to an ACO based on their utilization of primary care services furnished by an ACO professional who is a physician, our proposed methodology for assignment of beneficiaries is to assign beneficiaries to an ACO on the basis of receiving a plurality of their primary care services as described in section II.D. of this proposed rule from a physician, as defined in section 1861(r)(1) of the Act, with a specialty designation of general practice, family practice, internal medicine and geriatric medicine. Thus, as required by the statute, the assignment methodology requires data that identify the precise services rendered (that is, primary care HCPCS codes), type of practitioner providing the service (that is, a MD/DO as opposed to NP, PA, or clinical nurse specialist), and the physician specialty in order to be able to assign beneficiaries to ACOs.

At this time, FQHC claims for services furnished prior to January 1, 2011 do not include HCPCS codes that identify the specific service provided. Thus, although the claims do contain information concerning the attending physician and the rendering health professional (for example, physician, physician assistant, nurse practitioner), who actually provided the service, they do not currently provide for associating the rendering provider with the specific services furnished to the beneficiary.

RHCs predominantly provide primary care services to their populations. Most RHC services are provided by non-physician practitioners such as PAs and NPs. RHCs submit claims for each encounter with a beneficiary and receive payment based on an interim all-inclusive rate for the RHC. As in the case of FQHCs, RHC claims distinguish general classes of services (for example, clinic visit, home visit by RHC practitioner, mental health services) by revenue code, the beneficiary to whom the service was provided, and other information relevant to determining whether the all-inclusive rate can be paid for the service. These claims do not include HCPCS codes that identify the specific service provided. The claims also contain limited information concerning the individual practitioner, or even the type of health professional (for example, physician, PA, NP), who provided the service.

For FQHCs and RHCs, therefore, we currently lack the requisite data elements (service code, physician, physician specialty, and specific attribution of services to the rendering health care professionals) in the claims and payment systems to enable us to determine (1) beneficiary assignment during the performance year under section 1899(c) of the Act, which requires that assignment to an ACO be based on utilization of primary care services furnished by a physician; and (2) expenditures during the 3-year benchmark. In the case of FQHCs, we recently finalized regulations requiring the collection of HCPCS codes for services beginning in 2011, in preparation for the development of the FQHC PPS. However, there is no statutory requirement for collecting from FQHCs the other data elements, such as the direct link between provider and service, which would be required for beneficiary assignment under the Shared Savings Program. Moreover, there is neither the statutory requirement for collection of HCPCS codes from RHCs nor any plan to expand this data collection effort to RHCs. In both the case of FQHCs and RHCs, reporting the information necessary to participate in the Shared Savings Program would be a significant change in operations that we are reluctant to impose through regulation without either a statutory requirement or clear support for such a regulatory change from the FQHC and RHC community at large that they would be willing to have all RHC/FQHCs provide this information uniformly, solely to enable independent formation of an ACO for purposes of participation in the Shared Savings Program by the subset of those FQHC/RHCs that choose to do so.

Therefore, in the absence of the data elements required for assignment of beneficiaries, it is not possible for FQHCs and RHCs to participate in the Shared Savings Program by forming their own ACOs. It is, however, possible for them to join as an ACO participant in an ACO containing one or more of the statutory organizations eligible to form an ACO (as specified in section 1899(b)(1)(A)–(D) of the Act) and upon which assignment can be made consistent with the statute and the assignment methodology proposed in section II.D. of this proposed rule. However, we note that even in this case, for the reasons stated previously, we would not have the data necessary to consider FQHC or RHC patients in the assignment process. Thus, assignment of beneficiaries to ACOs in which FQHCs and RHCs are participating would have to be based solely on data from the other eligible ACO participants upon whom assignment can be based. As the Shared Savings Program develops, we will continue to assess the possibilities for collecting the requisite data from FQHCs and RHCs, and in light of any such developments we will consider

whether it is possible at some future date for Medicare beneficiaries to be assigned to an ACO on the basis of services furnished by an FQHC or RHC, thereby allowing these entities to have their Medicare beneficiaries included in the ACO's assigned population.

The situation is somewhat more complicated with regard to CAHs. Section 1834(g) of the Act provides for two payment methods for outpatient CAH services.

Under the method specified in section 1834(g)(1) of the Act (referred to as the standard method), facility services are paid at 101 percent of reasonable costs to the CAH through the Medicare fiscal intermediary or the Medicare Part A/B MAC, while payments for physician and other professional services are made separately to the physician or other practitioner under the MPFS through Medicare carriers. Accordingly, CAHs that bill under the standard method would not submit claims with information on individual practitioners, or the type of health professional (for example, physician, PA, NP), that provided a specific service.

Under the method specified in section 1834(g)(2) of the Act (referred to as method II), a CAH submits bills for both the facility and the professional services to its Medicare fiscal intermediary or its Medicare Part A/B MAC. If a CAH chooses this method for outpatient services, the physician or other practitioner must reassign his or her right to bill the Medicare program for those services to the CAH. Under method II, the CAH receives—(1) 101 percent of the reasonable cost payment for its facility costs; and (2) 115 percent of the amount otherwise paid under the MPFS for professional services under Medicare.

Thus, current Medicare payment and billing policies could generally support the formation of an ACO by a CAH billing under method II.

In summary, in this proposed rule, we considered three options for defining the range of potentially eligible providers and suppliers that would be eligible to form an ACO. One option that we considered would be to limit eligibility initially to the groups specifically identified in the statute. Under this option, only the four groups specified in section 1899(b)(1)(A)–(D) of the Act would be eligible to form an ACO and participate in the program.

A second option would be to narrowly define which groups of providers of services and suppliers are eligible to form an ACO and participate in the Shared Savings Program. The approach noted by MedPAC is one example of this option. This option would require the participation of a hospital in the ACO so that only partnerships or joint venture arrangements between hospitals and ACO professionals or hospitals employing ACO professionals (groups specified in 1899(b)(1)(C)–(D) of the Act) would be eligible to participate in the program. Another example of this option would be limiting participation to only those entities comprised of primary care professionals so that only ACO professionals in group practice arrangements or networks of individual practices of ACO professionals (groups specified in 1899(b)(1)(A)–(B) of the Act) would be eligible to form an ACO and participate in the program. This approach would be grounded in the premise that ACOs should be primary care-focused and that primary care professionals are in the best position to both reduce the fragmentation of services and improve the overall quality of care delivered to Medicare beneficiaries.

Under the third option, the four groups specified in section 1899(b)(1)(A)–(D) of the Act would be eligible to form an ACO and participate in the program, but in addition, we would employ the discretion provided to the Secretary under section 1899(b)(1)(E) of the Act to allow other Medicare enrolled entities, such as CAHs billing under method II to form an ACO. Additionally, employing Secretarial discretion to expand the definition of eligible providers or suppliers would allow other Medicare enrolled entities such as FQHCs and RHCs, to become ACO participants, if the ACO that is formed is able to meet the other qualifications to participate in the program.

After evaluating the three options for defining the range of potentially eligible providers and suppliers, we have decided to propose the third option. Under this proposal, the four groups specifically identified in section 1899(b)(1)(A)–(D) of the Act, and CAHs billing under method II, would have the opportunity to form ACOs independently. In addition, the four statutorily indentified groups, as well as CAHs billing under method II, could establish an ACO with broader collaborations by including additional Medicare enrolled entities such as FQHCs and RHCs and other Medicare-enrolled providers and suppliers as defined in the Act as ACO participants. While this proposal potentially increases the administrative complexity of implementing the program and could also require stronger measures to oversee the varied kinds of ACO arrangements that might evolve, we believe this approach best serves the goals of the program by allowing greater opportunities for broadly transforming the health care delivery system and increasing access to high quality and lower cost care under the Shared Savings Program for Medicare beneficiaries regardless of where they live. Specifically, this option allows for a wide variety of ACO configurations that incorporate a broad range of health care providers and suppliers, including safety net providers, post-acute care facilities, FQHCs, RHCs, and CAHs, which we believe will enable ACOs to offer more comprehensive care and better serve the needs of rural communities. The proposal also offers greater opportunity for innovation by ACOs in determining the most effective organizational structure to meet the needs of their respective populations.

In addition to requesting comment on this proposal generally, we are soliciting comment on the following: (1) The kinds of providers and suppliers that should or should not be included as potential ACO participants; (2) the potential benefits or concerns regarding including or not including certain provider or supplier types; (3) the administrative measures that would be needed to effectively implement and monitor particular partnerships; (4) other ways in which we could employ the discretion provided to the Secretary to allow the independent participation of providers and suppliers not specifically mentioned in the statute, for example, through an ACO formed by a group of FQHCs and RHCs; and (5) any operational issues associated with our proposal. We will consider whether it would be appropriate to expand the list of entities eligible to participate in the Shared Savings Program, either in the final rule or in future rulemaking, if we determine that it is feasible and consistent with the requirements of the program for more entities to participate as ACOs. In the interim, and until such time as FQHCs and RHCs would be eligible to form ACOs or have their patients assigned to an ACO, we are also proposing to provide an incentive for ACOs to include RHCs and FQHCs as ACO participants, by allowing ACOs that include such entities to receive a higher percentage of any shared savings under the program. We believe that this proposal to encourage participation by RHCs and FQHCs in ACOs is appropriate in light of the special role that these entities play in the health care delivery system, especially in providing care to otherwise underserved and vulnerable populations. We discuss how this proposal affects the determination

of shared savings under the program in section II.F. of this proposed rule.

2. Legal Structure and Governance

Section 1899(b)(2)(C) of the Act requires an ACO to "have a formal legal structure that would allow the organization to receive and distribute payments for shared savings" to "participating providers of services and suppliers." As previously noted, section 1899(b)(1) of the Act also requires ACO participants to have a "mechanism for shared governance" in order to participate in the program. Operationally, an ACO's legal structure must provide both the basis for its shared governance as well as the mechanism for it to receive and distribute shared savings payments to ACO participants and providers/suppliers.

a. Legal Entity

The ACO's legal entity may be structured in a variety of ways, including as a corporation, partnership, limited liability company, foundation, or other entity permitted by State law. As discussed previously in section II. B. of this proposed rule, and consistent with section 1899(b)(1)(A)–(D) of the Act, certain specified groups of providers of services and suppliers who have a mechanism of shared governance may be eligible to participate as ACOs in the Shared Savings Program. In addition to the groups specifically identified in the statute, we are proposing to use the Secretary's discretion under section 1899(b)(1)(E) of the Act to expand the list of eligible groups of providers and suppliers that may participate in the Shared Savings rogram. Specifically, we are proposing that ACOs may incorporate other groups of Medicare enrolled providers and suppliers, many of whom would not be able to form ACOs and participate in the program independently. As described previously, each of the Medicare-enrolled providers and suppliers that join together to form an ACO is identified by their Medicare-enrolled TIN and is referred to herein as an ACO participant. Regardless of whether an ACO participant is able to meet the eligibility criteria for participation in the Shared Savings Program independently or must join with others in order to meet criteria, we propose that the ACO must demonstrate a mechanism of shared governance that provides all ACO participants with an appropriate proportionate control over the ACO's decision making process.

In response to the request for information (RFI) that appeared in the November 17, 2010 **Federal Register** (75 FR 70165), we received comments regarding the need for us to remain flexible when defining the required legal structure to allow for a variety of structural options. For example, commenters noted that we should permit existing organizations to participate in the Shared Savings Program instead of requiring the formation of a new legal entity in order to avoid additional costs and duplication of organizational competencies. Commenters also recommended that the legal structure requirements should not disadvantage solo and small groups of physicians with fewer resources relative to larger hospital and physician groups by requiring the use of specific structures that may result in increased costs, implementation delays, and cumbersome operational requirements for these smaller entities. Moreover, our intent is to encourage participation by not-for-profit, community-based organizations.

When considering options for the legal structure of ACOs, we sought to balance the need for an organization to be recognized by the State with the need for flexibility to permit the participants to select the appropriate organizational structure for their ACO. We also considered the importance of minimizing costs related to organizing as a specific legal entity. In order to implement the statutory requirements that ACOs have a shared governance mechanism and a formal legal structure for receiving and distributing shared payments, we believe that it is necessary for each ACO to be constituted as a legal entity appropriately recognized and authorized to conduct its business under applicable State law in order to best achieve the objectives of the Shared Savings Program and that it must have a TIN. Therefore, we are proposing to require an ACO to be an organization that is recognized and authorized to conduct its business under applicable State law and is capable of—(1) Receiving and distributing shared savings; (2) repaying shared losses; (3) establishing, reporting, and ensuring ACO participant and ACO provider/supplier compliance with program requirements, including the quality performance standards; and (4) performing the other ACO functions identified in the statute.

We note that by proposing that the ACO be required to have a TIN, we are not proposing to require that the ACO itself be enrolled in the Medicare program, in contrast to this requirement for each ACO participant.

Also, by proposing that each ACO must be constituted as a legal entity appropriately recognized and authorized under applicable State law, we are not proposing to require that existing legal entities appropriately recognized under State law must form a separate new entity for the purpose of participating in the Shared Savings Program. If the existing legal entity meets the eligibility requirements to be an ACO, as described in this proposed rule, it may operate as an ACO, as long as it is recognized under applicable State law and is capable of receiving and distributing shared savings, repaying shared losses, and performing the other ACO functions identified in the statute and regulations, including the requirement for shared governance for ACO participants.

For example, a hospital employing ACO professionals, which is one of the entities identified in section 1899(b)(1) of the Act, may be eligible to participate in the Shared Savings Program as an ACO with its current legal structure, as recognized under applicable State law, and would not be required to develop a separate new entity. We recognize, however, that the absence of a separate legal entity to operate the ACO may make it more difficult for us to audit and otherwise assess ACO performance. We solicit comment on whether we should require all ACOs participating in the Shared Savings Program to be formed as a distinct legal entity appropriately recognized and authorized to conduct its business under applicable State law or whether an existing legal entity could be permitted to participate in the Shared Savings Program as an ACO, including entities that have similar arrangements with other payors. However, we propose that if an existing entity, such as a hospital employing ACO professionals would like to include as ACO participants other providers of services and suppliers who are not already part of its existing legal structure, a separate entity would have to be established in order to provide all ACO participants a mechanism for shared governance and decision making.

We propose that each ACO would certify that it is recognized as a legal entity under State law and authorized by the State to conduct its business. In addition, an ACO with operations in multiple States would have to certify that it is recognized as a legal entity in the State in which it was established and that it is authorized to conduct business in each State in which it operates. An ACO must provide in its application evidence that it is recognized as a legal entity in the State in which it was established and that it is authorized to conduct business in

each State in which it operates. We solicit comment on our proposal for the required legal structure and seek input on other suitable legal structure requirements that we should consider adding in the final rule or through subsequent rulemaking. Moreover, our intent is to encourage not-for-profit, community-based organizations to participate in the Shared Savings Program. We request comment on whether requirements for the creation of a separate entity would create disincentives for the formation of ACOs and whether there is an alternative requirement that could be used to achieve the aims of shared governance and decision making and the ability to receive and distribute payments for shared savings.

b. Governance

Although section 1899(b)(1) of the Act requires that an ACO have a "mechanism for shared governance" and section 1899(b)(2)(F) of the Act further requires that an "ACO shall have in place a leadership and management structure that includes clinical and administrative systems," the statute does not specify the elements that this shared governance mechanism or the accompanying leadership and management structures must possess. We believe that such a governance mechanism should allow for appropriate proportionate control for ACO participants, giving each ACO participant a voice in the ACO's decision making process, and be sufficient to meet the statutory requirements regarding clinical and administrative systems. We envision a mechanism that is transparent, accountable to the affected beneficiary community, and also accountable and responsive to the ACO participants and the ACO providers/suppliers they represent. Further, we would anticipate that the leadership and management structures would provide for adequate authority to enable the ACO to execute its core functions of enhancing the quality, efficiency, and patient-centeredness of the health care services furnished to assigned beneficiaries.

Commonly used mechanisms for establishing shared governance are a board of directors, board of managers, or other similar governing bodies that provide a mechanism for representation and control in shared decision-making for all ACO participants. Accordingly, we are proposing that an ACO must establish and maintain a governing body with adequate authority to execute the statutory functions of an ACO, as defined by the shared governance criterion described in more detail later in this proposed rule. The governing body may be a board of directors, board of managers, or any other governing body that provides a mechanism for shared governance and decision-making for all ACO participants, and that has the authority to execute the statutory functions of an ACO, including for example, to "define processes to promote evidence-based medicine and patient engagement, report on quality and cost measures, and coordinate care," as required under section 1899(b)(1)(G) of the Act. As discussed in more detail later in the document, this governing body would be comprised of the ACO participants or their designated representatives, include Medicare beneficiaries served by the ACO, and possess broad responsibility for the ACO's administrative, fiduciary, and clinical operations. While the representatives on the governing body could be serving in a similar or complementary manner for an ACO participant within the ACO, this body must be separate and unique to the ACO when the ACO participants are not already represented by an existing legal entity appropriately recognized and authorized to conduct its business under applicable State law. In those instances where the ACO is comprised of a self-contained financially and clinically integrated entity that has a pre-existing board of directors or other governing body, such as a hospital that employs ACO professionals, we are also proposing that the ACO would not need to form a separate governing body, as long as that governing body is able to meet all other criteria required for ACO governing bodies. In this case, the integrated entity's governing body would be the governing body of the ACO, and the ACO would be required to provide in its application evidence that its pre-existing board of directors or other governing body, meets all other criteria required for ACO governing bodies. Although we wish to provide potential ACOs with some flexibility on corporate governance and ACO formation, we are concerned that allowing existing entities to be ACOs would complicate our monitoring and auditing of the ACO. We solicit comment on this issue.

Moreover, our intent is to encourage not-for-profit, community-based organizations to participate in the Shared Savings Program. We request comment on whether requirements for the creation of a governing body as a mechanism for shared governance would create disincentives for the formation of ACOs and whether there is an alternative requirement that could be used to achieve the aims of shared governance and decision making.

c. Composition of the Governing Body

For purposes of the Shared Savings Program, the ACO is, by definition, comprised of groups of Medicare-enrolled providers and suppliers (ACO participants) that agree to work together to manage and coordinate care for beneficiaries, and have established a mechanism for shared governance—as opposed to an outside entity directing their day-to-day operations. Therefore, we believe that the ACO should be operated and directed by Medicare-enrolled entities that directly provide health care services to beneficiaries. Stakeholders have indicated to us that in the private sector, entrepreneurial management companies and health plans have expressed interest in forming or participating in ACOs. Often, small groups of providers lack both the capital and infrastructure necessary to form an ACO and to administer the programmatic requirements of the Shared Savings Program and could benefit from partnerships with non-Medicare-enrolled entities. For this reason, we propose that in order to be eligible for participation in the Shared Savings Program, the ACO participants must have at least 75 percent control of the ACO's governing body. In addition, each of the ACO participants must choose an appropriate representative from within its organization to represent them on the governing body. This proposal ensures that ACOs remain provider-driven, but also leaves room for both non-providers and small provider groups to participate in the program.

We are requesting comment on this proposal for whether more or less than 75 percent control of the governing body being held by the ACO participants is an appropriate percentage. We are also requesting comment on whether the appropriate representative should be held by persons employed by and representing Medicare-enrolled TINs.

As discussed in more detail later in the document, we believe a process for integrating community resources is an essential part of patient centeredness.

We are proposing that ACOs be required to describe how they will partner with community stakeholders as part of their application. ACOs that have a community stakeholder organization serving on their governing body would be deemed to have satisfied that application criterion.

Additionally, as discussed in more detail later in the document, we are proposing a requirement that ACOs provide for beneficiary involvement in

their governing processes. Specifically, we are proposing that ACOs will be required to demonstrate a partnership with Medicare FFS beneficiaries by having beneficiary representation in the ACO governing body.

3. Leadership and Management Structure

Section 1899(b)(2)(F) of the Act requires an eligible ACO to "have in place a leadership and management structure that includes clinical and administrative systems." We believe this structure should align with and support the goals of the Shared Savings Program and the three-part aim of better care for individuals, better health for populations, and lower growth in expenditures. Based on their experience with the PGP demonstration, participants identified several factors as critical to improving quality and the opportunity to share savings:

- An integrated organization with an environment that supports expending resources on multiple programs and initiatives to improve quality and reduce unnecessary services.
- Dedicated physician leadership with a proven ability to motivate physicians to participate in the development and implementation of quality improvement and other clinical programs and initiatives.
- Health information technology that facilitates the aggregation and analysis of data, allows patient-level feedback, and provides alerts and reminders at the point of care.
- Experience with non-Medicare payer initiatives, particularly through a managed care affiliate, to improve quality and reduce expenditure growth.

In addition, another important factor that must be considered is whether the leadership and management structure of the ACO should include appropriate safeguards to ensure the ACO's integration and likelihood of achieving quality improvements and cost efficiencies. The Antitrust Agencies have developed criteria to assess whether collaborations of otherwise competing health care providers should be condemned as per se illegal under antitrust law or subject to a more thorough evaluation under the "Rule of Reason," which would examine likely procompetitive or anticompetitive effects.[1] To avoid per se condemnation as "shams" that facilitate price fixing or other per se illegal activities, collaborations of competing health care providers must show that they are integrated ventures that are likely to, or do, enable their participants jointly to achieve cost efficiencies and quality improvements in providing services. The efficiency-enhancing integration "must likely generate procompetitive benefits that enhance the participants' ability or incentives to compete, and thus offset any anticompetitive tendencies of the arrangement."[2]

Accordingly, the antitrust perspective focuses on how collaboration, including coordinated care, can lower costs and improve quality, just as the intent of the Shared Savings Program under section 1899 of the Act is to promote accountability for Medicare beneficiaries, improve the coordination of FFS items and services, and encourage investment in infrastructure and redesigned care processes for high quality and efficient service delivery. For antitrust purposes, collaborations of competing health care providers may use either financial or clinical integration, or both, as means to achieve cost efficiencies and quality improvements.[3] To demonstrate financial integration, participants in collaboration must share substantial financial risk, so they have the incentive to cooperate in controlling costs and improving quality by managing the provision of services.[4] To demonstrate clinical integration, participants must show a degree of interaction and interdependence among providers in their provision of medical services that enables them to jointly achieve cost efficiencies and quality improvements.[5] The Federal Antitrust Agencies have concluded that successfully achieving clinical integration requires the establishment and operation of active and ongoing processes and mechanisms to facilitate, encourage, and assure the necessary cooperative interaction.[6]

We believe that these criteria also provide insight into the leadership and management structures, including clinical and administrative systems, necessary for ACOs to achieve the three-part aim of better care for individuals, better health for populations, and lower growth in expenditures. We also note that these criteria are very similar to the factors identified previously by participants in the PGP demonstration as critical to improving quality and controlling the cost of health care. Similarly, antitrust analyses have examined whether participants in such a collaboration are committed to the collective development and implementation of evidence-based protocols and benchmarks, to individual and group accountability for adherence to those protocols and benchmarks, to the development of technology to facilitate providers' compliance, to the measurement of compliance with those protocols, and to improved performance with respect to benchmarks, among other things.[7]

It is in the public interest to harmonize the eligibility criteria for ACOs that wish to participate in the Shared Savings Program with the similar antitrust criteria on clinical integration. As discussed in more detail in section II. I. of this proposed rule, competition between ACOs is expected to have significant benefits for Medicare beneficiaries, by improving the quality of care they receive, protecting their access to a variety of providers, and helping to sustain the Medicare program by controlling costs. Furthermore, because ACOs that operate in the Shared Savings Program are likely to use the same organizational structure and clinical care practices to serve both Medicare beneficiaries and consumers covered by commercial insurance, the certainty created by harmonizing our eligibility criteria with antitrust requirements will help to ensure that an ACO organization participating in the Shared Savings Program will not subsequently face an antitrust challenge that its conduct is per se illegal, which could prevent the ACO from fulfilling the 3-year term of its agreement under the Shared Savings Program.

Accordingly, we believe an ACO, the ACO participants, and ACO providers/suppliers should demonstrate an organizational commitment to the Shared Savings Program and the terms of the 3-year agreement, both as a group and individually, as well as the leadership and management capabilities

[1] *Arizona* v. *Maricopa County Medical Society,* 457 U.S. 332 (1982).

[2] Letter from Jeffrey Brennan, Assistant Director, Bureau of Competition, Federal Trade Commission to John J. Miles, Ober, Kaler, Grimes & Shriver (February 19, 2002), available at *http://www.ftc.gov/bc/adops/medsouth.shtm.*

[3] Department of Justice and Federal Trade Commission, Statements of Antitrust Enforcement Policy in Health Care, Statement 8 (1996), available at *http://www.ftc.gov/reports/hlth3s.pdf.*

[4] Id.

[5] See, for example, Letter from Markus Meier to John J. Miles, Ober, Kaler, Grimes & Shriver 7 (June 18, 2007), available at *http://www.ftc.gov/bc/adops/070618mewdsouth.pdf.*

[6] Id.

[7] *See, for example,* Letter from Markus H. Meier, Assistant Director, Bureau of Competition, Federal Trade Commission to Christi J. Braun, Ober, Kaler, Grimes & Shriver 8 (April 13, 2009), *available at http://www.ftc.gov/os/closings/staff/090413tristateaoletter.pdf;* Letter from Markus H. Meier, Assistant Director, Bureau of Competition, Federal Trade Commission to Christi J. Braun & John J. Miles, Ober, Kaler, Grimes & Shriver 7 (Sept. 17, 2007), *available at http://www.ftc.gov/bc/adops/gripa.pdf;* Letter from Jeffrey Brennan, Assistant Director, Bureau of Competition, Federal Trade Commission to John J. Miles, Ober, Kaler, Grimes & Shriver (Feb. 19, 2002), *available at http://www.ftc.gov/bc/adops/medsouth.shtm.*

necessary to achieve the three-part aim by managing and coordinating the care of assigned Medicare beneficiaries. We note that the statute permits ACO participants that form an ACO to use a variety of collaborative organizational structures, including collaborations short of merger, to evidence the required organizational commitment and leadership and management capabilities.

Thus, consistent with the requirement in section 1899(b)(2)(F) of the Act that an ACO have a leadership and management structure that includes clinical and administrative systems, we are proposing that ACOs meet the following criteria:

- The ACO's operations would be managed by an executive, officer, manager, or general partner, whose appointment and removal are under control of the organization's governing body and whose leadership team has demonstrated the ability to influence or direct clinical practice to improve efficiency processes and outcomes.
- Clinical management and oversight would be managed by a senior-level medical director who is a board-certified physician, licensed in the State in which the ACO operates, and physically present in that State.
- ACO participants and ACO providers/suppliers would have a meaningful commitment to the ACO's clinical integration program to ensure its likely success. Meaningful commitment may include, for example, a meaningful financial investment in the ACO, or a meaningful human investment (for example, time and effort) in the ongoing operations of the ACO such that the potential loss or recoupment of the investment is likely to motivate the participant to make the clinical integration program succeed.
- The ACO would have a physician-directed quality assurance and process improvement committee that would oversee an ongoing quality assurance and improvement program. The quality assurance program would establish internal performance standards for quality of care and services, cost effectiveness, and process and outcome improvements, and hold ACO providers/suppliers accountable for meeting the performance standards. The program would also have processes and procedures in place to identify and correct poor compliance with such standards and to promote continuous quality improvement.
- The ACO would develop and implement evidence-based medical practice or clinical guidelines and processes for delivering care consistent with the goals of better care for individuals, better health for populations, lower growth in expenditures. The guidelines and care delivery processes would cover diagnoses with significant potential for the ACO to achieve quality and cost improvements, taking into account the circumstances of the individual beneficiary, and could be accomplished, for example, through an integrated electronic health record with clinical decision support. ACO participants and ACO providers/suppliers would have to agree to comply with these guidelines and processes and to be subject to performance evaluations and potential remedial actions.
- The ACO would have an infrastructure, such as information technology, that enables the ACO to collect and evaluate data and provide feedback to the ACO providers/suppliers across the entire organization, including providing information to influence care at the point of care via, for example, shared clinical decision support, feedback from patient experience of care surveys or other internal or external quality and utilization assessments.

As discussed later in the document, and in section II. C. of this proposed rule, it is our expectation that ACO participants and ACO providers/suppliers participating in the ACO would make a commitment to participate in the ACO for not less than 3 years. However, we recognize it will be necessary for the ACO to include a remedial process for ACO participants that fail to comply with the ACO's internal procedures and performance standards, including the possibility of expulsion of significant outliers. We caution that expulsion cannot be used as a mechanism to avoid at-risk beneficiaries.

In order to determine an ACO's compliance with these requirements, as part of the application process, we are proposing that an ACO would submit all of the following:

- ACO documents (for example, participation agreements, employment contracts, and operating policies) that describe the ACO participants' and ACO providers/suppliers' rights and obligations in the ACO, the shared savings that will encourage ACO participants and ACO providers/suppliers to adhere to the quality assurance and improvement program and the evidenced-based clinical guidelines;
- Documents that describe the scope and scale of the quality assurance and clinical integration program, including documents that describe all relevant clinical integration program systems and processes, such as the internal performance standards and the processes for monitoring and evaluating performance;
- Supporting materials documenting the ACO's organization and management structure, including an organizational chart, a list of committees (including names of committee members) and their structures, and job descriptions for senior administrative and clinical leaders; and
- Evidence that the ACO has a board-certified physician as its medical director who is licensed in the State in which the ACO resides and that a principal CMS liaison is identified in its leadership structure.
- Evidence that the governing body includes persons who represent the ACO participants, and that these ACO participants hold at least 75 percent control of the governing body.

Additionally, upon request, the ACO would also be required to provide copies of the following documents:

- Documents effectuating the ACO's formation and operation, including charters, by-laws, articles of incorporation, and partnership, joint venture, management, or asset purchase agreements.
- Descriptions of the remedial processes that will apply when ACO participants and ACO providers/suppliers fail to comply with the ACO's internal procedures and performance standards, including corrective action plans and the circumstances under which expulsion could occur.

In an effort to allow flexibility and innovation, we are proposing that ACOs with innovative leadership and management structures have the opportunity to describe an alternative mechanism for how their leadership and management structure would conduct the activities noted previously in order to achieve the same goals so that they may be given consideration in the application process. That is, an organization that does not have one or more of the following: An executive, officer, manager, or general partner; senior-level medical director; or physician-directed quality assurance and process improvement committee, would be required in its application to describe how the ACO will perform these functions without such leadership. For example, if an ACO does not have a physician-directed quality assurance and process improvement committee, the ACO would need to describe how it plans to oversee an ongoing quality assurance and improvement program as described previously. Additionally, we seek comment on the requirement for

submission of certain documents as noted previously and whether an alternative method could be used to verify compliance with requirements. We request comment on the proposed leadership and management structure and whether the compliance burden associated with these requirements will discourage participation, hinder innovative organizational structures, or whether there are other or alternative leadership and management requirements that would enable these organizations in meeting the three-part aim.

4. Accountability for Beneficiaries

Section 1899(b)(2)(A) of the Act requires participating ACOs to "be willing to become accountable for the quality, cost, and overall care of the Medicare fee-for-service beneficiaries assigned to it." To satisfy this requirement, we are proposing that an ACO executive who has the authority to bind the ACO must certify to the best of his or her knowledge, information, and belief that the ACO participants are willing to become accountable for, and to report to us on, the quality, cost, and overall care of the Medicare FFS beneficiaries assigned to the ACO. The certification would be included as part of the ACO's application and 3-year participation agreement.

5. Agreement Requirement

Section 1899(b)(2)(B) of the Act requires participating ACOs to "enter into an agreement with the Secretary to participate in the program for not less than a 3-year period * * *." For the first round of the Shared Savings Program, we are proposing to limit participation agreements to a 3-year period. We are seeking comments on this proposal and whether a longer agreement period should be considered initially.

If the ACO is approved for participation, we propose that an authorized representative—specifically, an executive who has the ability to bind the ACO, must certify to the best of his or her knowledge, information, and belief that the ACO participants agree to the requirements set forth in the 3-year agreement between the ACO and us—sign a 3-year participation agreement and submit the signed agreement to us. This participation agreement would include an acknowledgment that the ACO agrees to comply with all of the requirements for participation in the Shared Savings Program and that all contracts or arrangements between or among the ACO, ACO participants, ACO providers/suppliers, and other entities furnishing services related to ACO activities must require compliance with the ACO's obligations under the 3-year agreement. The participation agreement would be signed by an authorized representative of the ACO after it has been approved for participation. The ACO would be responsible for providing a copy of the agreement to its ACO participants and ACO providers/suppliers. We are soliciting comment on this proposal, including any additional measures or alternative means that we should consider to fulfill this requirement.

We also recognize that, while having signed a 3-year participation agreement with us in good faith and with the intention to participate in the program for the full 3-year agreement period, there may be instances where an ACO might need to discontinue its participation in the Shared Savings Program prior to the end of the agreement period. As described in section II. H. Monitoring and Termination of ACOs of this proposed rule, we propose to require an ACO to give us 60 days advance written notice of its intention to terminate its agreement to participate in the Shared Savings Program and the effective date of its termination. As described in more detail in section II. F of this proposed rule, we propose the ACO will be subject to a 25 percent withhold of shared savings in order to offset any future losses under the two-sided model. We propose that if an ACO completes its 3-year agreement successfully, we will refund in full any portion of shared savings withheld during the course of the 3-year agreement period that is not needed to offset losses. We further propose that in the event an ACO's 3-year agreement is terminated before the completion of the 3 years, we will retain any portion of shared savings withheld.

Finally, it is our intention that all ACOs, ACO participants, and ACO providers/suppliers with direct or indirect obligations under the Shared Savings Program be subject to the requirements of the agreement between the ACO and CMS and that all certifications submitted on behalf of the ACO in connection with the Shared Savings Program application, agreement, shared savings distribution, as discussed in section II. F. or otherwise extend to all parties with obligations to which the particular certification applies.

We are considering the best way to achieve this end and solicit public comments on this issue.

6. Distribution of Savings

As discussed previously, an ACO must be a legal entity appropriately recognized and authorized to conduct its business under State law, and would be identified by a TIN. We propose to make any shared savings payments directly to the ACO as identified by its TIN. The TIN associated with the ACO's legal entity may, or may not, be enrolled in the Medicare program, unlike the ACO participant TINs that are Medicare-enrolled groups of providers of services and suppliers. Therefore, because the statute contemplates payment directly to the ACO, we are proposing to pay the ACO TIN directly. We acknowledge that this proposal could raise program integrity concerns, because allowing shared savings payments to be made directly to a non-Medicare-enrolled entity would likely impede the program's ability to recoup overpayments as there would be no regular payments that could be offset. This is part of the rationale for the payment withhold described in more detail in section II. F, Shared Savings Determination, as well as the other safeguards for assuring ACO repayment of shared losses described in section II.G.of this proposed rule. We solicit comments on our proposal to make shared savings payments directly to the ACO, as identified by its TIN. In addition, we are soliciting comment on our proposal to make shared savings payments to a non-Medicare-enrolled entity.

While section 1899(b)(2)(C) of the Act requires an ACO to have a formal legal structure that would allow the organization to receive and distribute payments for shared savings to participating providers of services and suppliers, the statute does not establish any requirements for the manner in which shared savings payments are distributed. We have considered whether it would be appropriate, under the broad discretion granted to the Secretary in implementing the Shared Savings Program, to propose criteria for the distribution of shared savings by the ACO. Although we do not believe we have the authority to specify how shared savings must be distributed (so long as the distribution is consistent with all applicable legal requirements), we believe it would be consistent with the purpose and intent of the statute to require the ACO to indicate as part of its application how it plans to use potential shared savings to meet the goals of the program. More specifically, ACOs would have to indicate how potential shared savings would be used to promote accountability for their Medicare population and the coordination of their care as well as how they might be invested in infrastructure

and redesigned care processes for high quality and efficient health care service delivery. Therefore, we propose to require ACOs to provide a description in their application of the criteria they plan to employ for distributing shared savings among ACO participants and ACO providers/suppliers, and how any shared savings will be used to align with the aims of better care for individuals, better health for populations, and lower growth in expenditures. We believe the proposed requirement would achieve the most appropriate balance among objectives for encouraging participation, innovation, and achievement of program while still focusing on the aims of better care for individuals, better health for populations, and lower growth in expenditures. Additionally, it is the intention of this requirement for ACOs to include this description in the application, to both guard against improper financial incentives as well as ensure appropriate beneficiary protections.

7. Sufficient Number of Primary Care Providers and Beneficiaries

Section 1899(b)(2)(D) of the Act requires participating ACOs to "include primary care ACO professionals that are sufficient for the number of Medicare fee-for-service beneficiaries assigned to the ACO * * *" and that at a minimum, "the ACO shall have at least 5,000 such beneficiaries assigned to it * * *" Physician patient panels can vary widely in the number of FFS Medicare beneficiaries served. In section II. C. of this proposed rule, we discuss our proposal to assign beneficiaries to an ACO on the basis of primary care services rendered by physicians with primary care specializations in general practice, internal medicine, family practice, and geriatric medicine. We are proposing that this algorithm will also be used to assign beneficiaries during the baseline years in order to establish a historical per capita cost benchmark against which the ACO would be evaluated during each year of the agreement period. We believe it is reasonable to assume that if by using this algorithm the ACO demonstrates a sufficient number of beneficiaries to fulfill this eligibility requirement for purposes of establishing a benchmark, then the ACO also contains a sufficient number of primary care professionals to provide care to these beneficiaries. It is also reasonable to assume the ACO would continue to approximate this number in each year of the agreement period. Thus, we are proposing that for purposes of eligibility under section 1899(b)(2)(D) of the Act, an ACO would be determined to have a sufficient number of primary care ACO professionals to serve the number of Medicare beneficiaries assigned to it if the number of beneficiaries historically assigned over the three-year benchmarking period using the ACO participant TINs exceeds the 5,000 threshold for each year. We are soliciting comment on this proposal as well as any additional guidance that could be considered for meeting these requirements.

While an ACO could meet the requirements in section 1899(b)(2)(D) of the Act when it applies to participate in the Shared Savings Program, the number of assigned beneficiaries could fall below the 5,000 level due to either significant events, such as when an ACO professional or group of professionals cease to participate in the ACO, or in those instances where the actual number of beneficiaries is close to 5,000 as a result of normal fluctuations in patient populations. The requirements under section 1899(b)(2)(D) of the Act are important with respect both to the sufficiency of the ACO to provide primary care services to its assigned beneficiary population and statistical stability for purposes of calculating per capita expenditures and assessing quality performance. Simply stated, and as described in detail in section II.D. of this proposed rule, as the number of assigned beneficiaries increases, the minimum savings rate (MSR) gets smaller. Conversely, as the number of assigned beneficiaries decreases, the MSR expands thus making it significantly more difficult for an ACO to obtain shared savings. So, retaining 5,000 assigned beneficiaries is important from both the perspective of the capacity of the ACO to provide primary care services to its assigned beneficiary population as well as the ability of the ACO to realize shared savings by exceeding the MSR.

Thus, we considered what action, if any, should be taken in the event the number of beneficiaries falls below 5,000. Specifically, we considered whether an ACO's participation in the program should be terminated or its eligibility for shared savings be deferred if the number of beneficiaries dropped below 5,000. We considered terminating the ACO for falling below 5,000 beneficiaries immediately or after giving the ACO an opportunity to implement a corrective action plan. We have concerns that immediately terminating an ACO or denying it an opportunity to share in savings because its population fell slightly may discourage participation among smaller ACOs. We believe this would be inconsistent with the goals of allowing greater opportunities for broadly transforming the health care delivery system and increasing access to high quality and lower cost care under the Shared Savings Program for Medicare beneficiaries regardless of where they live. Another option would be to take no action if the ACO falls below 5,000 assigned beneficiaries. Taking no action in these instances would be inconsistent with the statutory requirement that an ACO have 5,000 assigned beneficiaries in order to be eligible to participate in the Shared Savings Program and would reduce incentives for smaller provider organizations to affiliate with other providers and suppliers to be successful under the Shared Savings Program. A third option might be to adjust, or scale, the shared savings in those instances where the number of assigned beneficiaries falls below the floor of 5,000 over the course of a performance year. If shared savings are realized, and all other requirements of participation are met, an ACO that falls below the 5,000 assigned beneficiary floor could realize shared savings but at a reduced rate of savings that would parallel the number of beneficiaries assigned to the ACO. Thus, the amount of the incentive payment would be scaled to the number of beneficiaries in the ACO during the performance year. However, since the MSR adjusts with the number of assigned beneficiaries, there is a built-in incentive for ACOs to increase their beneficiary population.

We believe a reasonable compromise would balance the statutory requirements, program incentives, and recognition of expected variation in an ACO's assigned population. Thus, we are proposing that if an ACO's assigned population falls below 5,000 during the course of the agreement period, we would issue a warning and place the ACO on a corrective action plan. The ACO would remain eligible for shared savings for the performance year for which the warning was issued. We further propose that if the ACO fails to meet the eligibility criterion of having more than 5,000 beneficiaries by the completion of the next performance year, the ACO's participation agreement will be terminated and the ACO will not be eligible to share in savings for that year. Thus, for example, if during the first performance year, an ACO's assigned population fell below 5,000, we would issue a warning, notifying the ACO of the variation in their assigned population. The ACO would be placed on a corrective action plan which could include, for example, a plan to add more

primary care providers to the ACO. The ACO would remain eligible to share in savings for the first performance year. However, if the ACO's assigned population had not returned to at least 5,000 by the end of the second performance year, then that ACO's agreement will be terminated and the ACO would not be eligible to share in savings for the second performance year. We also propose to reserve the right to review the status of the ACO while on the corrective action plan and terminate the agreement on the basis that the ACO no longer meets eligibility requirements. We request comment on this proposal and on other potential options for addressing situations where the assigned beneficiary population falls below 5,000 during the course of an agreement period.

8. Required Reporting on Participating ACO Professionals

Section 1899(b)(2)(E) of the Act requires ACOs to "provide the Secretary with such information regarding ACO professionals participating in the ACO as the Secretary determines necessary to support the assignment of Medicare FFS beneficiaries to an ACO, the implementation of quality and other reporting requirements * * *, and the determination of payments for shared savings * * *." As discussed in sections II.B. and II.D. of this proposed rule, we are proposing to define an ACO operationally as a legal entity that is comprised of a group of ACO participants which are in turn defined to mean Medicare-enrolled providers or suppliers, as identified by their TINs. However, TIN level data alone may not be entirely sufficient for a number of purposes in the Shared Savings Program such as implementing our methodology for beneficiary assignment and calculating the quality performance score. Accordingly, to satisfy the requirements under section 1899(b)(2)(E) of the Act, we are proposing that entities applying to participate in the Shared Savings Program must provide not only the TINs of the ACO and the ACO participants, but also a list of national provider identifiers (NPIs) associated with the ACO providers/suppliers, which separately identifies the physicians that provide primary care.

We are also proposing to require an ACO to maintain, update, and annually report to us the TINs of its ACO participants and the NPIs associated with the ACO providers/suppliers. We believe that requiring this information offers the level of transparency needed to implement the Shared Savings Program.

9. Processes To Promote Evidence-Based Medicine, Patient Engagement, Reporting, and Coordination of Care

Section 1899(b)(2) of the Act establishes a number of requirements which ACOs must satisfy in order to be eligible to participate in the Shared Savings Program. Several of these standards deal with how patient care is provided by the ACO, with a focus on processes and methods to: (1) Promote higher quality of care; (2) better coordinate care; and (3) meet the needs and concerns of patients and their families, including effectively engaging patients and their families in medical decision-making. Specifically, section 1899(b)(2)(G) of the Act requires an ACO to "define processes to promote evidence-based medicine and patient engagement, report on quality and cost measures, and coordinate care, such as through the use of telehealth, remote patient monitoring, and other such enabling technologies."

With regard to each of the specific requirements under section 1899(b)(2)(G) of the Act, we have two options. One option is simply to propose to require documentation of an ACO's plans to "define processes to promote evidence-based medicine and patient engagement, report on quality and cost measures, and coordinate care, such as through the use of telehealth, remote patient monitoring, and other such enabling technologies." Under this option, we would not establish any more specific criteria for these requirements. However, we would expect that the required documentation present convincing evidence of concrete and effective plans to satisfy these requirements, by providing specific processes and criteria that the ACO intends to use for promoting, improving, and assessing evidence-based medicine, beneficiary engagement, reporting of quality and cost measures, and coordination of care. Such processes would have to include provisions for internal assessment of cost and quality of care within the ACO, and employ these assessments in continuous improvement of the ACO's care practices.

The other option is to identify specific criteria that we would propose to require ACOs to meet with regard to each of these requirements. For example, with regard to the requirement to promote evidence-based medicine, we could provide a detailed description of evidence-based guidelines for various conditions and diseases for which we would hold ACOs accountable, including specific instructions for how an ACO would demonstrate it is following these guidelines and monitoring compliance among its ACO participants and ACO providers/suppliers. We could also specify a number of conditions for which the ACO would maintain an evidence-based medicine preventive health guidelines program. Similarly, we could identify and require the use of specific decision support tools, patient activation measures, or other patient support tools in order for an ACO to satisfy the requirement for beneficiary engagement.

However, we have concerns that a prescriptive approach would be premature and potentially impede innovation and the goals of this program. Thus, for the requirements under section 1899(b)(2)(G) of the Act, we are proposing that in order to be eligible to participate in the Shared Savings Program, the ACO provide documentation in its application describing its plans to: (1) Promote evidence-based medicine; (2) promote beneficiary engagement; (3) report internally on quality and cost metrics; and (4) coordinate care. We are proposing this option in order to allow ACOs the flexibility to choose the tools for meeting these requirements that are most appropriate for their practitioners and patient populations. Over time, as we learn more about successful strategies in these areas, and as we have more experience assessing specific critical elements for success, the Shared Savings Program eligibility requirements with regard to section 1899(b)(2)(G) of the Act may be revised. We are also specifically soliciting comment on whether more prescriptive criteria may be appropriate for meeting some or all of these requirements under section 1899(b)(2)(G) of the Act for future rulemaking. Later in the document, we discuss the concepts of evidence-based medicine, patient engagement, internal quality and cost reporting, and coordination of care, and describe how Shared Savings Program applicants can establish compliance with the requirements of section 1899(b)(2)(G) of the Act.

a. Processes To Promote Evidence-Based Medicine

As stated previously, section 1899(b)(2)(G) of the Act requires an ACO to "define processes to promote evidence-based medicine * * *." Evidence-based medicine can be generally defined as the application of the best available evidence gained from the scientific method to clinical decision-making. It seeks to assess the strength of evidence of the risks and benefits of treatments (including lack of treatment) and diagnostic tests, and

applies this evidence to the processes of medical decision-making and treatment. In practice, such an approach should involve the establishment and implementation of evidence-based guidelines, based on the best available evidence concerning the effectiveness of medical treatments, at the organizational or institutional level. A genuine evidence-based approach would also involve regularly assessing and updating such guidelines to promote continuous improvement in the quality of care in light of new evidence concerning the effectiveness of medical treatments. We propose that as part of the application, the ACO would describe the evidence-based guidelines it intends to establish, implement, and periodically update.

b. Processes To Promote Patient Engagement

Section 1899(b)(2)(G) of the Act also requires an ACO to "define processes to promote * * * patient engagement." The term "patient engagement" is the active participation of patients and their families in the process of making medical decisions. Patient engagement in decision-making requires consideration not only of the best scientific evidence concerning medical treatment, but also the opportunity for patients and families to assess prospective treatment approaches in the light of their own values and convictions. Measures for promoting patient engagement may include, but are not limited to, the use of decision support tools and shared decision making methods with which the patient can assess the merits of various treatment options in the context of his or her values and convictions. Patient engagement also includes methods for fostering what might be termed "health literacy" in patients and their families. Health literacy is the possession of basic knowledge about maintaining good health, avoiding preventable medical conditions, managing existing conditions, as well as knowledge about how the care system works (for example, the roles of primary care physicians and specialist physicians, the nature and operation of both public and private health insurance, etc.).

We propose that as part of the application, the ACO would describe the patient engagement processes it intends to establish, implement, and periodically update.

c. Processes To Report on Quality and Cost Measures

Section 1899(b)(2)(G) of the Act requires an ACO to "define processes to * * * report on quality and cost measures." Processes that may be used for reporting on quality and cost measures may include, but are not limited to, developing a population health data management capability, or implementing practice and physician level data capabilities with point-of-service (POS) reminder systems to drive improvement in quality and cost outcomes. We would expect ACOs to be able to monitor both costs and quality internally and make appropriate modifications based upon their collection of such information.

We propose that as part of the application, the ACO would describe its process to report internally on quality and cost measures, and how it intends to use that process to respond to the needs of its Medicare population and to make modifications in its care delivery.

d. Processes To Promote Coordination of Care

Finally, section 1899(b)(2)(G) of the Act requires an ACO to "define processes to * * * coordinate care, such as through the use of telehealth, remote patient monitoring, and other such enabling technologies." Coordination of care involves strategies to promote, improve, and assess integration and consistency of care across primary care physicians, specialists, and acute and post-acute providers and suppliers, including methods to manage care throughout an episode of care and during its transitions, such as discharge from a hospital or transfer of care from a primary care physician to a specialist. Compliance with this requirement may involve a range of strategies which may include the following examples:

- A capability to use predictive modeling to anticipate likely care needs.
- Utilization of case managers in primary care offices.
- Having a specific transition of care program that includes clear guidance and instructions for patients, their families, and their caregivers.
- Remote monitoring.
- Telehealth.
- The establishment and use of health information technology, including electronic health records and an electronic health information exchange to enable the provision of a beneficiary's summary of care record during transitions of care both within and outside of the ACO.

The provisions of any free services (telehealth, case managers, etc.) between parties in a position to generate Federal health care program referrals could trigger evaluation under the relevant fraud and abuse laws. Stakeholders interested in this issue may also wish to comment on the joint OIG/CMS notice referenced in section II.I of this proposed rule.

The strategies employed by an ACO to optimize care coordination should not impede the ability of a beneficiary to seek care from providers that are not participating in the ACO, or develop policies to place any restrictions that are not legally required on the exchange of medical records with providers who are not part of the ACO. We are proposing to prohibit the ACO from developing any policies that would restrict a beneficiary's freedom to seek care from providers and suppliers outside of the ACO.

10. Patient-Centeredness Criteria

Section 1899(b)(2)(H) of the Act requires an ACO to "demonstrate to the Secretary that it meets patient-centeredness criteria specified by the Secretary, such as the use of patient and caregiver assessments or the use of individualized care plans." A patient-centered, or person-centered, orientation could be defined as care that incorporates the values (to the extent the informed, individual patient desires it) of transparency, individualization, recognition, respect, dignity, and choice in all matters, without exception, related to one's person, circumstances, and relationships in health care. Patient-centered care should extend not only to the patient but to the family and caregivers of the patient. Patient-centeredness is one of the Institute of Medicine's (IOM's) aims for improvement in health care. In IOM's report "Crossing the Quality Chasm: A New Health System for the 21st Century," providing patient-centered care is defined as "providing care that is respectful of and responsive to individual patient preferences, needs, and values, and ensuring that patient values guide all clinical decisions." (to view IOM's report discussed previously, visit *http://iom.edu/Reports/2001/Crossing-the-Quality-Chasm-A-New-Health-System-for-the-21st-Century.aspx*) The National Partnership for Women and Families suggests the following principles for patient-centered care: (1) Care is comprehensive, coordinated, personalized, and planned; (2) patients' experience of care is routinely assessed and improved; (3) patients and their caregivers are full partners in their care; (4) transitions between settings of care are smooth, safe, effective, and efficient; (5) patients can get care when and where they need it; (6) care is integrated with the community resources patients need to maintain health and wellbeing; and (7) continuous quality improvement and elimination of disparities are top

priorities. (To view the Statement of Debra L. Ness, President, Nat'l Partnership for Women & Families, Senate Finance Committee, Roundtable on Delivery System Reform April 21, 2009 visit *http://www.nationalpartnership.org/site/DocServer/090421_SenateFinanceRoundtableStatement_Ness.pdf?docID=4881*)

The statutory requirement for "patient-centeredness criteria" clearly implies that one goal of the Shared Savings Program is for ACOs to adopt a focus on patient-centeredness that is promoted by the governing body and integrated into practice by leadership and management working with the organization's health care teams. Drawing from the perspectives discussed previously, we believe the following list of proposed patient-centeredness principles should inform the care provided by an ACO participating in the Shared Savings Program:

- Care should be individualized based on the person's unique needs, preferences, values, and priorities.
- Beneficiaries should have access to their own medical records and to clinical knowledge so that they may make informed choices about their care.
- Beneficiaries (and their caregivers and/or family members where applicable) should be encouraged to be partners in care and make choices regarding the care they receive, based on both the medical record and clinical knowledge (that is, evidence-based medicine) provided by their ACO and the beneficiary's individual values.
- Beneficiary and caregiver and/or family experience of care should be routinely assessed and the ACO should seek to improve it where opportunities for improvement are identified.
- Care should be integrated with the community resources beneficiaries require to maintain well-being.
- Transitions in care among providers in the ACO, as well as other providers outside the ACO from whom the beneficiaries may also seek care, should be supported consistent with the patient-centeredness goals of coordinating care and having information follow patients by, for example, developing processes for the electronic exchange of information.

In the light of these principles, we believe the following processes and actions listed later in the document would be necessary to ensure the patient-centered orientation required by section 1899. We propose that an ACO would be considered patient-centered if it has all of the following:

- A beneficiary experience of care survey in place and a description in the ACO application how the ACO will use the results to improve care over time. As discussed in more detail later in the document, and as proposed in section II.E. of this proposed rule, scoring on this survey would help the ACO meet the quality performance standard.
- Patient involvement in ACO governance. As discussed in more detail later in the document, the ACO would be required to have a Medicare beneficiary on the governing board.
- A process for evaluating the health needs of the ACO's assigned population, including consideration of diversity in their patient populations, and a plan to address the needs of their population. As discussed in more detail later in this document, the ACO would be required to describe this process as part of the application and describe how it would consider diversity in its patient population and plans to address its population needs.
- Systems in place to identify high-risk individuals and processes to develop individualized care plans for targeted patient populations, including integration of community resources to address individual needs. This proposal and application requirements are discussed in more detail later in this document.
- A mechanism in place for the coordination of care (for example, via use of enabling technologies or care coordinators). The ACO would be required to describe its mechanism for coordinating care for Medicare beneficiaries. In addition, the ACO should have a process in place (or clear path to develop such a process) to electronically exchange summary of care information when patients transition to another provider or setting of care, both within and outside the ACO, consistent with meaningful use requirements under the EHR Incentive program. The ACO would be required to describe their process or their plan to develop a process to electronically exchange summary of care information during care transitions. Additionally, in section II.E. of this proposed rule, we propose to include care transitions measures as part of the assessment of ACO quality.
- A process in place for communicating clinical knowledge/evidence-based medicine to beneficiaries in a way that is understandable to them. This process should allow for beneficiary engagement and shared decision-making that takes into account the beneficiaries' unique needs, preferences, values, and priorities. The ACO would be required to describe its process, as discussed in section II.E. of this proposed rule, for communicating clinical knowledge/evidence-based medicine and describe how the ACO providers/suppliers will engage the beneficiary in shared decision-making.
- Written standards in place for beneficiary access and communication and a process in place for beneficiaries to access their medical record. As part of its application, the ACO would be required to submit its written standards for beneficiary access and communication. Additionally, the ACO would be required to describe its process for beneficiaries to access their medical record.
- Internal processes in place for measuring clinical or service performance by physicians across the practices, and using these results to improve care and service over time. As described previously, the documents submitted to meet leadership and management criteria related to quality assurance and clinical integration program would satisfy this patient-centeredness criterion.

We believe that this list provides a comprehensive set of criteria for realizing and demonstrating patient-centeredness in the operation of an ACO. Accordingly, we are proposing to require that ACOs demonstrate patient-centeredness as required by the statute by addressing all 8 areas outlined previously. We also considered confining the list of mandatory criteria to only those items specifically mentioned in section 1899(b)(2)(H) of the Act that is, to "the use of patient and caregiver assessments" and "the use of individualized care plans." However, the statute clearly identifies these two items only as examples of patient-centeredness, and specifies that an ACO must be required to demonstrate that it meets patient-centeredness criteria "specified by the Secretary." Thus, we believe the Secretary is required to define and has discretion to specify criteria in addition to the two criteria that are specifically mentioned in the statute.

We note there is substantial overlap and alignment between these patient centeredness criteria as defined by the Secretary in accordance with section 1899(b)(2)(H) of the Act and the processes ACOs are required to define and documents they are required to submit as discussed previously to fulfill eligibility as outlined in section 1899(b)(2)(G) of the Act and 1899(b)(2)(F) of the Act. Therefore, many of the ways an ACO defines certain processes required by statute may also serve to demonstrate it meets patient centeredness criteria as defined by the Secretary, thus reducing the

burden for the ACO in meeting eligibility requirements.

We are soliciting comment on whether there are redundancies in the list of the 8 criteria or other considerations that might justify narrowing the list. We are also interested in whether the patient centeredness criteria as defined by the Secretary are sufficient to ensure that ACOs participating in the Shared Savings Program meet the eligibility requirement to demonstrate patient centeredness or whether there are additional patient centeredness criteria that should be added to our proposed list in order to meet the goals of improving the quality of health care delivery and improving patient satisfaction with their care. Additionally, we seek comment on whether these criteria are burdensome and whether they might create disincentives to participate or make it difficult for small entities to participate in the program.

Later in the document, we discuss 4 of the 8 criteria in detail and solicit comment regarding (a) Implementation of the beneficiary experience of care survey; (b) beneficiary involvement in governance; (c) identification of population health needs and consideration of diversity; and (d) implementation of individualized care plans and integration of community resources.

a. Beneficiary Experience of Care Survey

As discussed previously, we propose that ACOs have a beneficiary experience of care survey in place and that the ACO's application should describe how the ACO will use the survey results to improve care over time. Surveys are important tools for assessing beneficiary experience of care and outcomes. As part of the requirement to implement a beneficiary experience of care survey, we propose to require ACOs to collect and report on measures of beneficiaries' experience of care and we expect ACOs to submit their plan on how they will promote, assess, and continually improve in weak areas identified by the survey.

Many surveys are being used in both the private and public sectors, including the Medicare Health Outcomes Survey used by Medicare Advantage (MA) plans, Consumer Assessment of Healthcare Providers and Systems (CAHPS) survey tools, and Health Resources Services Administration's (HRSA's) Health Center Patient Satisfaction Survey. We are proposing that ACOs be required to use a specified survey that assesses beneficiary experience of care and functional status. As proposed in section II.E. of this proposed rule, scoring on the patient experience of care survey would become part of the assessment of the ACOs quality performance. Specifically, we are proposing that ACOs be required to use the Clinician and Group CAHPS survey. We also propose to require adoption of an appropriate functional status survey module that may be incorporated into the CAHPS survey. The CAHPS Survey is a nationally recognized survey, developed by the Agency for Healthcare Research and Quality (AHRQ), which is widely used across the health care spectrum. The survey is designed to standardized patient questionnaires that can be used to compare results across sponsors and over time, which identifies the issues that are salient to consumers and influence their decisions. Since the ACO must contain primary care ACO professionals but otherwise has flexibility to incorporate other types of ACO participants, we believe the Clinician and Group CAHPS Survey is an appropriate tool to assess beneficiary experience of care and functional status in the ACO. Using this standard and well established survey instrument, we can more easily compare outcomes and beneficiary satisfaction across ACOs, as well as in certain modules in common between ACOs and Medicare FFS and MA plans. It would also help to ensure that survey measures are adequate to meet the program's purposes and that measures employed in the instrument are valid and reliable. However, we recognize that requiring the use of a specific survey instrument would increase the administrative burden of the Shared Savings Program on ACOs who are not currently using the specified instrument. Accordingly, we are soliciting comment on whether other existing survey tools would be more appropriate for ACO quality assessment.

We also considered proposing to allow ACOs to continue using the survey tools with which they are already familiar or of their own choosing at least in the initial stages of the program. Allowing ACOs to employ survey tools of their own choosing would provide maximum flexibility for ACOs, and would be least disruptive to existing ACO initiatives to survey beneficiary experience. However, allowing ACOs to employ survey tools of their own choosing would severely impede our ability to compare beneficiary experience across ACOs. Moreover, in some instances, the instruments selected by ACOs may use measures that are insufficient to meet the program's purposes, or measures which are not valid and reliable. In other instances, it might be that ACOs using more comprehensive survey tools would be unfairly penalized from the perspective of the performance standards in comparison to ACOs using less extensive surveys.

b. Patient Involvement in Governance

Another of the proposed patient-centered criteria discussed previously is the requirement that ACOs provide for patient involvement in their governing processes. We are proposing that, in order to satisfy this criterion, ACOs will be required to demonstrate a partnership with Medicare FFS beneficiaries by having representation by a Medicare beneficiary serviced by the ACO, in the ACO governing body. We believe the best way to demonstrate a patient-centered program is for Medicare beneficiaries to have a voice in the decision making process. Although, there may be concerns or differences in the ability of some ACOs to include a beneficiary on the governing board, given State laws, we are seeking comment on the inclusion of a Medicare beneficiary serviced by the ACO on the governing body. In order to safeguard against any conflicts of interest, any patient(s) included in an ACO's governing body, or an immediate family member, must not have any conflict of interest, and they may not be an ACO provider/supplier within the ACO's network.

We recognize that a requirement for representation by a Medicare beneficiary serviced by the ACO, on an ACO's governing body will not necessarily guarantee outcomes that are in line with the goals of the Shared Savings Program in general or patient-centered criteria in particular. Medicare beneficiary representation on an ACO's governing body may even be relatively ineffectual if Medicare beneficiaries hold relatively few seats on the governing body. Furthermore, such a requirement may pose difficulties for ACOs that already have a governing body and bylaws that do not require or may even prohibit Medicare beneficiary presence, and this requirement may therefore reduce the number of ACOs that participate in the Shared Savings Program, at least in its initial stages. However, we believe it is important to the patient-centered orientation of the Shared Savings Program to provide for beneficiaries to have a voice in ACO governance.

We considered proposing that, instead of requiring direct Medicare beneficiary representation on ACO governing bodies, ACOs could demonstrate a partnership with Medicare FFS

beneficiaries by having a Medicare beneficiary advisory committee or panel. Such a proposal would also serve to indicate the importance of beneficiary engagement in the ACO's activities to improve the quality and efficiency of health care services. It would also provide ACOs with the opportunity to form committees or panels that represent the voices of all of their patient types, including Medicare FFS beneficiaries. In addition, a unified advisory committee voice may, under some circumstances at least, be more effective than, a single beneficiary representative in the ACO governing body in advancing the goal of beneficiary participation in ACO governance. Furthermore, it would avoid requiring existing ACO governing bodies that do not currently have or whose bylaws do not permit Medicare beneficiary representation to revise their bylaws or to forego participation in the Shared Savings Program. However, a pure advisory committee or panel may be an inadequate conduit for Medicare beneficiary participation in ACO governance compared to their presence on the actual decision-making body of the ACO. Presence on the governing body would provide beneficiaries with an active role in the decision-making process and thus give beneficiaries more influence over the ACO's activities. In contrast, as an advisory committee or panel member, the beneficiary's voice provides guidance on the Shared Savings Program ACO's decision-making without the benefit of more active control over ACO activities.

Therefore, we are proposing that ACOs be required to demonstrate a partnership with Medicare FFS beneficiaries and meet patient centeredness criteria by including a Medicare beneficiary serviced by the ACO on the ACO governing body. We are soliciting comment on whether the requirement for beneficiary participation should include a minimum standard for such beneficiary participation on ACO governing bodies (for example, a minimum number of beneficiaries, or a minimum proportion of control over an ACO's governing body.). In addition, we are soliciting comment on the possible role of a Medicare beneficiary advisory panel or committee in promoting the goal of engaging patients in ACO governance. In particular, we seek comment on whether—(1) a Medicare beneficiary advisory panel or committee would be sufficient in and of itself in providing for appropriate patient participation in ACO governance; and (2) establishing Medicare beneficiary advisory panels or committees should be required in addition to requiring patient representation on ACO governing bodies.

We request comment on the proposal to engage in partnership with Medicare beneficiaries. We are specifically interested in whether this requirement will create disincentives for participation among smaller entities.

c. Evaluation of Population Health Needs and Consideration of Diversity

A third proposed patient-centered criterion on which we are seeking comments is the requirement that an ACO has a process for evaluating the health needs of the population, including consideration of diversity in its patient populations, and a plan to address the needs of its populations. Several institutions and associations such as National Committee for Quality Assurance (NCQA) and AHRQ have made recommendations regarding evaluation of population health and diversity. For example, NCQA has developed multicultural health care standards and guidelines which include requirements for collecting of patient information that help the organization understand the composition of the population, providing culturally and linguistically appropriate services, and detecting health care disparities. Other institutions and associations have developed similar guidelines which emphasize promoting cultural sensitivity and addressing disparities through provider/management education and the translation of surveys and health promoting literature distributed by the provider into languages relevant to the provider's population. Establishing partnerships with a State or local health department which performs community health needs assessments and applying these findings to the ACO's population and activities may be another viable option for meeting this criterion.

Accordingly, we propose that, in order to satisfy this patient-centered criterion, ACOs would be required to describe in their application their process for evaluating the health needs of their Medicare population, including consideration of diversity, and a plan to address the needs of their Medicare population.

d. Implementation of Individualized Care Plans and Integration of Community Resources

Finally, we are proposing that ACOs must have systems in place to identify high-risk individuals and processes to develop individualized care plans for targeted patient populations. The plan must be tailored to—(1) The beneficiary's health and psychosocial needs; (2) account for beneficiary preferences and values; and (3) identify community and other resources to support the beneficiary in following the plan. This plan would be voluntary for the beneficiary, privacy protected, and would not be shared with Medicare or the ACO governing body; it would solely be used by the patient and ACO providers/suppliers for care coordination. If applicable, and the beneficiary consents, the care plan should be shared with the caregiver, family, and others involved in the beneficiary's care. We propose that an ACO would be required to have a process in place for developing, updating, and, as appropriate, sharing the beneficiary care plan with others involved in the beneficiary's care, and providing it in a format that is actionable by the beneficiary.

We are requesting comments on our proposal that ACOs be required to demonstrate use of individualized care plans for targeted beneficiary populations in order to be eligible for the Shared Savings Program. In order to satisfy this requirement fully, we propose that the development of such individualized care plans must grow from adherence of a related patient-centeredness criterion, that is, their development should be a result of shared decision-making which fully engages beneficiaries and their families, taking into account their values and preferences in developing a unique plan of care for each individual.

The individualized care plans should include identification of community and other resources to support the beneficiary in following the plan. To this end, we believe that a process for integrating community resources into the ACO is an important part of patient centeredness. A wide variety of organizations, although not necessarily ACO participants, may be considered a community resource, including: Employers, commercial health plans, local businesses, State/local government agencies, local quality improvement organizations or collaboratives (such as health information exchanges). Collaboration with these types of community resources can be an important part of enabling ACOs to take account of the entirety of Medicare beneficiary population's needs relative to their environment. Community stakeholder engagement in an ACO could be explicitly incorporated via community representation on the governing body, by having a community representative on an advisory board, or by other innovative mechanisms.

Individualized plans of care are not only an integral part of providing quality health care to both high-risk patients or patients with multiple chronic conditions, but are equally important in proactively maintaining the health for any beneficiary. For purposes of the application to participate in the Shared Savings Program, we propose that an ACO would be required to submit a description of its individualized care program, along with a sample care plan, and explain how this program is used to promote improved outcomes for, at a minimum, their high-risk and multiple chronic condition patients. In addition, the ACO should describe additional target populations that would benefit from individualized care plans. We also propose that ACOs be required to describe how they will partner with community stakeholders as part of their application. ACOs that have a stakeholder organization serving on their governing body would be deemed to have satisfied this requirement. We request comment on these proposals. We are specifically interested in whether these requirements will create disincentives for participation among smaller entities.

11. ACO Marketing Guidelines

We believe there is a potential for beneficiaries to be misled about Medicare services available from an ACO or about the providers and suppliers from whom they can receive those services. We realize that care coordination is an important component of the Shared Savings Program; however, the potential for shared savings may be an incentive for ACOs, ACO participants, or ACO providers/suppliers to engage in behavior that may confuse or mislead beneficiaries about the Shared Savings Program or their Medicare rights. For example, although it is expected that ACO providers/suppliers participating in an ACO will refer patients to other ACO providers/suppliers in the ACO, we are concerned that beneficiaries may be misled into thinking the ACO is similar to a managed care organization, and that they may only receive services or only certain services from the other participating ACO providers/suppliers.

Although section 1899 of the Act is silent with regard to marketing activities and other forms of beneficiary communications by ACOs, section 1899(b)(2)(H) of the Act requires an ACO to demonstrate "that it meets patient-centeredness criteria." We believe that in order to be truly patient-centered, an ACO must not only provide care coordination that is tailored to the needs of the individual beneficiary, but also avoid engaging in activities that may prevent its assigned beneficiaries from taking advantage of the full range of benefits to which they are entitled under the Medicare FFS program, including the right to choose between healthcare providers and care settings. As a result, issuing beneficiary communications or engaging in marketing activities that may be confusing or misleading would not be patient-centered because these activities restrict the ability of beneficiaries and/or their caregivers to be informed about their health care choices and thus limit the opportunity for beneficiaries to be properly involved in the management of their own care.

Accordingly, we think it would be appropriate and consistent with the purpose and intent of the statute to limit and monitor the use of beneficiary communications specifically related to the ACO operations or functions as well as ACO marketing activities and materials by ACOs to ensure that such communications and marketing by ACOs are used only for appropriate purposes, such as notification that a beneficiary's healthcare provider is participating in the ACO, issuance of any CMS required notices, notification of provider or ACO terminations. This policy will protect Medicare beneficiaries by minimizing the potential that they will be misled or confused by ACO marketing. Additionally, the policy is consistent with marketing provisions used in other Medicare programs such as MA.

We are proposing that all ACO marketing materials, communications, and activities related to the ACO and its participation in the Shared Savings Program, such as mailings, telephone calls or community events, that are used to educate, solicit, notify, or contact Medicare beneficiaries or providers/suppliers regarding the ACO and its participation in the Shared Savings Program, be approved by us before use to protect beneficiaries and to ensure that they are not confusing or misleading. This requirement would also apply to any materials or activities used by ACO participants or ACO providers/suppliers on behalf of the ACO to communicate about the ACO's participation in the Shared Savings Program in any manner to Medicare beneficiaries. In addition, we would want to ensure that materials distributed to beneficiaries do not misrepresent Shared Savings Program policies or suggest that we endorse the ACO, its ACO participants, or its ACO providers/suppliers.

We are further proposing that before any changes can be made to any approved materials, the revised materials must be approved by us before use. Finally, because the failure to comply with these requirements would demonstrate that the ACO does not meet the patient-centeredness criteria and therefore may no longer be eligible to participate in the program, we propose that an ACO that fails to adhere to these requirements may be placed under a corrective action plan or terminated, at our discretion.

For purposes of the Shared Savings Program, we are proposing to define ACO marketing materials, communications, and activities as including, but not limited to, general audience materials such as brochures, advertisements, outreach events, letters to beneficiaries, web pages, mailings, or other activities, conducted by or on behalf of the ACO, or by ACO participants, or ACO providers/suppliers participating in the ACO, or by other individuals on behalf of the ACO or its participating providers and suppliers. If these materials or activities are used to educate, solicit, notify, or contact Medicare beneficiaries or providers and suppliers regarding the ACO and its participation in the Shared Savings Program, they must be approved by us.

We do not believe that the following materials and activities would be subject to our approval: Beneficiary communications that are informational materials, that are customized or limited to a subset of beneficiaries; and materials that do not include information about the ACO or providers in the ACO; materials that cover beneficiary-specific billing and claims issues or other specific individual health related issues; and educational information on specific medical conditions, (for example, flu shot reminders), or referrals, for example, as discussed in section II. C. of this proposed rule, exceptions to the definition of "marketing" under the HIPAA Privacy Rule.

12. Program Integrity Requirements

Section 1899(a)(1)(A) of the Act authorizes the Secretary to specify criteria that ACO participants must meet in order to work together to manage and coordinate care for Medicare FFS beneficiaries through an ACO. Using this authority, we propose several program integrity criteria to protect the Shared Savings Program from fraud and abuse and to ensure that the Shared Savings Program does not become a vehicle for, or increase the potential for, fraud and abuse in other parts of the

Medicare program or in other Federal health care programs.

a. Compliance Plans

We are proposing that an ACO must have a compliance plan that addresses how the ACO will comply with applicable legal requirements. We recognize that the specific design and structure of an effective compliance plan may vary depending on the size and business structure of the ACO. We are proposing that the ACO demonstrate that it has a compliance plan that includes at least the following elements, which are common in the compliance industry: A designated compliance official or individual who is not legal counsel to the ACO and who reports directly to the ACO's governing body; mechanisms for identifying and addressing compliance problems related to the ACO's operations and performance; a method for employees or contractors of the ACO or ACO providers/suppliers to report suspected problems related to the ACO; compliance training of the ACO's employees and contractors; and a requirement to report suspected violations of law to an appropriate law enforcement agency. Nothing in this rule would prevent an ACO from using or building on an existing compliance program, if it has one (or if its ACO participants have programs that can be incorporated). To achieve an effective compliance program, an ACO may also want to consider coordinating its compliance efforts with existing compliance efforts of its ACO providers/suppliers. It is not our intention that an ACO would need to engage in duplicative efforts to meet the compliance program requirement. The goal is for ACOs to have effective compliance mechanisms.

b. Compliance With Program Requirements

We propose that, notwithstanding any relationships that the ACO may have with other entities related to ACO activities, the ACO maintains ultimate responsibility for compliance with all terms and conditions of its agreement with us. We propose to require that all contracts or arrangements between or among the ACO, its ACO participants and ACO providers/suppliers, and other entities furnishing services related to ACO activities require compliance with the obligations under the 3-year agreement, including the document retention and access requirements discussed in section II.H of this proposed rule. We solicit comments on our proposal.

We must ensure the accuracy, completeness, and truthfulness of information submitted to us to determine an organization's eligibility to participate in the Shared Savings Program as an ACO, its compliance with program requirements, its eligibility for shared savings payments, and the amount of any payments owed to or by the ACO. To that end, we propose that an authorized representative of the ACO—specifically, an executive who has the ability to legally bind the ACO—must certify the accuracy, completeness, and truthfulness of information contained in its Shared Savings Program application, 3-year agreement, and submissions of quality data and other information. The certification must be made at the time the application, agreement, and information is submitted.

We further propose that, as a condition of receiving a shared savings payment, an authorized representative with authority to legally bind the ACO must make a written request to us for payment of the shared savings in a document that certifies the ACO's compliance with program requirements as well as the accuracy, completeness, and truthfulness of any information submitted by the ACO the ACO participants, or the ACO providers/suppliers to us, including any quality data or other information or data relied upon by us in determining the ACO's eligibility for, and the amount of, a shared savings payment or the amount owed by the ACO to us. We further propose that, if such data are generated by ACO participants or another individual or entity, or a contractor, or subcontractor of the ACO or the ACO participants, such ACO participant, individual, entity, contractor, or subcontractor must similarly certify the accuracy, completeness, and truthfulness of the data and provide the government with access to such data for audit, evaluation, and inspection.

c. Conflicts of Interest

We are proposing that the ACO governing body have a conflicts of interest policy that applies to members of the governing body. The purpose of this proposal is to ensure that members of the governing body act in the best interests of the ACO and Medicare beneficiaries We propose that the conflicts of interest policy must require members of the governing body to disclose relevant financial interests. Further, the policy must provide a procedure for the ACO to determine whether a conflict of interest exists and set forth a process to address any conflicts that arise. Such a policy would also address remedial action for members of the governing body that fail to comply with the policy. We solicit comments on this proposal, including the scope and content of such a policy.

d. Screening of ACO Applicants

The Medicare program includes substantial screens of enrolling providers and suppliers, including, for example, newly enrolling ACO participants. ACOs will not be subject to those existing screens because they are not enrolling in Medicare. Consistent with our efforts throughout the Medicare program to strengthen provider enrollment standards and encourage compliance with program requirements, we are considering screening ACOs during the Shared Savings Program application process with regard to their program integrity history, including any history of program exclusions or other sanctions and affiliations with individuals or entities that have a history of program integrity issues. ACOs whose screening reveals a history of program integrity issues and/or affiliations with individuals or entities that have a history of program integrity issues may be subject to rejection of their Shared Savings Program applications or the imposition of additional safeguards or assurances against program integrity risks. We solicit comments on the nature and extent of such screening and the screening results that would justify rejection of an application or increased scrutiny.

e. Prohibition on Certain Required Referrals and Cost-Shifting

In section II.D. of this proposed rule, we propose to assign beneficiaries to an ACO after the conclusion of a performance period, but we also indicate that we are considering assigning beneficiaries to an ACO on a prospective basis at the beginning of a performance period. We are concerned that ACOs or ACO participants may offer or be offered inducements to overutilize services or to otherwise increase costs for Medicare or other Federal health care programs with respect to the care of individuals who are not assigned to the ACO under the Shared Savings Program. The risk of such abuse might be heightened if the final rule provides for prospective assignment of beneficiaries. To address the risk of inappropriate cost-shifting within Medicare and other Federal health care programs, we are considering prohibiting ACOs and their ACO participants from conditioning participation in the ACO on referrals of Federal health care program business

that the ACO or its ACO participants know or should know is being provided to beneficiaries who are not assigned to the ACO.

C. Establishing the 3-Year Agreement With the Secretary

1. Options for Start Date of the Performance Year

Section 1899 (b)(2)(B) of the Act, as added by section 3022 of the Affordable Care Act provides that an "ACO shall enter into an agreement with the Secretary to participate in the [Shared Savings Program] for no less than a 3-year period * * *" In establishing the requirement for a minimum 3-year agreement period, the statute does not prescribe a particular application period or specify a start date for ACO agreements. In this section of this proposed rule, we will discuss our proposals for establishing an application period and for setting the start date for the 3-year agreements with ACOs.

We considered several options for establishing start dates, with the corresponding 3-year agreement periods: Annual start dates; semiannual start dates; rolling start dates; and delayed start dates. In our consideration of these options, we attempted to balance the need for maximum flexibility for program applicants with the advantages of establishing a streamlined administrative approach. Adopting an annual application period and start date would create cohorts of ACO applicants, which would be simultaneously evaluated for eligibility to participate in the program. Agreements with ACOs of the same cohort would take effect on the same date each year. This would allow for more streamlined processes around agreement renewal and performance analysis, evaluation and monitoring.

However, under section 1899(a)(1) of the Act, the Secretary must establish the Shared Savings Program by not later than January 1, 2012. Given the short timeframe for implementation of the program and our desire to permit as many qualified ACOs as possible to participate in the first year, we also gave a great deal of consideration to alternative approaches that would provide flexibility to program applicants. For instance, we could allow ACOs to apply on a "rolling" basis in which applications are accepted and evaluated any time of year and the ACO's agreement period would begin after a determination that the eligibility requirements had been met. In this way, applicants could apply throughout the course of the year as they become ready and we could review and approve applications and begin performance periods on a rolling basis.

After exploring the various alternatives, it has become clear that the greatest barrier to any option other than an annual uniform start date relates to appropriate beneficiary assignment, particularly for markets where there may be multiple ACOs. First, if ACO agreements begin more often than once a year, beneficiaries could be assigned to two ACOs for an overlapping period. As discussed in section II.D. of this proposed rule, we propose that beneficiaries will be assigned to ACOs based upon where they receive the plurality of their primary care services. Since the physician associated with the plurality of a beneficiary's primary care services could vary from year to year, having multiple start dates could result in a beneficiary being assigned to multiple ACOs for an overlapping period. This scenario would result in confusion for beneficiaries and the potential for duplicate shared savings payments for care provided to a single beneficiary. Problems with patient assignment may cause unintended consequences for per capita costs, making it difficult to make comparisons of one ACO's performance to another that has a different start date. In addition, adopting multiple start dates within a year would require multiple cycles for application review and approval, calculation of baselines and targets, data sharing, quality reporting, and financial reconciliation, which would impose a significant administrative challenge.

After evaluating the various options for start date, we are proposing to establish an application process with an annual application period during which a cohort of ACOs would be evaluated for eligibility to participate in the Shared Savings Program. We further propose that the performance years be based on the calendar year to be consistent with most CMS payment and quality incentive program cycles. In other words, we propose: (1) To adopt the general requirement that ACO applications must be submitted by a deadline established by us; (2) we will review the applications and approve applications from eligible organizations prior to the end of the calendar year; (3) the requisite 3-year agreement period will begin on the January 1 following approval of an application; and (4) the ACO's performance periods under the agreement will begin on January 1 of each respective year during the agreement period.

However, we are concerned that, in light of the short time frame for implementing the Shared Savings Program in the first year of the program, a January 1 start date might not provide the flexibility necessary to allow all interested ACOs to complete their application packages. Accordingly, we solicit comment on any alternatives to a January 1 start date that would allow the greatest number of qualified organizations to apply to participate in the first year of the program. One specific example of an alternative to a single start date of January 1 for the first year of the Shared Savings Program might be to add an additional start date of July 1 and to allow the agreement period for ACOs with a July 1 start date to be increased to 3.5 years. Under this example, the first performance year of the agreement period would be defined as 18 months in order that all of the agreement periods would synchronize with ACOs entering the program on January 1 of the following year. We envision that if adopted, this alternative would only be available in the first year of the program and for all subsequent years all applications would have to be reviewed and accepted prior to the beginning of the applicable calendar year and all agreements would be for 3 years.

2. Timing and Process for Evaluating Shared Savings

Section 1899(d)(1) of the Act, as added by section 3022 of the Affordable Care Act, provides that an ACO shall be eligible to receive shared savings payments for each year of the agreement period, if the ACO has met the quality performance standards established under section 1899(b)(3) of the Act and has achieved the required percent of savings below its benchmark. However, the statute is silent with respect to when the shared savings determination should be made. Potential ACOs have indicated that they need timely feedback on their performance in order to develop and implement improvements in care delivery. In developing our proposals, we have therefore been attentive to the importance of determining shared savings payments and providing feedback to ACOs on their performance in a timely manner while at the same time not sacrificing the accuracy needed to calculate per capita expenditures.

Our determination of an ACO's eligibility to receive a payment for shared savings will be based upon an analysis of the claims submitted by providers and suppliers for services and supplies furnished to beneficiaries assigned to the ACO. There is an inherent lag between when a service is performed and when a claim is submitted to us for payment. Additionally, there is also a time lag

between when the claim is received by us and when the claim is paid. For this reason, all Medicare service and expenditure data have what can be defined as a claims run-out period. The claims run-out period is the time between when a Medicare-covered service has been furnished to a beneficiary and when the final payment is actually issued for the respective service.

From the perspective of the utilization and expenditure data that would be needed in order to determine an ACO's eligibility to receive shared savings and to provide performance feedback reports, the longer the claim run-out period, the more complete and accurate the utilization and expenditure data would be for any given year. Higher completion percentages are associated with longer run out periods and thus would necessitate a longer delay before we could determine whether an ACO is eligible to receive shared savings and provide performance feedback. Conversely, a lower completion percentage would be associated with a shorter run out period and thus a quicker turnaround for the shared savings determination and for the provision of performance feedback. Based upon historical trends, a 3-month run-out would result in a completion percentage of approximately 98.5 percent for physician services and 98 percent for Part A services. A 6-month run-out of claims data results in a completion percentage of approximately 99.5 percent for physician services and 99 percent for Part A services. Since neither a 3-month nor a 6-month run-out of claims data would offer complete calendar year utilization and expenditure data, we would have to work with our Office of the Actuary to determine if the calculation of a completion percentage is warranted. If determined necessary, the completion percentage would be applied to ensure that the shared savings determination reflects the full costs of care furnished to assigned beneficiaries during a given calendar year. Thus, we must balance the need to ensure accurate and complete claims data are used to determine shared savings with the need to provide timely feedback to ACOs participating in the Shared Savings Program. Additionally, regardless of whether we use a 3-month or 6-month claims run-out period, we are concerned that some claims (for example, high cost claims) may be filed after the claims run-out period which would affect the accuracy of the amount of the shared savings payment. We are considering, and seek comment on, ways to address this issue, including applying an adjustment factor determined by CMS actuaries to account for incomplete claims, termination of the ACO's agreement with us for ACOs found to be holding claims back, or attributing claims submitted after the run-out period to the following performance period.

We propose using a 6-month claims run-out to calculate the benchmark and per capita expenditures for the performance year. A 6-month claims run-out will allow us to more accurately determine the per capita expenditures associated with each respective ACO. Although the use of a 6-month claims run out will delay the computation of shared savings payments and the provision of feedback to participating ACOs, the trade-off for a more accurate calculation of per capita costs is warranted. More accurately defining the per capita expenditures will allow us to share the appropriate amount of savings or alternatively, if no shared savings are realized, it will allow the ACO to focus on potential areas for improvement. However, we seek comment on whether there are additional considerations that might make a 3-month claims run-out more appropriate.

3. Data Sharing

Under section 1899(b)(2)(A) of the Act, as added by section 3022 of the Affordable Care Act, an ACO must, "be willing to become accountable for the quality, cost, and overall care of the Medicare fee-for-service beneficiaries assigned to it." Section 1899 of the Act does not address what data, if any, we should make available to ACOs on their assigned beneficiary populations to support them in evaluating the performance of ACO participants and ACO providers/suppliers, conducting quality assessment and improvement activities, and conducting population-based activities relating to improved health. In agreeing to become accountable for a group of Medicare beneficiaries, we generally expect that participating ACOs are able to, or are working toward, independently identifying and producing the data they believe are necessary to best evaluate the health needs of their patient population, improve health outcomes, monitor provider/supplier quality of care and patient experience of care, and produce efficiencies in utilization of services. Moreover, this ability to self-manage is a critical skill for each ACO to develop, leading to an understanding of the unique patient population that it serves.

However, we also recognize that while an ACO typically should have, or is moving toward having, complete information for the services it provides to or coordinates on behalf of its FFS beneficiary population, it may not have complete information on a FFS beneficiary who, for example, has chosen to receive services, medications or supplies from providers of services and suppliers outside its organization. We believe that providing ACOs with an opportunity to request CMS claims data, as described later in this proposed rule, on their potentially assigned beneficiary population would allow them to understand the totality of care provided to beneficiaries assigned to them by identifying the services and supplies that fee-for-service beneficiaries receive during the performance year both within and outside of the ACO. We believe that access to this data would promote coordinated care and a better understanding of the population served by the ACO with resulting positive impacts on both the quality and efficiency of ease of delivered. ACOs represent a positive step toward transforming the current health care system and we want to ensure that participating organizations have access to information that will assist them in achieving both improvements in the quality of care and a better understanding of the population served by the ACO while simultaneously lowering the growth in health care costs.

We could provide data to ACOs in different forms with a focus on different levels of information, for example, aggregated population level data or beneficiary identifiable data. These data could be combined with data collected within the ACO. For example, our data could be combined with provider level data compiled within the ACO. Combining aggregate and beneficiary identifiable data as well as provider level and other internally generated data would provide ACOs with a more complete picture about the care their assigned beneficiaries receive both within and outside the ACO, their ACO participants and ACO providers/suppliers' patterns of care, and could be used to assess their performance relative to their previous years' performance. With this information, in accordance with established privacy and security protections, ACOs would be able to identify how its ACO participants and ACO providers/suppliers measure up to benchmarks and targets, how they perform in relation to peers internally, and identify which categories of beneficiaries would benefit most from care coordination and other patient-centered approaches. For a more complete discussion of the requirements

associated with the sharing of internally generated data, please see section II.B. of this proposed rule

4. Sharing Aggregate Data

Because we believe that ACOs have the potential to significantly improve the quality of care provided to Medicare beneficiaries while improving the efficiency and cost-effectiveness of that care, we believe that, where feasible, we should provide information to help ACOs improve the quality of care, improve the health of their beneficiary population, and create efficiencies within their systems. One possible approach is to provide aggregated data on beneficiary use of health care services. An ACO should be able to use aggregated data reports on its assigned or potentially assigned beneficiary population to monitor, understand, and manage its utilization and expenditure patterns as well as to develop, target, and implement quality improvement programs and initiatives. For example, if data shows that an ACO's beneficiary population had a high rate of hospital readmissions, the ACO could consider the need for actions to improve discharge coordination among its attending physicians, hospitals, and post-acute care providers or to improve access to primary care clinics. Similarly, an analysis of aggregated Part D data that shows beneficiaries were not filling their prescriptions could lead to interventions applicable to all beneficiaries designed to assess and develop strategies to overcome difficulties in filling prescriptions. Likewise, aggregated data could show a relatively high incidence within the ACO's beneficiary population of certain types of procedures relative to national benchmarks, potentially prompting an ACO to further explore and examine the appropriateness of its ACO participants' and ACO providers/suppliers' practice patterns by using provider-level data.

In the PGP demonstration, we provided several types of aggregate data to the participating group practices. We generated an annual profile report that provided the following information:

- Financial performance including number of patients seen, number of patients assigned, per capita expenditures, risk score, benchmark, total assigned beneficiary expenditures, minimum savings amount, shareable savings, and annual performance payment.
- Quality performance scores, including numerator, denominator, and rate for each measure along with the target benchmark for each measure.
- Aggregated metrics on the assigned beneficiary population, including a breakdown of the population into high risk score beneficiaries, beneficiaries with 1 or more hospitalizations, and chronic disease subpopulations such as patients with congestive heart failure, coronary artery disease, hypertension, chronic obstructive pulmonary disease, and diabetes.
- The number of patients overall and in each subpopulation with emergency department visits, hospital discharges, physician visits and their corresponding rate for the assigned population.

The feedback received on the PGP demonstration suggested that making these data available was helpful to the participating practices; they noted the benefits of having aggregate data that were more easily digestible compared to "data dumps" comprised of claims-based data.

In general, by making similar types of aggregate, data available to ACOs participating in the Shared Savings Program, we believe ACOs would have a more complete picture of the services rendered to their assigned FFS beneficiaries, which would allow the pursuit of a variety of strategies to streamline and consolidate care provision in a way that enhances quality and slows the growth in Medicare expenditures for their assigned beneficiary population. Thus, providing aggregated Medicare data reports to ACOs in the beginning of the program may be especially helpful to ACOs as they identify priority areas of care upon which to focus. Accordingly, similar to the PGP demonstration, we propose to provide aggregate data reports which would include, when available, aggregated metrics on the assigned beneficiary population, and beneficiary utilization data at the start of the agreement period based on historical data used to calculate the benchmark. We further propose to include these data in conjunction with the yearly financial and quality performance reports. Additionally, we propose to provide quarterly aggregate data reports to ACOs based upon the most recent 12 months of data from potentially assigned beneficiaries. We request comments on these proposals as well as the kinds of aggregate data and frequency of data reports that would be most helpful to the ACO's efforts in coordinating care, improving health, and producing efficiencies.

5. Identification of Historically Assigned Beneficiaries

Based upon feedback from the PGP demonstration, the RFI comments on the Shared Savings Program, and Shared Savings Program Open Door Forums, we propose to make certain limited beneficiary identifiable data available at the beginning of the first performance year. In addition to sharing aggregated data reports based on the ACO's historically assigned beneficiary population, we believe the ACO would benefit from understanding which of their fee-for-service beneficiaries were used to generate the aggregated data reports. Accordingly, we propose to disclose the name, date of birth (DOB), sex and Health Insurance Claim Number (HIC) of the historically assigned beneficiary population. We believe that knowing these identifiers would be useful to the ACO in two ways: First, the ACO providers could use the information to identify the beneficiaries, review their records, and identify care processes that may need to change. For example, the ACO might look at whether an inability to get a timely clinic appointment resulted in an avoidable emergency room visit for a particular patient. Second, experience with the PGP demonstration has suggested that a high percentage of historically assigned patients will continue to receive care from the ACO participants and ACO providers/suppliers. Knowing individuals who have been assigned in the past would help the ACO participants to identify individuals who may benefit from improved care coordination strategies going forward.

Providing a list of historically assigned patients to the ACO may also raise concerns. In section II.D. of this proposed rule, we have proposed to assign beneficiaries to the ACO retrospectively. One reason for this is that we believe that the ACO should be evaluated on the quality and cost of care furnished to those beneficiaries who actually chose to receive care from ACO participants during the course of each performance year. Another reason for retrospective assignment is to encourage the ACO to redesign its care processes for all Medicare FFS beneficiaries, not just for the subset of beneficiaries upon whom the ACO is being evaluated. We recognize that providing a list of historically assigned beneficiaries may provide an opportunity for the ACO to identify and avoid at-risk beneficiaries that appear on the list so that the costs of these beneficiaries do not appear in the calculation of the ACO's actual expenditures during a performance year. We are addressing this concern through the proposal described in section II.H. of this proposed rule, that takes steps to ensure ACOs do not avoid at-risk beneficiaries.

Furthermore, we recognize that there are a number of issues and sensitivities surrounding the disclosure of

individually-identifiable (patient-specific) health information, and note that a number of laws place constraints on the sharing of individually identifiable health information. For example, section 1106 of the Act generally bars the disclosure of information collected under the Act without consent unless a law (statute or regulation) permits for the disclosure. In this instance, the HIPAA Privacy Rule permits that legal authority and provides for this proposed disclosure of individually identifiable health information by us.

Under the HIPAA Privacy Rule, covered entities (defined as health care plans, providers that conduct covered transactions, and health care clearinghouses) are barred from using or disclosing individually identifiable health information (called "protected health information" or PHI) in a manner that is not explicitly permitted or required under the HIPAA Privacy Rule. When another entity conducts a function or activity involving the use or disclosure of individually identifiable health information on behalf of a covered entity, that entity is a business associate of the covered entity. (45 CFR 160.103). Under the HIPAA Privacy Rule, a covered entity may disclose PHI to business associates if it obtains "satisfactory assurances that the business associate will appropriately safeguard the information" (45 CFR 164.502(e)). These satisfactory assurances generally take the form of contractual obligations to protect the data as the covered entity is required to do under the HIPAA Privacy Rule. Any use or disclosure of PHI that a covered entity can make under the HIPAA Privacy Rule can also be performed on its behalf by a business associate if the use or disclosure is authorized in the contract between the covered entity and the business associate.

The Medicare FFS program, a "health plan" function of the Department, is subject to the HIPAA Privacy Rule limitations on the disclosure of PHI. The ACO participants and ACO providers/suppliers are also covered entities, provided they are health care providers as defined by 45 CFR 160.103 and they or their agents electronically engage in one or more HIPAA standard transactions, such as for claims, eligibility or enrollment transactions. Similarly, an ACO may itself be a HIPAA covered entity if it is a health care provider that conducts such transactions. Alternatively, based on their work on behalf of ACO participants and ACO providers/suppliers in conducting quality assessment and improvement activities, the ACOs will qualify as the business associates of their covered entity ACO participants and ACO providers/suppliers.

In light of these relationships, the proposed disclosure of the four identifiers would be permitted by the HIPAA Privacy Rule under the provisions that permit disclosures of PHI for "health care operations" purposes. Under those provisions, a covered entity is permitted to disclose PHI to another covered entity for the recipient's health care operations purposes if both covered entities have or had a relationship with the subject of the PHI to be disclosed (which is true here), the PHI pertains to that relationship (which is also true here) and the recipient will use the PHI for a "health care operations" function that falls within the first two paragraphs of the definition of "health care operations" in the HIPAA Privacy Rule. (45 CFR 164.506(c)(4)). The first paragraph of the definition of health care operations includes "population-based activities relating to improving health or reducing health costs, protocol development, case management and care coordination" (45 CFR 164.501). We believe that this provision is extensive enough to cover the uses we would expect an ACO to make of the identifying data elements for the historically assigned patients. In coming to this conclusion, we recognize that an individual's authorization is generally required before using or disclosing PHI for marketing purposes, 45 CFR 164.508, but we also note that both those ACOs acting as a covered entity (as opposed to business associates) and those ACOs acting on behalf of covered entity ACO participants and ACO providers/suppliers as business associates will be able to use the four data elements to communicate with individuals on the list to describe available services and for case management and care coordination purposes under the exceptions to the definition of "marketing" under the HIPAA Privacy Rule, 45 CFR 164.501.

Furthermore, when using or disclosing PHI, or when requesting this information from another covered entity, covered entities must make "reasonable efforts to limit" the information that is used, disclosed or requested the "minimum necessary" to accomplish the intended purpose of the use, disclosure or request, 45 CFR 164.502(b). We believe that the provision of the four proposed data elements would constitute the minimum data necessary to accomplish the Shared Savings Program goals of the ACO.

The Privacy Act of 1974 also places limits on agency data disclosures. The Privacy Act is a Federal withholding statute. It applies when the Federal government maintains a system of records by which information about individuals is retrieved by use of the individual's personal identifiers (names, Social Security numbers, or any other codes or identifiers that are assigned to the individual). The Privacy Act generally prohibits disclosure of information from a system of records to any third party without the prior written consent of the individual to whom the records apply, 5 U.S.C. 552a(b). "Routine uses" are an exception to this general principle. A routine use is a disclosure outside of the agency that is compatible with the purpose for which the data was collected. Routine uses are established by means of a publication in the **Federal Register** about the applicable system of records describing to whom the disclosure will be made and the purpose for the disclosure. We believe that the proposed data disclosures are consistent with the purpose for which the data discussed in this rule was collected, and thus, should not run afoul of the Privacy Act, provided we ensure that an appropriate Privacy Act system of records "routine use" is in place prior to making any disclosures.

Therefore, at the beginning of the agreement period, at the request of the ACO, we are proposing to provide the ACO with a list of beneficiary names, date of birth, sex, and HICN derived from the assignment algorithm used to generate the 3-year benchmark. As discussed in section II.B. of this proposed rule, these are beneficiaries who received the plurality of primary care services from primary care physicians who are ACO participants. We seek comment on this proposal and on whether and how this information would be beneficial to the goals of improved care coordination and improving care delivery for the ACO's assigned beneficiary population.

6. Sharing Beneficiary-Identifiable Claims Data

While the availability of aggregate beneficiary information and the identification of the beneficiaries used to determine the benchmark should assist ACOs in the overall redesign of care processes and coordination of care for their assigned beneficiary populations, we believe that more complete beneficiary-identifiable information would enable practitioners in an ACO to better coordinate and target care strategies towards the individual beneficiaries who may

ultimately be assigned to them. For example, knowing which beneficiaries have frequent emergency department visits could help the ACO develop systems to ensure these beneficiaries have timely access to office-based care.

The PGP demonstration provided beneficiary identifiable claims data to the participating sites but the beneficiary identifiable claims data that was provided was the previous year's historical data on those beneficiaries that might be assigned to the site. The feedback we received from the PGP demonstration was that the historical beneficiary identifiable claims data was useful in some instances but that current year beneficiary claims data would be preferred and result in a more proactive approach to coordinating care. Through comments on the November 17, 2010 RFI, open door forums, and other venues, stakeholders have expressed the importance of timely data on their patient population. They submit that they will need detailed data for their patients so they can establish baseline levels of utilization and patient morbidity, identify key beneficiaries and subpopulations for proactive care coordination efforts, and track their progress against defined performance measures. These data are especially important for ACOs made up of small and individual practices that may not have fully developed information technology systems. Additionally, stakeholders have expressed a desire to receive updated beneficiary identifiable claims data on either a monthly or quarterly basis.

For these reasons we believe sharing beneficiary identifiable claims data with ACOs will assist them in improving care for individuals, improving health of their population, and reducing the growth in expenditures for their assigned beneficiary population. However, there are clear legal and practical limitations on how useful these CMS claims data may be to an ACO. For example, providers have said that they would like to know when their patients are admitted to the hospital in "real time". We are not able to provide this type of data since we generally only become aware of a hospital admission at the time of discharge when the hospital bills us for the service. So, there will always be a claims lag that will make our data less useful for "real time" responses. Unlike claims data, real time information may be more readily available through development and use of an interoperable electronic health record or participation in local/regional health information exchanges, or through more effective coordination with admitting and discharging personnel in hospitals that the ACO's patients utilize, something that is consistent with the overall purpose and intent of the Shared Savings Program (see Section II.B. of this proposed rule). Moreover, unlike MA plans, under the Shared Savings Program, freedom of choice for FFS beneficiaries is retained, which means that a full analysis of the beneficiary population cared for by the ACO during the course of the performance year can only be performed retrospectively.

It should also be noted that 42 U.S.C. 290dd–2 and implementing regulations at 42 CFR part 2 restrict the disclosure of patient records by Federally conducted or assisted substance abuse programs, except as expressly authorized. The law states that "records of the identity, diagnosis, prognosis, or treatment of any patient which are maintained in connection with the performance of any program or activity relating to substance abuse education, prevention, training, treatment, rehabilitation, or research, which is conducted, regulated, or directly or indirectly assisted by any department or agency of the United States shall * * * be confidential." Such data may be disclosed only with the prior written consent of the patient, or as otherwise provided in the statute and regulations. Consistent with this requirement, claims containing this specifically protected information would not be included in any beneficiary identifiable claims data shared with ACOs.

As discussed later in the document in more detail, we are proposing to give the ACO the opportunity to request certain beneficiary identifiable claims data on a monthly basis, in compliance with applicable laws, in the form of a standardized data set about the beneficiaries currently being served by the ACO participants and ACO providers/suppliers. We propose to limit the beneficiaries covered by such data sets to those who have received a service from a primary care physician participating in the ACO during the performance year, and who have not opted out of having us share their claims data with the ACO. In order to obtain beneficiary information that is subject to 42 CFR 290dd, the individual must have provided his or her prior written consent. Furthermore, we also propose to limit the content of this data set to the minimum data necessary for the ACO to effectively coordinate care of its patient population.

As noted previously, there are limitations on the content and timeliness of data that we can share with an ACO. If an ACO chooses to request beneficiary identifiable claims data as part of the application process, we propose that the ACO will be required to explain how it intends to use these data to evaluate the performance of ACO participants and ACO providers/suppliers, conduct quality assessment and improvement activities, and conduct population-based activities to improve the health of its assigned beneficiary population. If an ACO does not choose to request these data at the time of its application, it will be required to submit a formal request for data during the agreement period that includes a description of how it intends to use the requested data for the purposes noted previously. We solicit comment on these proposals.

Additionally, when an ACO is accepted to participate in the Shared Savings Program, we propose to require ACOs to enter into a Data Use Agreement (DUA) prior to receipt of any beneficiary identifiable claims data. Under the DUA, the ACO would be prohibited from sharing the Medicare claims data that we provide through the Shared Savings Program with anyone outside the ACO. In addition, we propose to require in the DUA that the ACO agree not to use or disclose the claims data obtained under the DUA in a manner in which a HIPAA covered entity could not, without violating the HIPAA Privacy Rule. We propose to make compliance with the DUA a condition of the ACO's participation in the Shared Savings Program—non-compliance with this requirement would result in the ACO no longer being eligible to receive data, and could lead to termination from the Shared Savings Program or additional sanctions and penalties available under the law. For example, under the Privacy Act, any "person who knowingly and willfully requests or obtains any record concerning an individual from an agency under false pretenses shall be guilty of a misdemeanor and fined not more than $5,000" 5 U.S.C. 552a(i)(3). In those instances where an ACO does not choose to request the data at the time of their application, the ACO will be required to submit a formal request for data during the agreement period. We propose that the ACO would be required to certify compliance with the DUA in the same manner in which prospective ACOs did in the original application process. We solicit comment on these proposals.

a. Legal Authority To Disclose Beneficiary-Identifiable Claims Data to ACOs

As noted previously, section 1106 of the Act generally bars the disclosure of information absent patient authorization

that is collected under the Act unless a law (statute or regulation) provides for disclosure. Once again, we believe that the HIPAA Privacy Rule permits disclosure for purposes of sharing Medicare Part A and B claims data with ACOs participating in the Shared Savings Program. Similarly, we believe the regulations governing the sharing of Part D data would permit us to share information regarding prescription drug claims with ACOs. We also believe that the proposed disclosures of claims data under Parts A, B, and D are consistent with the purposes for which the data were collected, and thus, for the reasons discussed previously would be permitted under the Privacy Act if we ensure that an appropriate Privacy Act System of Records "routine use" is in place prior to making any disclosures.

(1) Sharing Data Related to Medicare Parts A and B

As discussed in section II.B. of this proposed rule, the ACOs are tasked with working with ACO participants and ACO providers/suppliers to evaluate their performance, conduct quality assessment and improvement activities, and conduct population-based activities relating to improved health for their assigned beneficiary population. When done by or on behalf of a covered entity, these are covered functions and activities that would qualify as "health care operations" under the first and second paragraphs of the definition of health care operations at 45 CFR 164.501. These activities are done by the ACOs either on their own behalf as covered entities, or on behalf of their covered entity ACO participants and ACO providers/suppliers, in which case the ACOs would be the business associate of its ACO participants and ACO providers/suppliers.

The proposed disclosure of Part A and B claims data would be permitted by the HIPAA Privacy Rule provisions governing disclosures for "health care operations." As discussed previously in the context of our proposed disclosure of the four data elements about the historically assigned beneficiary population, a covered entity is permitted to disclose PHI to another covered entity for the recipient's health care operations if both covered entities have or had a relationship with the subject of the records to be disclosed (which is true here), the records pertain to that relationship (which is also true here) and the recipient plans to use the records for a "health care operations" function that falls within the first two paragraphs of the definition of "health care operations" in the HIPAA Privacy Rule. 45 CFR 164.506(c)(4). The first two paragraphs of the definition of health care operations include a covered entity or its business associate evaluating a provider's or supplier's performance, conducting quality assessment and improvement activities, and conducting population-based activities relating to improved health. 45 CFR 164.501. We believe that these provisions are extensive enough to cover the uses we would expect an ACO to make of the Parts A and B claims data set that we are proposing to make available to them. Thus, we believe that there is authority for us to disclose to an ACO, as the business associate of the covered entity, the minimum Medicare Parts A and B data necessary to allow ACOs to conduct the health care operation activities outlined previously.

Accordingly, barring a beneficiary requesting to opt-out of having his or her information shared as described later in the document, and subject to applicable confidentiality laws, we are proposing to make Part A and Part B data about patients who have had a visit with a primary care physicians participation in the ACO during the performance year available upon request to participating ACOs this data would be used for the purposes of aiding the ACO as it evaluates the performance of ACO participants and ACO providers/suppliers, conducts quality assessment and improvement activities, and conducting population-based activities relating to improved health. In doing so, we will only disclose the minimum data necessary to accomplish these purposes in accordance with the requirements of the HIPAA Privacy Rule. We believe that the minimum necessary Parts A and B data elements would include data elements such as: Procedure code, diagnosis code, beneficiary ID; date of birth; gender; and, if applicable, date of death; claim ID; the from and thru dates of service; the provider or supplier ID; and the claim payment type.

As discussed previously, we will not disclose any patient information related to alcohol and substance abuse that is subject to 42 CFR 290dd without the patient's written consent.

Similar to the process by which ACOs can receive the four beneficiary identifiable data points, under this proposal, in order to receive data, ACOs would be required to attest in either their initial application or in their subsequent formal request for data if they failed to request data in the application stage, that; (1) They are a covered entity or a business associate of covered entity ACO participants and ACO suppliers/providers under the Shared Savings Program; (2) their business associate agreement with these ACO participants and ACO providers/suppliers authorizes them to seek PHI on behalf of the ACO participants and ACO providers/suppliers for one of the health care operations purposes laid out previously; (3) their request reflects the minimum data necessary to do that health care operations work; and (4) that their use of these requested data would be limited to the Shared Savings Program activities related to one or more of the health care operations purposes laid out previously or (1) They are a HIPAA covered entity; (2) they are requesting the claims data about their own patients for one of the health care operations purposes laid out previously; (3) their request reflects the minimum data necessary to do that health care operations work; and (4) that their use of these requested data would be limited to the Shared Savings Program activities related to one or more of the health care operations purposes laid out previously.

(2) Sharing Data Related to Medicare Part D

Beneficiary identifiable Medicare prescription drug information could also be beneficial to ACOs for improving the care coordination of their patient population. Having a complete picture, for example, of the beneficiary's medication regimen can assist in avoiding duplication or adverse interactions among medications.

We issued a final rule in May of 2008 authorizing the Secretary to recollect Part D claims data that were originally collected for Part D payment purposes for research, analysis, reporting, and public health functions (73 FR 30664). In that final rule, we noted our intent to use the data for a wide variety of purposes including "supporting care coordination and disease management programs," and "supporting quality improvement and performance measurement activities." (42 CFR 423.505(f)(3)(v), (vi)). We also expressed our view that "it is in the interest of public health to share the information collected…with entities outside of CMS for legitimate research, or in cases of other governmental agencies, for purposes consistent with their mission." (73 FR 30666). Accordingly, the regulations specified when data would be shared with outside entities, such as other government agencies, and external entities, including researchers.

The Part D data rule did not expressly address the question of whether Part D data could be shared with external entities, such as ACOs, for purposes other than research. However, in the rule, we noted that sharing Part D claims data, in addition to Parts A and B data, could have salutary effects on

the evaluation and functioning of the Medicare programs as well as improving the clinical care furnished to beneficiaries. Furthermore, the rule explicitly contemplated the use of Part D data to support care coordination and disease management programs, as well as quality improvement and performance measurement activities, which are central to the Shared Savings Program and its success.

We believe that ACOs participating in the Shared Savings Program would use information on prescription drug use in order to improve the quality of care furnished to their assigned beneficiaries and to enhance care coordination for these beneficiaries. As a result, although the Part D data rule did not expressly address the question of whether Part D data could be shared with external entities for purposes other than research, we believe that the release of Part D claims data to ACOs for the purpose of supporting care coordination, quality improvement, and performance measurement activities, would be consistent with the purposes outlined in the Part D data rule. The Part D data will be released in accordance with the requirements outlined in the regulations at 42 CFR 423.505(m)(1). As a result, certain data elements may be unavailable or available only in an aggregated format.

Accordingly, consistent with the regulations governing the release of Part D data, we propose to provide ACOs with the minimum Part D data necessary to permit the ACO to undertake evaluation of the performance of ACO participants and ACO providers/suppliers, conduct quality assessment and improvement activities with and on behalf of the ACO participants and ACO providers/suppliers, and conduct population-based activities relating to improved health for Medicare beneficiaries who have a primary care visit with a primary care physician used to assign patients to the ACO during a performance year. We propose that the minimum data elements necessary to perform these functions could include data elements such as: beneficiary ID, prescriber ID, drug service date, drug product service ID, and indication if the drug is on the formulary.

a. Beneficiary Opportunity To Opt-Out of Claims Data Sharing

Although we have the legal authority within the limits described previously to share Medicare claims data with ACOs without the consent of the patients, and while we believe that these data will provide a valuable tool to assist ACOs in evaluating the performance of ACO participants and ACO providers/suppliers, conducting quality assessment and improvement activities, and conducting population-based activities relating to improved health, we nevertheless believe that beneficiaries should be notified of, and have meaningful control over who, has access to their personal health information for purposes of the Shared Savings Program. Thus, we are proposing to require that, as part of its broader activities to notify patients at the point of care that their provider or supplier is participating in an ACO, as discussed in Section II. D., the ACO must also inform beneficiaries of its ability to request claims data about them if they do not object. We believe that this notification will give the beneficiaries meaningful choice as to whether this information may be shared. The only exceptions to this advanced notice would be the initial four data points (the beneficiary's name, date of birth, sex, and HICN) that we will provide to ACOs for individuals in the 3-year data set used to determine the ACO's benchmark.

We believe that to be meaningful, the opportunity to make a choice as to whether their information may be shared would: (1) Allow the individual advance notice and time to make a decision; (2) be accompanied by adequate information about the benefits and risks of making their data available for the proposed uses; (3) not compel consent; and (4) not use the choice to permit their information to be shared for discriminatory purposes.

We considered two alternative mechanisms for implementing meaningful beneficiary choice: having beneficiaries affirmatively choose to permit us to share their protected health information through the signing of a consent or authorization ("opt-in"); and sharing protected health information with the ACO unless beneficiaries indicate that they choose not to have this information shared ("opt-out").

A requirement of patient choice about whether to participate in a system of information exchange, whether opt-in or opt-out should provide an excellent opportunity for providers to engage patients in true patient-centered care, creating a strong incentive for an ACO and its ACO participants and ACO providers/suppliers to forge a positive relationship with each beneficiary. Consumers have consistently expressed strong support for the implementation and exchange of electronic health information, believing that these technologies have the potential to improve care coordination, reduce paperwork, and reduce the number of unnecessary and repeated tests and procedures.[8] Successful electronic health information exchange systems have engaged consumers, physicians and other stakeholders at an early stage to ensure that choice is integrated into the architecture of the systems.[9]

Many organizations engaging in health information exchange have selected opt-in models for patient consent. For example, the Massachusetts eHealth Collaborative (MAeHC) achieved an average of 90 percent participation in three pilot communities using an opt-in system. The New York Clinical Information Exchange (NYCLIX) has also realized high patient participation rates by using an opt-in method of patient choice.[10] An opt-in method has several advantages. Consumers have consistently expressed a desire that their consent should be sought before their health information may be shared.[11] Obtaining affirmative written permission would also provide documentation of the beneficiary's choice.

However, many organizations find that an opt-in approach significantly reduces both provider and beneficiary participation for administrative reasons, and not because patients are making an active choice not to participate.[12] Where

[8] See Schneider, S. et al. "Consumer Engagement in Developing Electronic Health Information System." Prepared for: *Agency for Healthcare Research and Quality,* July 2009, at 16. Available at: *http://www.healthit.ahrq.gov/portal/server.pt/gateway/PTARGS_0_1248_888520_0_0_18/09%E2%80%900081%E2%80%90EF.pdf%00%00* at 16; Markle Foundation. *Survey Finds Americans Want Electronic Personal Health Information to Improve Own Health Care,* November 2006, at 1. Available at: *http://www.markle.org/downloadable_assets/research_doc_120706.pdf.*

[9] See Goldstein, M.M. and A.L. Rein. *Consumer Consent Options for Electronic Health Information Exchange: Policy Considerations and Analysis,*" March, 2010. Available at: *http://healthit.hhs.gov/portal/server.pt/gateway/PTARGS_0_11673_911197_0_0_18/ChoiceModelFinal032610.pdf.*

[10] J. Shapiro, J. Bartley, G. Kuperman, Health Information Exchange Consent Policy Influences: Emergency Department Patient Data Accessibility. ACEP 2010. See also N. Daurio, et al. Implementation of an Enterprise-wide Electronic Health Record: A Nurse-Physician Partnership, in K. Saranto *et al.,* eds, Connecting Health and Humans (IOS Press 2009).

[11] Schneider, at 36–37. Public Attitudes Toward Medical Privacy. (2000). Conducted by The Gallup Organization on behalf of the Institute for Health Freedom. Available at: *http://forhealthfreedom.org/Gallupsurvey/IHF–Gallup.html.*

[12] See Micky Tripathi, David Delano, Barbara Lund and Lynda Rudolph. "Engaging Patients for Health Information Exchange." Health Affairs. Volume 28, Number 2. March/April 2009; Missouri Office of Health Information Technology. *Opt-in Versus Opt-out: Consent Models for Health Information Exchange through Missouri's Statewide Health Information Exchange Network.* Jefferson City: Missouri. Department of Social Services (2010). Available online at *http://www.dss.mo.gov/*

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opt-in rates are very high, significant paperwork burdens arise as providers must track consents for the majority of their patient population. Reducing such burdens is one of the major reasons that other organizations engaged in health information exchange have adopted an opt-out approach. [12] [13] An opt-out approach is used successfully in most systems of electronic exchange of information [13] because it is significantly less burdensome on consumers and providers while still providing an opportunity for caregivers to engage with patients to promote trust and permitting patients to exercise control over their data. We are concerned about the effect of an opt-in approach on beneficiary participation and the additional administrative burdens on physician practices. Therefore, we propose affording beneficiaries the ability to opt-out of sharing their protected health information with the ACO. We believe this opportunity coupled with notification of how protected health information will be shared and used affords beneficiaries meaningful choice. An example of the opt-out approach would be that when a beneficiary has a visit with their primary care physician, their physician would inform them at this visit that he or she is an ACO participant or ACO provider/supplier and that the ACO would like to be able to request claims information from us in order to better coordinate the beneficiary's care. If the beneficiary objects, we propose that the beneficiary would be given a form stating that they have been informed of their physician's participation in the ACO and explaining how to opt-out of having their personal data shared. The form could include a phone number and/or e-mail address for beneficiaries to call and request that their data not be shared. As discussed in section II. D., the Shared Savings Program lays the foundation for a beneficiary-centered delivery system that should create a new relationship between beneficiaries and care providers based, in large part, on patient engagement in the new care system. The successful creation of this relationship is not possible when beneficiaries are not aware of the new delivery system available through ACOs, and the possibility of being included in the population assigned to an ACO.

We therefore propose to develop a communications plan, discussed in more detail in section II. D of this proposed rule, that will offer insight into both the Shared Savings Program in general and the beneficiaries' right to opt-out of the data sharing portion of the ACO Shared Savings Program.

As noted previously, ACOs will only be allowed to request beneficiary identifiable claims data for beneficiaries who have (1) visited a primary care participating provider during the performance year, and (2) have not chosen to opt-out of claims data sharing.

A beneficiary that chooses to opt-out is only opting out of the data sharing portion of the program. The decision to opt-out in no way effects use of the beneficiaries' data or assignment to the ACO for purposes of determining such calculations as ACO benchmarks, per capita costs, quality performance, or performance year per capita expenditures. Our data contractor will maintain a running list of all HICNs that have chosen to opt-out of data sharing. We will monitor whether ACOs continue to request data on beneficiaries who have opted out of having their data shared and will take appropriate actions against any ACO that is found to violate this requirement.

We request comments on our proposals related to the provision of both aggregate and beneficiary identifiable data to ACOs. We are particularly interested in comments on the kinds and frequency of data that would be useful to ACOs, potential privacy and security issues, and the implications for sharing protected health information with ACOs, and the use of a beneficiary opt-out, as opposed to an opt-in, to obtain beneficiary consent to the sharing of their information.

7. New Program Standards Established During 3-Year Agreement Period

The Shared Savings Program is a new program designed to encourage providers to redesign care processes in order to achieve the outcomes of better care for individuals, better health for populations, and lower growth in expenditures for Medicare FFS beneficiaries. We anticipate that as we continue to work with the stakeholder community and learn what methods and measures work most effectively for the Shared Savings Program, we will make changes and improvements to the Shared Savings Program. For example, we expect to integrate lessons learned from Innovation Center initiatives to shape and change the Shared Savings Program over time. Because we expect that these changes may occur more frequently than the length of the 3-year agreement periods, the question arises as to whether those ACOs that have already committed to a 3-year agreement to participate in the Shared Savings Program should be subject to those changes. It is not unprecedented for Medicare agreements to include a provision requiring that the agreement is subject to changes in laws and regulations. For example, the contracts with Medicare Advantage organizations contain such a clause. However, these contracts are for a term of 1 year, as opposed to 3 or more years. As a result, there are more frequent opportunities for these organizations to reassess whether they wish to continue to participate in the program in light of changes to the laws and regulations governing the program.

In the Shared Savings Program, regulatory changes could affect a variety of different components of the program, including quality measures, reporting requirements, monitoring requirements, program integrity, and eligibility requirements. If the agreements are subject to all changes in the applicable regulations, it is possible that some ACOs that were eligible for participation in the program at the start of their respective 3-year agreement might become ineligible based upon modifications to the regulations. Creating an environment in which the continued eligibility of existing program participants is uncertain could be detrimental to the success of program and could deter program participation. Conversely, the ability to incorporate regulatory changes into the agreements with ACOs would facilitate the administration of the program because all ACOs would be subject to the requirements imposed under the current regulations, rather than up to 3 different sets of requirements, based upon the year in which the ACO entered the program. Additionally, requiring ACOs to adhere to certain regulatory changes related to quality measures, routine program integrity changes, processes for quality management and patient engagement, and patient-centeredness criteria that are up to date with current clinical practice ensures that ACO activities keep pace with changes in clinical practices and developments in evidence-based medicine. We do not believe that requiring ACOs to adhere to

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hie/leadership/pdf2010/optin_vs_optout_overview.pdf.

[12] See Goldstein, M.M. and A.L. Rein. *Consumer Consent Options for Electronic Health Information Exchange: Policy Considerations and Analysis,*" March, 2010, at 35. Available at: *http://healthit.hhs.gov/portal/server.pt/gateway/PTARGS_0_11673_911197_0_0_18/ChoiceModelFinal032610.pdf.*

[13] See Goldstein, M.M. and A.L. Rein. *Consumer Consent Options for Electronic Health Information Exchange: Policy Considerations and Analysis,*" March, 2010, at 35. Available at: *http://healthit.hhs.gov/portal/server.pt/gateway/PTARGS_0_11673_911197_0_0_18/ChoiceModelFinal032610.pdf.*

regulatory modifications related to quality measures, routine program integrity changes, processes for quality management and patient engagement, and patient centeredness criteria is likely to affect either the ACOs' underlying organizational structure or their continued eligibility to participate in the Shared Savings Program—although it may necessitate changes in how ACOs design and deliver care to meet these program requirements, as compared to descriptions of these processes in their initial applications.

We propose that ACOs be subject to future changes in regulation with the exception of the following program areas:

- Eligibility requirements concerning the structure and governance of ACOs;
- Calculation of sharing rate; and
- Beneficiary assignment.

For example, ACOs would be subject to changes in regulation related to the quality performance standard. The language of the ACO agreement would be explicit to ensure that ACOs understand the dynamic nature of this part of the program and what specific programmatic changes would be incorporated into the agreement. We further propose that in those instances where regulatory modifications effectuate changes in the processes associated with an ACO pertaining to design, delivery, and quality of care that the ACO will be required to submit to us for review and approval, as a supplement to their original application, an explanation of how they will address key changes in processes resulting from these modifications. If an ACO fails to effectuate the changes needed to adhere to the regulatory modifications, we propose that the ACO would be placed on a corrective action plan, and if after being given an opportunity to act upon the corrective action plan, the ACO still fails to come into compliance, it would be terminated from the program. For a more detailed discussion of the process for requiring and implementing a corrective action plan, please refer to the section II. H. of this proposed rule. We propose that ACO participants shall continue to be subject to all requirements applicable to FFS Medicare, such as routine CMS business operations updates and changes in FFS coverage decisions, as they may be amended from time to time. In other words, nothing in the Shared Savings Program shall be construed to affect the payment, coverage, program integrity, and other requirements that apply to providers and suppliers under FFS Medicare.

8. Managing Significant Changes to the ACO During the Agreement Period

Aside from changes that an ACO may experience as a result of regulatory changes, the ACO itself may also experience significant changes within the course of its 3-year agreement period due to such events as: The following:

- Deviations from approved application for reasons such as the drop out of an ACO participant upon which assignment is based; changes in overall governing board composition (in terms of interests represented) or leadership; changes in ACO's eligibility to participate in the program, including changes to the key processes pertaining to the design, delivery and quality of care (such as processes for quality management and patient engagement and patient centeredness criteria) as outlined in the application criteria for acceptance into the program; or changes in planned distribution of shared savings.
- A material change, as defined in detail in section II. H. of ACOs of this proposed rule, in the ACOs provider composition, including the addition of ACO providers/suppliers such that the ACO requires a mandatory antitrust review or re-review as discussed in section II. I. Coordination with Other Agencies., and other circumstances under which an ACO or an ACO participant is unable to complete its 3-year commitment.
- Government-required ACO reorganization, or exclusion of ACO participants or ACO providers/suppliers, or conduct restriction due to: OIG excluding the ACO, an ACO participant, or an ACO provider/supplier for any reason authorized by law; CMS revoking an ACO, ACO participant or ACO provider/supplier's Medicare billing privileges under 42 CFR 424.535, for noncompliance with billing requirements or other prohibited conduct; or reorganization or conduct restrictions to resolve antitrust concerns.

Whenever an ACO reorganizes its structure, we must determine if the ACO remains eligible to participate in the Shared Savings Program. Since an ACO is admitted to the program based on its application, adding ACO participants during the course of the 3-year agreement may deviate from its approved application and jeopardize the ACO's eligibility since the ACO would differ from its approved application and could be subject to further antitrust review. Changes such as this may result in termination of the 3-year agreement and forfeiture of the 25 percent withhold of shared savings earned by the original ACO participants. We therefore propose that the ACO may not add ACO participants during the course of the 3-year agreement. In order to maintain flexibility, however, we propose that the ACO may remove ACO participants (TINs) or add/subtract ACO providers/suppliers (NPIs). We request comment on this proposal that ACOs may not add ACO participants and how this proposal might impact small or rural ACOs. We propose that the ACO be required to notify us in order to have its new structure approved whenever significant changes, such as those referenced previously, occur to its structure. We have identified five outcomes that may result from our review:

- The ACO may continue to operate under the new structure with savings calculations for the performance year based upon the updated list of ACO participants and ACO providers/suppliers.
- The remaining ACO structure qualifies as an ACO but is so different from the initially approved ACO structure that the ACO must start over as a new ACO with a new 3-year agreement, including an antitrust review, if warranted.
- The remaining ACO structure qualifies as an ACO but is materially different from the initially approved ACO structure because of the inclusion of additional ACO providers/suppliers that the ACO must obtain approval from a reviewing Antitrust Agency before it can continue in the program.
- The remaining ACO structure no longer meets the eligibility criteria for the program, and the ACO would no longer be able to participate in the program, for example, if the ACO's assigned population falls below 5,000 during an agreement year as discussed in section II. B. of this proposed rule.
- CMS and the ACO may mutually decide to terminate the agreement.

We propose that when an ACO reorganizes its structure by excluding ACO participants or by adding or excluding ACO providers/suppliers, deviates from its approved application, changes information contained in its approved application, or experiences other changes which may make it unable to complete its 3-year agreement, it must notify us within 30 days of the event for reevaluation of its eligibility to continue to participate in the Shared Savings Program. We would respond in one of the five ways specified previously. We request comment on this proposal.

9. Future Participation of Previously Terminated Program Participants

As described in section II.H. of the proposed rule, there are a number of circumstances under which we may terminate our agreement with an ACO, including avoidance of at-risk beneficiaries and failure to meet the quality performance standards. In contrast, there are also many reasons why an ACO participant TIN, used for assignment, or individual ACO providers/suppliers may drop out of an ACO; such as government exclusion, relocation, retirement, a voluntary decision to terminate participation, or bankruptcy.

Permanently barring former program participants from subsequent participation in the Shared Savings Program due to a voluntary or forced termination from an ACO appears unduly harsh given the dynamic nature of organizational membership. Alternatively, we do want to ensure our policy on subsequent participation in the Shared Savings Program does not provide a second chance for under-performing organizations or to providers or suppliers who have been terminated for failing to meet program integrity requirements.

We propose the ACO disclose to CMS whether the ACO, its ACO participants, or its ACO providers/suppliers have participated in the program under the same or a different name, and specify whether it was terminated or withdrew voluntarily from the program. If the ACO, its ACO participants or ACO providers/suppliers were previously terminated from the program, the applicant must identify the cause of termination and what safeguards are now in place to enable the prospective ACO to participate in the program for the full period of the 3-year agreement period. We propose that such ACOs may not begin another 3-year agreement period until the original agreement period has lapsed. Additionally, because we believe that subsequent participation in the Shared Savings Program should not provide a second chance for under-performing organizations, we propose that an ACO may not reapply to participate in the Shared Savings Program if it previously experienced a net loss during its first 3-year agreement period. We seek comment on these proposals and whether requirements for denying participation to ACOs that previously under-perform would create disincentives for the formation of ACOs. We are specifically interested in whether this requirement will create disincentives for participation among smaller entities.

D. Assignment of Medicare Fee-for-Service Beneficiaries

Section 1899(c) of the Act, as added by section 3022 of the Affordable Care Act, requires the Secretary to "determine an appropriate method to assign Medicare FFS beneficiaries to an ACO based on their utilization of primary care services provided under this title by an ACO professional described in subsection (h)(1)(A)." Subsection 1899(h)(1)(A) of the Affordable Care Act constitutes one element of the definition of the term "ACO professional." Specifically, this subsection establishes that "a physician (as defined in section 1861(r)(1))" is an "ACO professional" for purposes of the Shared Savings Program. Section 1861(r)(1) of the Act in turn defines the term physician as "* * * a doctor of medicine or osteopathy legally authorized to practice medicine and surgery by the State in which he performs such function or action." In addition, subsection 1899(h)(1)(B) defines an ACO professional to include practitioners described in section 1842(b)(18)(C)(i) of the Act, such as PAs and NPs.

Thus, although the statute defines the term "ACO professional" to include both physicians and non-physician practitioners, such as advance practice nurses, physician assistants, and nurse practitioners, for purposes of beneficiary assignment to an ACO, the statute requires that we consider only beneficiaries' utilization of primary care services provided by ACO professionals who are physicians. The method of assigning beneficiaries therefore must take into account the beneficiaries' utilization of primary care services rendered by physicians. Therefore, for purposes of the Shared Savings Program, the inclusion of practitioners described in section 1842(b)(18)(C)(i) of the Act, such as PAs and NPs in the statutory definition of the term "ACO professional" is a factor in determining the entities that are eligible for participation in the program (for example, "ACO professionals in group practice arrangements" in section 1899(b)(1)(A) of the Act). However, assignment of beneficiaries to ACOs is to be determined only on the basis of primary care services provided by ACO professionals who are physicians.

Assigning Medicare beneficiaries to ACOs also requires several other elements: (1) An operational definition of an ACO (as distinguished from the formal definition of an ACO and the eligibility requirements that we discuss in section II.B. of this proposed rule) so that ACOs can be efficiently identified, distinguished, and associated with the beneficiaries for whom they are providing services; (2) a definition of primary care services for purposes of determining the appropriate assignment of beneficiaries; (3) a determination concerning whether to assign beneficiaries to ACOs prospectively, at the beginning of a performance year on the basis of services rendered prior to the performance year, or retrospectively, on the basis of services actually rendered by the ACO during the performance year; and (4) a determination concerning the proportion of primary care services that is necessary for a beneficiary to receive from an ACO in order to be assigned to that ACO for purposes of this program.

The term "assignment" in this context refers only to an operational process by which Medicare will determine whether a beneficiary has chosen to receive a sufficient level of the requisite primary care services from physicians associated with a specific ACO so that the ACO may be appropriately designated as exercising basic responsibility for that beneficiary's care. Consistent with section 1899(b)(2)(A), the ACO will then be held accountable "for the quality, cost, and overall care of the Medicare FFS beneficiaries assigned to it." The ACO may also qualify to receive a share of any savings that are realized in the care of these assigned beneficiaries due to appropriate efficiencies and quality improvements that the ACO may be able to implement. It is important to note that the term "assignment" for purposes of this provision in no way implies any limits, restrictions, or diminishment of the rights of Medicare FFS beneficiaries to exercise complete freedom of choice in the physicians and other health care practitioners and suppliers from whom they receive their services.

Thus, while the statute refers to the assignment of beneficiaries to an ACO, we would characterize the process more as an "alignment" of beneficiaries with an ACO as the exercise of free choice by beneficiaries in the physicians and other health care providers and suppliers from whom they receive their services is a presupposition of the Shared Savings Program. Therefore, an important component of the Shared Savings Program will be timely and effective communication with beneficiaries concerning the Shared Savings Program, their possible assignment to an ACO, and their retention of freedom of choice under the Medicare FFS program. The issues of beneficiary information and notification regarding their potential assignment to an ACO are further discussed at the end of this section.

1. Operational Identification of an ACO

The first step in developing a method for assigning beneficiaries is to establish a clear operational method of identifying an ACO that correctly associates its health care professionals and providers with the ACO. It is designed to be consistent with the statutory definition of an ACO as well as the eligibility and other requirements for an organization to participate in the Shared Savings Program as an ACO. As discussed in section II.B. of this proposed rule, section 1899(a)(1)(A) of the Act defines ACOs as "groups of providers of services and suppliers" who work together to manage and coordinate care for Medicare fee-for-service beneficiaries. More specifically, the Act refers to group practice arrangements, networks of individual practices of ACO professionals, partnerships or joint venture arrangements between hospitals and ACO professionals, hospitals employing ACO professionals, or other combinations that the Secretary determines appropriate.

From a technical, operational perspective, there are two data sources that could be used to identify the specific providers of services and suppliers participating in these kinds of arrangements as ACOs—specifically, their—(1) National Provider Identifier (NPI); and (2) TIN. Under the Medicare program, individual practitioners are defined by their NPI, but generally file and receive payment for Medicare claims based on their TIN. The TIN may be an employer identification number (EIN) or social security number (SSN). Some individual physicians and other ACO professionals, for example, do not have EINs, and enroll in the Medicare program through their SSNs. Physicians and other ACO professionals who are members of a group practice and bill for their services through the group may not have individual EINs but may use a group EIN for billing Medicare rather than their individual SSNs. While all physicians and practitioners have TINs (either EINs or SSNs), not all physicians and practitioners have Medicare enrolled TINs. For example, physicians and other ACO professionals who are members of a group practice often bill for their services through the group and may not have individual Medicare enrolled TINs. Groups of physicians and practitioners, however, necessarily have TINs which they employ for billing Medicare, because a TIN must be used for billing purposes. It should be noted that, under the Shared Savings Program, the standard restrictions on disclosure of information apply. (For a discussion regarding the public disclosure of information under the Shared Savings Program, see the discussion in section II.E. of this proposed rule.)

Under the PGP demonstration, beneficiaries were assigned and group quality performance was measured by identifying practices operationally as a collection of Medicare enrolled TINs. Through this demonstration we found that TINs provide the most direct link between the beneficiary and the practice providing primary care services. Further, TINs are more stable than NPIs and more likely to provide complete longitudinal data required for benchmarking and beneficiary assignment, and to promote the stability necessary for the ACO to commit to redesigning care processes and complete the required 3-year agreement period. The reason NPIs tend to be less stable is because individual physicians and practitioners often change from one practice to another, potentially rendering data continuity and beneficiary assignment problematic when only NPIs are available. In the PGP demonstration, the individual NPIs associated with the TIN were identified from claims data and provider enrollment information, providing for more effective monitoring of performance within the ACO. Finally, reporting at the TIN level appeared to reduce the reporting burden for practices participating in the PGP demonstration.

Therefore, we are proposing to identify an ACO operationally as a collection of Medicare enrolled TINs. More specifically, an ACO will be identified operationally as a set of one or more TINs currently practicing as a "group practice arrangement" or in a "network" such as where "hospitals are employing ACO professionals" or where there are "partnerships or joint ventures of hospitals and ACO professionals" as stated under section 1899(b)(1)(A) through (E) of the Act. For example, a single group practice that participates in the Shared Savings Program would be identified by its TIN. A network of independent practices that forms an ACO would be identified by the set of TINs of the practices constituting the ACO. We are proposing to require that organizations applying to be an ACO provide their ACO participant TINs. Each TIN can be systematically linked to an individual physician specialty code by us. Therefore, under this approach, beneficiaries would be assigned to an ACO through a TIN based on the primary care services they received from physicians billing under that TIN.

We also propose that ACO professionals within the respective TIN on which beneficiary assignment is based, will be exclusive to one ACO agreement in the Shared Savings Program. This exclusivity will only apply to the primary care physicians (defined as physicians with a designation of internal medicine, geriatric medicine, family practice, and general practice, as discussed in this rule) by whom beneficiary assignment is established.

ACO participant TINs upon which beneficiary assignment is not dependent (for example, acute care hospitals, surgical and medical specialties, RHCs, and FQHCs) would be required to agree to participate in the ACO for the term of the 3-year agreement, but would not be restricted to participation in a single ACO. As stated in section II.G. of this proposed rule, competition in the marketplace promotes quality of care for Medicare beneficiaries, protects access to a variety of providers, and helps sustain the Medicare program by controlling cost pressures. All of these benefits to Medicare patients would be reduced or eliminated if we allow the creation of ACOs with significant market power. This is especially important in certain areas of the country that might not have many specialists. In addition, exclusivity of ACO participant TINs upon which beneficiary assignment is not dependent might also contribute to the prospects that ACOs could develop excessive market power, especially in areas with shortages of physicians. In turn, greater market power could provide opportunities for these organizations to engage in activities that raise issues of fraud and abuse, such as those related to self-referrals. For these reasons, physicians upon whom assignment is dependent would be committed for a 3-year period and be exclusive to one ACO. Conversely, to ensure that physicians and other entities upon which assignment is not dependent (that is, hospitals, FQHC, RHCs, specialists) can participate in more than one ACO, and thereby facilitate the creation of competing ACOs, these providers and suppliers would be committed to the 3-year agreement but would not be exclusive and would have the flexibility to join another ACO.

Based on our experience, we recognize that the TIN level data alone will not be entirely sufficient for a number of purposes in the Shared Savings Program. In particular, NPI data will be useful to assess the quality of care furnished by an ACO. For example, NPI information will be necessary to determine what percent of physicians

and other practitioners in the ACO are registered in the HITECH program (discussed in section II.E. of this proposed rule). NPI data will also be helpful in our monitoring of ACO activities (which we discuss in section II.H. of this proposed rule). Therefore, we are also proposing to require that organizations applying to be an ACO must provide not only their TINs but also a list of associated NPIs for all ACO professionals, including a list that separately identifies physicians that provide primary care. As we discuss in more detail later in the document, for purposes of the Shared Savings Program, we are proposing to define primary care physicians as those physicians that practice in the areas of internal medicine, general practice, family practice, and geriatric medicine. We welcome comments on our proposal to require reporting of TINs along with information about the NPIs associated with the ACO.

In summary, we believe that our proposal to define the ACO operationally as a group of Medicare-enrolled TINs, while also collecting information about the NPIs associated with those TINs, allows us to link the beneficiary, type of service provided, and the type of physician providing the services for purposes of beneficiary assignment to the ACO as required by statute. This approach also offers the most complete longitudinal data required for benchmarking and beneficiary assignment, most effectively limits administrative burden for participating providers and suppliers, and makes it possible for us to take advantage of infrastructure and methodologies already developed for group-level reporting and evaluation. Moreover, this option affords us the most flexibility and statistical stability for monitoring and evaluating quality and outcomes for the population of patients assigned to the ACO.

2. Definition of Primary Care Services

Section 1899(c) of the Act requires the Secretary to assign beneficiaries to an ACO "based on their utilization of primary care services" provided by a physician. However, the statute does not specify which kinds of services should be considered "primary care services" for this purpose, nor the amount of those services that would be an appropriate basis for making assignments. We discuss issues concerning the appropriate proportion of such services in the next section. In this section of this proposed rule, we discuss how to identify the appropriate primary care services on which to base the assignment and our proposal for defining primary care services for this purpose.

In order to ensure the statistical reliability of the required performance measurements and benchmarks, ACOs must have a sufficient number of assigned beneficiaries. Having too few beneficiaries assigned to a participating ACO will impede determining whether changes in cost and quality measures are likely a reflection of normal variation rather than real improvement in the delivery of care. Section 1899(b)(2)(D) of the Act specifically provides that the composition of the ACO shall include sufficient numbers of ACO primary care professionals so that at least 5,000 beneficiaries are assigned to the ACO.

Primary care services can generally be defined based on the type of service provided or the type of provider specialty that provides the service. The PGP demonstration has helped inform assignment methodologies. Under the PGP demonstration, the assignment methodology incorporated outpatient evaluation and management (E&M) services provided by both primary care and specialist providers. One reason for this is that certain specialists (for example, cardiologists, endocrinologists, neurologists, oncologists) are often the principal primary care provider for elderly and chronically ill patients who do not otherwise have a primary care provider, and it is reasonable to expect them to take responsibility for these patients' care. Another reason is that the assignment methodology provided an opportunity for specialists to take responsibility for ensuring that their patients' primary care needs were being met even if the specialist provided care initially on a referral basis.

We would note that in defining primary care services, certain Affordable Care Act provisions also rely on a blend of the type of service and type of provider delivering the service. For example, section 5501 of the Affordable Care Act makes incentive payments available to primary care practitioners for whom primary care services account for at least 60 percent of the allowed charges under Part B. For purposes of this provision, a "primary care practitioner" is defined as a physician "who has a primary specialty designation of family medicine, internal medicine, geriatric medicine, or pediatric medicine," or as a "nurse practitioner, clinical nurse specialist, or physician assistant." In that section, "primary care services" are defined as a set of services identified by these HCPCS codes: 99201 through 99215; 99304 through 99340; and 99341 through 99350. Additionally, we would consider the Welcome to Medicare visit (G0402) and the annual wellness visits (G0438 and G0439) as primary care services for purposes of the Shared Savings Program.

In developing our proposal, we have considered three options with respect to defining "primary care services" for the purposes of assigning beneficiaries under the Shared Savings Program: (1) Assignment of beneficiaries based upon a predefined set of "primary care services;" (2) assignment of beneficiaries based upon both a predefined set of "primary care services" and a predefined group of "primary care providers;" and (3) assignment of beneficiaries in a step-wise fashion. Under this option, beneficiary assignment would proceed by first identifying primary care physicians (internal medicine, family practice, general practice, geriatric medicine) who are providing primary care services, and then identifying specialists who are providing these same services for patients who are not seeing any primary care professional.

The first option would assign beneficiaries by defining "primary care services" on the basis of the select set of E&M services, specifically those defined as "primary care services" in section 5501 of the Affordable Care Act, and including G-codes associated with the annual wellness visit and Welcome to Medicare benefit regardless of provider specialty. This option would increase the number of potential beneficiaries assigned to the ACO in areas with primary care shortages (where specialists would necessarily be providing more primary care services as defined by the code set). It is also administratively straightforward, and we have experience with the similar methodology initially used in the PGP demonstration. However, assigning beneficiaries to ACOs based only on primary care services without distinction of caregiver specialty increases the likelihood of assigning beneficiaries to a specialist over a primary care provider. In addition, it would appear to be somewhat inconsistent with section 5501 of the Affordable Care Act, which, for purposes of establishing an incentive payment for primary care services, first defines a set of primary care practitioners, and then identifies a set of HCPCS codes as "primary care services." The primary care services are recognized for the incentive payment only when they are provided by primary care practitioners. It is dubious whether the codes identified in section 5501 of the Affordable Care Act alone, when they are not provided by primary care

doctors and other practitioners, truly constitute primary care services. Rather, these codes alone simply represent outpatient cognitive services (generally, consultations and office visits) that are provided for in all sorts of health care situations, including primary care but also specialty care, and are provided by many types of physicians. As such, this option has the potential to diminish the appropriate level of emphasis on a primary care core in the Shared Savings Program, by failing to place any priority on the services of designated primary care providers (for example, internal medicine, general practice, family practice, and geriatric medicine) in the assignment process.

The second option that we have considered is therefore to assign beneficiaries to physicians designated as primary care providers (internal medicine, general practice, family practice, and geriatric medicine) who are providing the appropriate primary care services to beneficiaries. As in the case of the first option, we would define "primary care services" on the basis of the select set of HCPCS codes identified in section 5501 of the Affordable Care Act, including G-codes associated with the annual wellness visit and Welcome to Medicare visit. This option more closely aligns the definition of primary care services with the definition in section 5501 of the Affordable Care Act. As in the case of the first option, this option would be relatively straightforward administratively. However, this option could reduce the number of beneficiaries assigned to an ACO, by excluding primary care services delivered by specialists, especially in some areas that may have shortages of primary care physicians but a relatively greater number of specialists. Consequently, this option could make it difficult for ACOs to form in some geographic regions with such primary care shortages.

The third option we have considered is to assign beneficiaries in a step-wise fashion. Under this option, beneficiary assignment would proceed by first identifying primary care physicians (internal medicine, family practice, general practice, geriatric medicine) who are providing primary care services, and then identifying specialists who are providing these same services for patients who are not seeing any primary care professional. This option would introduce a greater level of operational complexity compared to the two other options we considered. In addition, it could undermine our goal of ensuring competition among ACOs by reducing the number of specialists that can participate in more than one ACO, since specialists to whom beneficiaries are assigned would be required to be exclusive to one ACO. As noted previously, the ability of specialists to participate in more than one ACO is especially important in certain areas of the country that might not have many specialists. On the other hand, a "step-wise approach" would not affect all specialists and it would reflect many of the advantages of the other two approaches, balancing the need for emphasis on a primary care core with a need for increased assignment numbers in areas with primary care shortages.

After considering these options, we are proposing the second option, which would assign beneficiaries with physicians designated as primary care providers (internal medicine, general practice, family practice, and geriatric medicine) who are providing the appropriate primary care services to beneficiaries. We believe that this option best aligns with other Affordable Care Act provisions related to primary care by placing an appropriate level of emphasis on a primary care core in the Shared Savings Program. That is, this option places priority on the services of designated primary care physicians (for example, internal medicine, general practice, family practice, and geriatric medicine) in the assignment process. This option also allows ACOs to focus their efforts to coordinate and redesign care for patients seeing primary care providers and creates incentives for ACOs to establish primary care linkages for their patients who may not have a primary care provider. The option is also relatively straightforward administratively.

However, we are also concerned that this proposal may not adequately account for primary care services delivered by specialists, especially in certain areas with shortages of primary care physicians, and that it may make it difficult to obtain the minimum number of beneficiaries to form an ACO in geographic regions with such primary care shortages. Therefore, while we are proposing to assign beneficiaries to physicians designated as primary care providers (internal medicine, general practice, family practice, and geriatric medicine) who are providing the appropriate primary care services to beneficiaries, we invite comments on this proposal and other options that may better address the delivery of primary care services by specialists. In the final rule, we could consider adopting another option; therefore we are seeking comments on the definition of primary care services approach as well as the "step-wise" approach as described previously.

3. Prospective vs. Retrospective Beneficiary Assignment To Calculate Eligibility for Shared Savings

Section 1899(d)(1) of the Act provides that an ACO may be eligible for shared savings with the Medicare program if the ACO meets performance standards established by the Secretary (which we discuss in section II.E. of this proposed rule) and meets the requirements for realizing savings for its assigned beneficiaries against the benchmark established by the Secretary under section 1899(d)(1)(B) of the Act. Thus, for each year of an agreement period each ACO will have an assigned population of beneficiaries. Eligibility for shared savings will be based on whether the requirements for receiving shared savings payments are met for this assigned population. We refer to each year for which such determinations must be made as a "performance year."

There are two basic options for assigning beneficiaries to an ACO to calculate eligibility for shared savings for a performance year. The first option is that beneficiary assignment could occur at the beginning of the performance year, or prospectively, based on utilization data demonstrating the provision of primary care services to beneficiaries in prior periods. The second option is that beneficiary assignment could occur at the end of the performance year, or retrospectively, based on utilization data demonstrating the provision of primary care services to beneficiaries by ACO physicians during the performance year.

Many observers and prospective ACO managers have argued that it is essential for an ACO to know who is included in its assigned population prior to the start of the performance year. While they intend to treat all patients the same, they assert that it is fundamental to population management to be able to profile a population, identify individuals at high risk, develop outreach programs, and proactively work with patients and their families to establish care plans. These observers also argue that, as with any well managed enterprise, it is essential to have operational goals and targets to manage effectively. Thus, they would like to be able to track prospective targeted expenses, in order to gauge their results as they go through the performance year. These observers also understand that even prospective assignment methodologies will require a retrospective definition of the population to adjust for a variety of changes in the population that occur during a performance year. Some current patients of the practice will

become eligible for Medicare. Some will join a Medicare Advantage (MA) plan and, although they may continue to receive care furnished by the ACO, these beneficiaries can no longer be considered part of the assigned population of the ACO for purposes of computing shared savings. Individuals will move in and out of the service area during the year. For all these reasons, any methodology will require a retrospective redefinition of the assigned population.

Advocates for the retrospective approach start with the observation that the actual population seen by a set of physicians changes significantly from year to year. Medicare FFS beneficiaries' right to see any enrolled physician typically leads to more year-to-year variability in treating physicians compared to patients in managed care programs. Analysis of the PGP population did show approximately a 25 percent variation in assignment from year to year. Prospective assignment of a population seems inherently inaccurate from this perspective. If beneficiary assignment changes by 25 percent from year to year, a prospective assignment would not be an accurate reflection of those beneficiaries that were actually seen by physicians in the ACO during the performance year. Retrospective assignment of the population, on the other hand, appropriately holds the ACO accountable for the actual population it cared for during the performance year.

Proponents of the retrospective approach also make a second argument. They suggest that identifying a population prospectively may lead an ACO to focus only on providing care coordination and other ACO services to this limited population, ignoring other beneficiaries in their practices or hospitals. Given that the goal of the Shared Savings Program is to change the care experience for all beneficiaries, ACOs should not be told who among their patients are likely to be in their assigned population. ACO participants and ACO providers/suppliers should have incentives to treat all patients equally, using standardized evidence-based care processes, to improve the quality and efficiency of all of the care they provide, and in the end they should see positive results in the retrospectively assigned population.

We believe there are merits in both approaches. It does seem appropriate for an ACO to have information regarding the population it will likely be responsible for in order to target its care improvements to those patients who would benefit the most. At the same time, we do not want to encourage ACOs to limit their care improvement activities to a subset of their patients that they believe may be assigned to them. Finally, we believe it is critical that the assessment of ACO performance in any year be based on patients who received the plurality of their primary care from the ACO in that year, rather than an earlier period. As noted previously, even under a prospective assignment approach, a retrospective redefinition of the assigned population to account for changes from prior periods would be required or the ACO would be held accountable for patients that it did not provide services for during the performance year. Under a prospective system, the assignment would have to be adjusted every year to account for beneficiaries entering and leaving FFS Medicare as well as for those patients who move in and out of the geographic area of the ACO, as well as potentially other adjustments such as when a beneficiary remains in the area but chooses to receive their care outside of the ACO based upon where the plurality of their primary care services are being performed. Considering the merits of both approaches, we believe that the retrospective approach to beneficiary assignment for purposes of determining eligibility for shared savings is compelling. We believe that the assignment process should accurately reflect the population that an ACO is actually caring for, in order to ensure that the evaluation of quality measures is fair and that the calculation of shared savings, if any, accurately reflects the ACO's success in improving the quality and efficiency of the care provided to the beneficiaries for which it was actually accountable. In contrast, as we noted previously, a prospective approach has intrinsic inaccuracies, and requires additional adjustments in order to achieve the requisite level of accuracy for purposes of the Shared Savings Program.

In response to the November 17, 2010 RFI, of the few commenters favoring retrospective alignment, a group of commenters suggested the use of retrospective alignment for determining utilization and shared savings, but prospective assignment for purposes of CMS sharing beneficiary identifiable data with ACOs. We agree that, given appropriate safeguards for maintaining the confidentiality of patient information, providing ACOs with meaningful information about their "expected assigned population" with the potential to identify an "estimated benchmark target" will be helpful. We address our proposals for providing information to ACOs to help them understand their patient populations and better manage their care in section II.C. of this proposed rule.

Therefore, we are proposing the combined approach of retrospective beneficiary assignment for purposes of determining eligibility for shared savings balanced by the provision of aggregate beneficiary level data for the assigned population of Medicare beneficiaries during the benchmark period. (As we discuss in section II.C. of this proposed rule, we will provide ACOs with a list of beneficiary names, date of birth, sex, and other information derived from the assignment algorithm used to generate the 3-year benchmark.) Although the assignment methodology for the PGP demonstration was different from the proposed Shared Savings Program assignment methodology, when the PGP data is modeled with the Shared Savings Program assignment methodology, the assigned patient population would vary by approximately 25 percent from year to year. We believe that providing data on those beneficiaries that are assigned to an ACO in the benchmark period is a good compromise that will allow ACOs to have information on the population they will likely be responsible for in order to target their care improvements to that population while still not encouraging ACOs to limit their care improvement activities to only the subset of beneficiaries they believe will be assigned to them in the performance year. We believe that such a combined approach provides the best of both approaches while minimizing the disadvantages of either. ACO physicians will have the information they need to manage their population and estimate a target to manage towards, while they will still be encouraged to provide high-quality, efficient, and well-coordinated services to all Medicare FFS beneficiaries because they will not know for sure who will be in the assigned population. However, the ultimate evaluation of their effectiveness will be based on the actual population they served. We solicit comments on this combined approach of retrospective beneficiary assignment for purposes of determining eligibility for shared savings balanced by the provision of beneficiary data (names, date of birth, etc.) and aggregate beneficiary level data for the assigned population of Medicare beneficiaries during the benchmark period. We also seek comment on alternate assignment approaches, including the prospective method of assignment.

4. Majority vs. Plurality Rule for Beneficiary Assignment

Section 1899(c) of the Act requires that Medicare FFS beneficiaries be assigned to "an ACO based on their utilization of primary care services" furnished by an ACO professional who is a physician, but it does not prescribe the methodology for such assignment, nor criteria on the level of primary care services utilization that should serve as the basis for such assignment. Rather, the statute requires the Secretary to "determine an appropriate method to assign Medicare FFS beneficiaries to an ACO" on the basis of their primary care utilization.

An obvious general approach is to make such an assignment on the basis of some percentage level of the primary care services a beneficiary receives from an ACO physician. The more specific issue under such an approach is whether to assign beneficiaries to the ACO when they receive a plurality of their primary care services from that ACO, or to adopt a stricter standard under which a beneficiary will be assigned to an ACO only when he or she receives a majority of their primary care services from an ACO.

Under the PGP demonstration beneficiaries were assigned to a practice based on the plurality rule. By employing a plurality standard for primary care services, our analysis indicates that between 78 and 88 percent of the patients seen for primary care services at the PGP during the year were subsequently assigned to that PGP group. As measured by allowed charges (evaluation and management CPT codes), the PGP provided on average 95 percent of all primary care services provided to the assigned patients.

Alternatively, it could be argued that adopting a majority standard might enhance an ACO's sense of responsibility for its assigned patients, which is certainly consistent with the general goals of the Shared Savings Program. However, adopting a majority standard would likely somewhat reduce the number of beneficiaries assigned to an ACO and more beneficiaries would be unassigned to any ACO. On balance, we believe that a majority rule for assignment is too strict a standard to employ in a system where many Medicare beneficiaries may regularly receive primary care services from two or more primary care practitioners (for example, an internal medicine physician and a geriatric medicine physician). As such, this standard could undermine the development and sustainability of ACOs. Therefore, we are proposing to assign beneficiaries for purposes of the Shared Savings Program to an ACO if they receive a plurality of their primary care services from primary care physicians within that ACO. We believe that the plurality rule provides a sufficient standard for assignment because it ensures that beneficiaries will be assigned to an ACO when they receive more primary care from that ACO than from any other provider. This will result in a greater number of beneficiaries assigned to ACOs, which may enhance the viability of the Shared Savings Program, especially in its initial years of operation. We welcome comments on our proposal to assign patients based upon a plurality rule. Additionally we would also welcome any comments on whether there should be a minimum threshold number of primary care services that a beneficiary should receive from physicians in the ACO in order to be assigned to the ACO under the plurality rule and if so, where that minimum threshold should be set.

Finally, we can determine when a beneficiary has received a plurality of primary care services from an ACO either on the basis of a simple service count or on the basis of the accumulated allowed charges for the services delivered. The method of using a plurality of allowed charges would provide a greater weight to more complex primary care services in the assignment methodology, while a simple service method count would weigh all primary care encounters equally in determining assignment. We have previous experience with the method of using a plurality of allowed charges in the PGP demonstration. One advantage of this method is that it would not require tie-breaker rules, since it is unlikely that allowed charges by two different entities would be equal. On the other hand, this method does not necessarily assign the beneficiary to the entity that saw the patient most frequently, but rather to the entity that provided the highest complexity and intensity of primary care services. Assignment of beneficiaries on the basis of plurality in a simple service method count would require tie-breaker rules for those rare occasions when two or more entities delivered an equal number of services to a beneficiary. One possible tie-breaker for such cases is to assign the beneficiary to the ACO if it is the entity that most recently provided primary care services.

We propose to implement the method of using a plurality of allowed charges for primary care services to assign beneficiaries to ACOs. Allowed charges are a reasonable proxy for the resource use of the underlying primary care services, so the method of using a plurality of allowed charges assigns beneficiaries to ACOs according to the intensity of their primary care interactions, not merely the frequency of such services.

5. Beneficiary Information and Notification

Section 1899(c) of the Act, as added by section 3022 of the Affordable Care Act, does not state whether beneficiaries should be informed in any way about the Shared Savings Program. Thus, it does not specify any information to be provided to beneficiaries about the Shared Savings Program in general, whether they are receiving services from an ACO participant or ACO provider/supplier, or whether they have been assigned to an ACO for purposes of determining that ACO's performance with respect to the quality standards and its possible shared savings under the Shared Savings Program.

As discussed previously, the term "assignment" as used in the statute for purposes of this provision in no way implies any limits, restrictions, or diminishment of the rights of Medicare FFS beneficiaries to exercise freedom of choice in the physicians and other health care practitioners from whom they receive their services. Rather, the statutory term "assignment" in this context refers only to an operational process by which Medicare will determine whether a beneficiary has chosen to receive a sufficient level of the requisite primary care services from a specific ACO so that the ACO may be appropriately designated as being accountable for that beneficiary's care. For example, if a beneficiary's physician becomes part of an ACO and the beneficiary does not wish to receive health care services under the ACO care coordination and management efforts, the beneficiary has the freedom of choice to go to a different physician. The continued exercise of free choice by beneficiaries in selecting the physicians and other health care practitioners from whom they receive their services is thus a presupposition of the Shared Savings Program. The exercise of free choice, however, can be undermined or even nullified if beneficiaries do not possess adequate information to assess the possible consequences of available choices, or to evaluate which available options are most consistent with their values and preferences concerning their own health care. We therefore believe that an important component of the Shared Savings Program must be timely and effective communication with beneficiaries concerning the Shared Savings Program, their potential

assignment to an ACO, and what that may mean for the beneficiaries' care.

Furthermore, the Shared Savings Program lays the foundation for a beneficiary-centered delivery system that should create a strong relationship between beneficiaries and care providers based, in large part, on patient engagement in the new care system. Such engagement would be more difficult when beneficiaries are not aware of the new delivery system available from ACOs, and the possibility of being included in the population assigned to an ACO. In short, transparency must be a central feature of the Shared Savings Program.

Therefore, we intend to develop a communications plan, including educational materials and other forms of outreach, to provide beneficiaries in a timely manner with accurate, clear, and understandable information about the Shared Savings Program in general, about their utilization of services furnished by a provider or supplier participating in an ACO, about the possibility of their being assigned to an ACO for quality and shared savings purposes, and about the potential that their health information may be shared with the ACO, and their ability to opt-out of that data sharing. Accordingly, we will update the annual Medicare handbook to contain information about the Shared Savings Program, ACOs, and what receiving care from an ACO means for the Medicare FFS beneficiary.

One limitation on the timing of the information that we provide to beneficiaries arises from our proposal to assign beneficiaries to an ACO retroactively, that is, after the end of a performance year, on the basis of a beneficiary's actual primary care service utilization during the year. It is therefore not possible to inform beneficiaries of their assignment to an ACO in advance of the period in which they may seek services from the ACO. However, we believe that it is essential for beneficiaries to receive some form of advance notification that a physician or other provider from whom they are receiving services is participating in an ACO. The only practical manner in which such notification could be provided in a timely manner is to require ACOs to provide such notification to beneficiaries when they seek services from ACO providers/suppliers. Specifically, we propose to require ACOs to post signs in the facilities of participating ACO providers/suppliers indicating their participation in the Shared Savings Program and to make available standardized written information to Medicare FFS beneficiaries whom they serve. ACOs would provide standardized written notice to beneficiaries of both their participation in the Shared Savings Program and the potential for CMS to share beneficiary identifiable data with ACOs when a beneficiary receives services from a physician on whom assignment to ACO is based. We also plan to instruct ACOs to supply a form allowing beneficiaries to opt-out of having their data shared. The form would be provided to each beneficiary as part of their office visit with a primary care physician, and must include a phone number, fax or e-mail for beneficiaries to contact and request that their data not be shared.

Likewise, in instances where either an ACO chooses to no longer participate in the Shared Savings Program or we have terminated a participation agreement with an ACO, beneficiaries should be made aware of this change. Thus, we are proposing that ACOs be required to provide beneficiaries notice in a timely manner if they will no longer be participating in the Shared Savings Program. It should include the effective date of the termination of their agreement with us. As discussed in section II.C. of this proposed rule, we are also proposing to require an ACO seeking to terminate its participation in the Shared Savings Program to provide us with advanced notice.

We recognize that such a requirement could place an administrative burden on ACOs. However, we believe that such notification is essential to enhance patient engagement and understanding of their care. As discussed in section II.B. of this proposed rule, section 1899(b)(2)(H) of the Act requires that the "ACO * * * demonstrate to the Secretary that it meets patient-centeredness criteria specified by the Secretary * * *." We believe that providing notice of participation in or termination from the Shared Savings Program to beneficiaries is essential to the ability of beneficiaries to exercise free choice, and therefore would be an appropriate patient-centered criterion to be designated by the Secretary. In addition to notifying beneficiaries that they are seeking services from a provider or supplier participating in an ACO under the Shared Savings Program, this proposed notification will inform beneficiaries how assignment with an ACO is likely to affect (and not affect) the care they receive from the providers they have chosen. We seek comment on the appropriate form and content of this notification. For example, we seek comment on the utility of informing consumers about those objectives of the Shared Savings Program that might have the most impact on the beneficiary as a consumer of services from an ACO professional, such as the following:

- Easing the burden on consumers to coordinate their own care among different providers,
- Fostering follow-up with patients as they receive care from different providers,
- Facilitating greater dialogue between and among beneficiaries and providers about how health care is delivered, and
- Providing beneficiaries with quality measures by which they can evaluate the performance of their providers compared to regional and national norms.

We also seek comment on the most important items to communicate to beneficiaries about matters that will not change under the Shared Savings Program, including the fact that their cost-sharing will continue to be the same, and they remain free to seek care from providers of their choosing.

We welcome comments not only on our proposal to establish these notification requirements, but also on all matters concerning the appropriate form and content of such notification. If we adopt a notification requirement in the final rule, we will take comments on the issues such as the appropriate form and content of such a notification into account as we develop more detailed instructions for ACOs on beneficiary notification through guidance.

E. Quality and Other Reporting Requirements

1. Introduction

As discussed in section I. of this proposed rule, the intent of the Shared Savings Program is to: (1) Promote accountability to Medicare beneficiaries; (2) improve the coordination of FFS items and services; and (3) encourage investment in infrastructure and redesigned care processes to achieve high health care quality and efficient service delivery. In conjunction with the Shared Savings Program and other provisions of the Affordable Care Act, we have adopted three goals for improvement of the health care of Medicare beneficiaries and, by extension, of all Americans. These goals include: (1) Better care for individuals; (2) better health for populations; and (3) lower growth in expenditures. (We define better health care for individuals as health care that is safe, effective, patient-centered, timely, efficient, and equitable, as described in the IOM's six aims for changing U.S. health care delivery.) [14] This section of this

[14] Committee on Quality of Health Care in America, Institute of Medicine. Crossing the Quality

proposed rule pertains to the first two goals.

In this portion of the proposed regulation, we propose: (1) Measures to assess the quality of care furnished by an ACO; (2) requirements for data submission by ACOs; (3) quality performance standards; (4) the incorporation of reporting requirements under section 1848 of the Act for the Physician Quality Reporting System; and (5) requirements for public reporting by ACOs.

2. Proposed Measures To Assess the Quality of Care Furnished by an ACO

a. General

Section 1899(b)(3)(A) of the Act, requires the Secretary to determine appropriate measures to assess the quality of care furnished by the ACO, such as measures of clinical processes and outcomes; patient, and, wherever practicable, caregiver experience of care; and utilization (such as rates of hospital admission for ambulatory sensitive conditions). Section 1899(b)(3)(B) of the Act requires ACOs to submit data in a form and manner specified by the Secretary on measures that the Secretary determines necessary for the ACO to report in order to evaluate the quality of care furnished by the ACO. We believe that the Secretary's authority to determine the form and manner of data submission allows for establishing requirements for submission of data on measures the Secretary determines to be appropriate for evaluating the quality of care furnished by the ACO, without regard to whether the Secretary has established a specific quality performance standard with respect to those measures that must be met in order to be eligible for shared savings.

We propose that an ACO be considered to have met the quality performance standard if they have reported quality measures and met the applicable performance criteria in accordance with the requirements detailed in rulemaking for each of the three performance years. We further propose to define the quality performance standard at the reporting level for the first year of the Shared Savings Program and to define it based on measure scores in subsequent program years. We have listed the measures we propose to use to establish quality performance standards that ACOs must meet for shared savings for the first performance period in Table 1. Quality measures for the remaining two years of the 3-year agreement will be proposed in future rulemaking.

b. Considerations in Selecting Measures

We view value-based purchasing as an important step to revamping how care and services are paid for, moving increasingly toward rewarding better value, outcomes, and innovations instead of merely volume. The Shared Savings Program is a critical element of our Medicare value-based purchasing initiative. In implementing these value-based purchasing initiatives, we seek to meet certain common goals, as follows:

1. Use of Measures

- Value-based payment systems and public reporting should rely on a mix of standards, processes, outcomes, and patient experience measures, including measures of care transitions and changes in patient functional status. Across all programs, we seek to move as quickly as possible to the use of outcome and patient experience measures. To the extent practicable and appropriate, these outcome and patient experience measures should be adjusted for risk or other appropriate patient population or provider characteristics.
- To the extent possible, and recognizing differences in payment system maturity and statutory authorities, measures should be aligned across Medicare and Medicaid's public reporting and payment systems. We seek to evolve 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 and measures for that provider.
- The collection of information should minimize the burden on providers to the extent possible. As part of that effort, we have begun and will continuously seek to align Shared Savings Program measures with the methods and measures included in the Medicare and Medicaid EHR Incentive Programs to enable the collection and reporting of performance information to be a seamless part of care delivery and the meaningful use of certified EHR technology.
- To the extent practicable, measures used by us should be nationally endorsed by a multi-stakeholder organization. Measures should be aligned with best practices among other payers and the needs of the end users of the measures.

2. 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 more weighted 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.

Consistent with these value-based purchasing principles, our principal goal in selecting quality measures for ACOs is to identify measures of success in the delivery of high-quality health care at the individual and population levels. We considered a broad array of process and outcome measures and accounted for a variety of factors in arriving at the proposed measures, prioritizing measures that meet the following:

- Address the goals we previously identified: Improving individual health and improving the health of populations.
- Address an array of quality domains, priorities, and aims, including the IOM six quality aims previously described and the National Quality Strategy, and other HHS priorities, such as prevention, care of chronic illness, treatment of high prevalence conditions such as cardiovascular disease, patient safety, patient and caregiver engagement, and care coordination.
- Support the goals for the Shared Savings Program, as stated in section 1899(a)(1) of the Act, of promoting provider accountability for a patient population, coordinating care furnished under Medicare Parts A and B, and encouraging investment in infrastructure and redesigned care processes for high quality and efficient service delivery. Thus, measures should have high impact in terms of accountability and cost, particularly for vulnerable populations, when comparing beneficiary care received in ACOs to beneficiary care received in non-ACO Medicare FFS.
- Align with other Medicare incentive programs such as the Physician Quality Reporting System ("PQRS"; formerly known as the Physician Quality Reporting Initiative), Electronic Prescribing Incentive Program, Electronic Health Records (EHR) Incentive Programs, Hospital Inpatient Quality Reporting Program, and also Medicaid and private sector initiatives that align with the three-part aim.

Chasm: A New Health System for the 21st Century. Washington, DC, USA: National Academies Press; 2001.

- Include the quality performance standards that ACOs must meet in order to be eligible for shared savings, which should be well-established, correlate with improved patient outcomes, and be accepted by the professional and provider community, such as through National Quality Forum (NQF) endorsement.
- Are consistent across ACOs, regardless of ACO composition.
- Offer key opportunities for improvement in care and significantly impact the health status and outcomes of care for the Medicare beneficiaries served by the ACO.
- Are limited to those that have high impact, and/or are cross-cutting to the extent possible, with parsimony serving to focus clinical attention, and limiting the burden of data collection and reporting.
- Exhibit sensitivity to administrative burden and seek to become less burdensome over time.

c. Proposed Quality Measures for Use in Establishing Quality Performance Standards That ACOs Must Meet for Shared Savings

Based upon the principles described, we are proposing 65 measures (see Table 1) for use in the calculation of the ACO Quality Performance Standard. We propose that ACOs will submit data on these measures using the process described later in this proposed rule and meet defined quality performance thresholds. We propose that ACOs be required to report quality measures and meet applicable performance criteria, as defined in rulemaking, for all 3 years within the 3-year agreement period to be considered as having met the quality performance standard. Specifically, for the first year of the program, we propose for the quality performance standard to be at the level of full and accurate measures reporting; for subsequent years, we propose the quality performance standard be based on a measures scale with a minimum attainment level as described in section II.E.4 of this proposed rule.

ACOs that do not meet the quality performance thresholds for all proposed measures would not be eligible for shared savings, regardless of how much per capita costs were reduced. Specifically, as discussed in section II.H. of this proposed rule, in those instances where an ACO fails to meet the minimum attainment level for 1 or more domains, we propose to give the ACO a warning and to re-evaluate the following year. If the ACO continues to underperform on the quality performance standards in the following year, the agreement will be terminated. We also propose that if an ACO fails to report 1 or more measures, we would send the ACO a written request to submit the required data by a specified date and to provide a reasonable written explanation for its delay in reporting the required information. If the ACO fails to report by the requested deadline and does not provide a reasonable explanation for delayed reporting, we would immediately terminate the ACO for failing to report quality measures. ACOs that exhibit a pattern of inaccurate or incomplete reporting or fail to make timely corrections following notice to resubmit may be terminated from the program. We note that since meeting the quality standard is a condition for sharing in savings, the ACO would be disqualified from sharing in savings in each year in which it underperforms. Termination from the Shared Savings Program is discussed further in sections II.H and II.C. of this proposed rule.

In addition to categorizing each of the proposed measures into the goals of better care for individuals and better health for populations, Table 1 includes the domain each of the proposed measures addresses, the measure title, a brief description of the data the measure captures, applicable Physician Quality Reporting System or EHR Incentive Programs information, the measure steward or, if applicable, NQF measure number, the proposed method of data submission for each measure, and the Measure Type. Under Measure Type, we have listed Patient Experience of Care, Process, or Outcome, consistent with the domains proposed in the Hospital Value Based Purchasing rule (76 FR 2457), for each of the proposed Shared Savings Program quality measures.

In an effort to provide focus to ACO quality improvement activity, we have identified 5 key domains within the dimensions of improved care and improved health that we propose will serve as the basis for assessing, benchmarking, rewarding, and improving ACO quality performance. These 5 domains are as follows:

- Better Care for Individuals:
  - ++ Patient/Caregiver Experience
  - ++ Care Coordination
  - ++ Patient Safety
- Better Health for Populations:
  - ++ Preventive Health
  - ++ At-Risk Population/Frail Elderly Health

We note that while many of the proposed measures have NQF endorsement or are currently used in other CMS quality programs, the specifications for some of the proposed measures will need to be refined in order to be applicable to an ACO population. However, we propose to align the quality measures specifications for the Shared Savings Program with the measures specifications used in our existing quality programs to the extent possible and appropriate for purposes of the Shared Savings Program. We plan to make the specifications for the proposed measures available on our Web site prior to the start of the Shared Savings Program.

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Table 1. Proposed Measures for Use in Establishing Quality Performance Standards that ACOs Must Meet for Shared Savings

	Domain	Measure Title & Description	CMS Program, NQF Measure Number, Measure Steward	Method of Data Submission	Measure Type
AIM: Better Care for Individuals					
1.	Patient/Care Giver Experience	**Clinician/Group CAHPS:** Getting Timely Care, Appointments, and Information	NQF #5	Survey	Patient Experience of Care
2.	Patient/Care Giver Experience	**Clinician/Group CAHPS:** How Well Your Doctors Communicate	NQF #5	Survey	Patient Experience of Care
3.	Patient/Care Giver Experience	**Clinician/Group CAHPS:** Helpful, Courteous, Respectful Office Staff	NQF #5	Survey	Patient Experience of Care
4.	Patient/Care Giver Experience	**Clinician/Group CAHPS:** Patients' Rating of Doctor	NQF #5	Survey	Patient Experience of Care
5.	Patient/Care Giver Experience	**Clinician/Group CAHPS:** Health Promotion and Education	NQF #5	Survey	Patient Experience of Care
6.	Patient/Care Giver Experience	**Clinician/Group CAHPS:** Shared Decision Making	NQF #5	Survey	Patient Experience of Care
7.	Patient/Care Giver Experience	**Medicare Advantage CAHPS:** Health Status/Functional Status	NQF #6	Survey	Patient Experience of Care
8.	Care Coordination/Transitions	**Risk-Standardized, All Condition Readmission:** The rate of readmissions within 30 days of discharge from an acute care hospital for assigned ACO beneficiary population.	CMS	Claims	Outcome

	Domain	Measure Title & Description	CMS Program, NQF Measure Number, Measure Steward	Method of Data Submission	Measure Type
9.	Care Coordination/Transitions	**30 Day Post Discharge Physician Visit**	CMS	Group Practice Reporting Option (GPRO) Data Collection Tool	Process
10.	Care Coordination/Transitions	**Medication Reconciliation:** Reconciliation After Discharge from an Inpatient Facility Percentage of patients aged 65 years and older discharged from any inpatient facility (eg, hospital, skilled nursing facility, or rehabilitation facility) and seen within 60 days following discharge in the office by the physician providing on-going care who had a reconciliation of the discharge medications with the current medication list in the medical record documented.	NQF #554	Group Practice Reporting Option (GPRO) Data Collection Tool	Process
11.	Care Coordination/Transitions	**Care Transition Measure:** Uni-dimensional self-reported survey that measures the quality of preparation for care transitions. Namely: 1. Understanding one's self-care role in the post-hospital setting 2. Medication management 3. Having one's preferences incorporated into the care plan	NQF #228 or alternate	Survey or Group Practice Reporting Option (GPRO) Data Collection Tool	Patient Experience of Care

	Domain	Measure Title & Description	CMS Program, NQF Measure Number, Measure Steward	Method of Data Submission	Measure Type
12.	Care Coordination	**Ambulatory Sensitive Conditions Admissions: Diabetes, short-term complications** (AHRQ Prevention Quality Indicator (PQI) #1) All discharges of age 18 years and older with ICD-9-CM principal diagnosis code for short-term complications (ketoacidosis, hyperosmolarity, coma), per 100,000 population.	NQF #272	Claims	Outcome
13.	Care Coordination	**Ambulatory Sensitive Conditions Admissions: Uncontrolled Diabetes** (AHRQ Prevention Quality Indicator (PQI) #14) All discharges of age 18 years and older with ICD-9-CM principal diagnosis code for uncontrolled diabetes, without mention of a short-term or long-term complication, per 100,000 population.	NQF # 638	Claims	Outcome
14.	Care Coordination	**Ambulatory Sensitive Conditions Admissions: Chronic obstructive pulmonary disease** (AHRQ Prevention Quality Indicator (PQI) #5) All discharges of age 18 years and older with ICD-9-CM principal diagnosis code for COPD, per 100,000 population.	NQF #275	Claims	Outcome

	Domain	Measure Title & Description	CMS Program, NQF Measure Number, Measure Steward	Method of Data Submission	Measure Type
15.	Care Coordination	**Ambulatory Sensitive Conditions Admissions: Congestive Heart Failure** (AHRQ Prevention Quality Indicator (PQI) #8) All discharges of age 18 years and older with ICD-9-CM principal diagnosis code for CHF, per 100,000 population.	NQF #277	Claims	Outcome
16.	Care Coordination	**Ambulatory Sensitive Conditions Admissions: Dehydration** (AHRQ Prevention Quality Indicator (PQI) #10) All discharges of age 18 years and older with ICD-9-CM principal diagnosis code for hypovolemia, per 100,000 population.	NQF # 280	Claims	Outcome
17.	Care Coordination	**Ambulatory Sensitive Conditions Admissions: Bacterial pneumonia** (AHRQ Prevention Quality Indicator (PQI) #11) All non-maternal discharges of age 18 years and older with ICD-9-CM principal diagnosis code for bacterial pneumonia, per 100,000 population.	NQF # 279	Claims	Outcome

	Domain	Measure Title & Description	CMS Program, NQF Measure Number, Measure Steward	Method of Data Submission	Measure Type
18.	Care Coordination	**Ambulatory Sensitive Conditions Admissions: Urinary infections** (AHRQ Prevention Quality Indicator (PQI) #12) All discharges of age 18 years and older with ICD-9-CM principal diagnosis code of urinary tract infection, per 100,000 population.	NQF # 281	Claims	Outcome
19.	Care Coordination/Information Systems	**% All Physicians Meeting Stage 1 HITECH Meaningful Use Requirements**	CMS	Group Practice Reporting Option (GPRO) Data Collection Tool / EHR Incentive Program Reporting	Process
20.	Care Coordination/Information Systems	**% of PCPs Meeting Stage 1HITECH Meaningful Use Requirements**	CMS	Group Practice Reporting Option (GPRO) Data Collection Tool / EHR Incentive Program Reporting	Process

	Domain	Measure Title & Description	CMS Program, NQF Measure Number, Measure Steward	Method of Data Submission	Measure Type
21.	Care Coordination/Information Systems	**% of PCPs Using Clinical Decision Support**	CMS EHR Incentive Program – Core Measure	Group Practice Reporting Option (GPRO) Data Collection Tool/ EHR Incentive Program Reporting	Process
22.	Care Coordination/Information Systems	**% of PCPs who are Successful Electronic Prescribers Under the eRx Incentive Program**	CMS EHR Incentive Program – Core Measure	Group Practice Reporting Option (GPRO) Data Collection Tool / eRx Incentive Program Reporting	Process
23.	Care Coordination/Information Systems	**Patient Registry Use**	CMS EHR Incentive Program – Menu Set Measure	Group Practice Reporting Option (GPRO) Data Collection Tool	Process

	Domain	Measure Title & Description	CMS Program, NQF Measure Number, Measure Steward	Method of Data Submission	Measure Type
24.	Patient Safety	**Health Care Acquired Conditions Composite:** • Foreign Object Retained After Surgery • Air Embolism • Blood Incompatibility • Pressure Ulcer, Stages III and IV • Falls and Trauma • Catheter-Associated UTI • Manifestations of Poor Glycemic Control • Central Line Associated Blood Stream Infection (CLABSI) • Surgical Site Infection • AHRQ Patient Safety Indicator (PSI) 90 Complication/Patient Safety for Selected Indicators (composite) ○ Accidental puncture or laceration ○ Iatrogenic pneumothorax ○ Postoperative DVT or PE ○ Postoperative wound dehiscence ○ Decubitus ulcer ○ Selected infections due to medical care (PSI 07: Central Venus Catheter-related Bloodstream Infection) ○ Postoperative hip fracture ○ Postoperative sepsis	CMS (HACs), NQF #531 (AHRQ PSI)	Claims or CDC National Healthcare Safety Network	Outcome

	Domain	Measure Title & Description	CMS Program, NQF Measure Number, Measure Steward	Method of Data Submission	Measure Type
25.	Patient Safety	**Health Care Acquired Conditions: CLABSI Bundle**	NQF #298	Claims or CDC National Healthcare Safety Network	Process
AIM: Better Health for Populations					
26.	Preventive Health	**Influenza Immunization:** Percentage of patients aged 50 years and older who received an influenza immunization during the flu season (September through February).	Physician Quality Reporting System Measure #110 EHR Incentive Program – Clinical Quality Measure NQF #41	Group Practice Reporting Option (GPRO) Data Collection Tool	Process
27.	Preventive Health	**Pneumococcal Vaccination:** Percentage of patients aged 65 years and older who have ever received a pneumococcal vaccine.	Physician Quality Reporting System Measure #111 EHR Incentive Program – Clinical Quality Measure NQF #44	Group Practice Reporting Option (GPRO) Data Collection Tool	Process

	Domain	Measure Title & Description	CMS Program, NQF Measure Number, Measure Steward	Method of Data Submission	Measure Type
28.	Preventive Health	**Mammography Screening:** Percentage of women aged 40 through 69 years who had a mammogram to screen for breast cancer within 24 months.	Physician Quality Reporting System Measure #112 EHR Incentive Program – Clinical Quality Measure NQF #31	Group Practice Reporting Option (GPRO) Data Collection Tool	Process
29.	Preventive Health	**Colorectal Cancer Screening:** Percentage of patients aged 50 through 75 years who received the appropriate colorectal cancer screening.	Physician Quality Reporting System Measure #113 EHR Incentive Program – Clinical Quality Measure NQF #34	Group Practice Reporting Option (GPRO) Data Collection Tool	Process

	Domain	Measure Title & Description	CMS Program, NQF Measure Number, Measure Steward	Method of Data Submission	Measure Type
30.	Preventive Health	**Cholesterol Management for Patients with Cardiovascular Conditions:** • The percentage of members 18–75 years of age who were discharged alive for AMI, coronary artery bypass graft (CABG) or percutaneous coronary interventions (PCI) of the year prior to the measurement year, or who had a diagnosis of ischemic vascular disease (IVD) during the measurement year and the year prior to the measurement year, who had each of the following during the measurement year.LDL-C screening • LDL-C control (<100 mg/dL)	EHR Incentive Program – Clinical Quality Measure NQF # 75	Group Practice Reporting Option (GPRO) Data Collection Tool	Process & Outcome
31.	Preventive Health	**Adult Weight Screening and Follow-up**: Percentage of patients aged 18 years and older with a calculated BMI in the past six months or during the current visit documented in the medical record AND if the most recent BMI is outside parameters, a follow-up plan is documented. Parameters: Age 65 and older BMI ≥ 30 or < 22; Age 18-64 BMI ≥ 25 or < 18.5	Physician Quality Reporting System Measure #128 EHR Incentive Program – Clinical Quality Measure NQF #421	Group Practice Reporting Option (GPRO) Data Collection Tool	Process

	Domain	Measure Title & Description	CMS Program, NQF Measure Number, Measure Steward	Method of Data Submission	Measure Type
32.	Preventive Health	**Blood Pressure Measurement:** Percentage of patient visits with blood pressure measurement recorded among all patient visits for patients aged > 18 years with diagnosed hypertension.	Physician Quality Reporting System #TBD EHR Incentive Program – Clinical Quality Measure NQF #13	Group Practice Reporting Option (GPRO) Data Collection Tool	Process
33.	Preventive Health	**Tobacco Use Assessment and Tobacco Cessation Intervention:** Percentage of patients who were queried about tobacco use. Percentage of patients identified as tobacco users who received cessation intervention.	Physician Quality Reporting System #TBD EHR Incentive Program – Clinical Quality Measure NQF #28	Group Practice Reporting Option (GPRO) Data Collection Tool	Process
34.	Preventive Health	**Depression Screening:** Percentage of patients aged 18 years and older screened for clinical depression using a standardized tool and follow up plan documented.	Physician Quality Reporting System #134 NQF #418	Group Practice Reporting Option (GPRO) Data Collection Tool	Process
35.	At Risk Population - Diabetes	**Diabetes Composite (All or Nothing Scoring):** • Hemoglobin A1c Control (<8%) • Low Density Lipoprotein (<100) • Blood Pressure <140/90 • Tobacco Non Use • Aspirin Use	NQF #575*, 64*, 61*, 28*, TBD	Group Practice Reporting Option (GPRO) Data Collection Tool	Process & Outcome

	Domain	Measure Title & Description	CMS Program, NQF Measure Number, Measure Steward	Method of Data Submission	Measure Type
36.	At Risk Population – Diabetes	**Diabetes Mellitus: Hemoglobin A1c Control (<8%)** Percentage of patients aged 18 through 75 years with diabetes mellitus who had most recent hemoglobin A1c less than 8.0%.	EHR Incentive Program – Clinical Quality Measure NQF #575	Group Practice Reporting Option (GPRO) Data Collection Tool	Outcome
37.	At Risk Population – Diabetes	**Diabetes Mellitus: Low Density Lipoprotein (LDL-C) Control in Diabetes Mellitus** Percentage of patients aged 18 through 75 years with diabetes mellitus who had most recent LDL-C level in control (less than 100 mg/dl).	Physician Quality Reporting System Measure #2 EHR Incentive Program – Clinical Quality Measure NQF #64	Group Practice Reporting Option (GPRO) Data Collection Tool	Outcome
38.	At Risk Population - Diabetes	**Diabetes Mellitus: Tobacco Non Use** Tobacco use assessment and cessation	Physician Quality Reporting System #TBD EHR Incentive Program – Clinical Quality Measure NQF #28	Group Practice Reporting Option (GPRO) Data Collection Tool	Process
39.	At Risk Population - Diabetes	**Diabetes Mellitus: Aspirin Use** Daily aspirin use for patients with diabetes & cardiovascular disease	NQF TBD	Group Practice Reporting Option (GPRO) Data Collection Tool	Process

	Domain	Measure Title & Description	CMS Program, NQF Measure Number, Measure Steward	Method of Data Submission	Measure Type
40.	At Risk Population - Diabetes	**Diabetes Mellitus: Hemoglobin A1c Poor Control(>9%):** Percentage of patients aged 18 through 75 years with diabetes mellitus who had most recent hemoglobin A1c greater than 9.0%.	Physician Quality Reporting System Measure #1 EHR Incentive Program – Clinical Quality Measure NQF #59	Group Practice Reporting Option (GPRO) Data Collection Tool	Outcome
41.	At Risk Population - Diabetes	**Diabetes Mellitus: High Blood Pressure Control in Diabetes Mellitus:** Percentage of patients aged 18 through 75 years with diabetes mellitus who had most recent blood pressure in control (less than 140/90 mmHg).	Physician Quality Reporting System Measure #3 EHR Incentive Program – Clinical Quality Measure NQF #61	Group Practice Reporting Option (GPRO) Data Collection Tool	Outcome
42.	At Risk Population - Diabetes	**Diabetes Mellitus: Urine Screening for Microalbumin or Medical Attention for Nephropathy in Diabetic Patients** Percentage of patients aged 18 through 75 years with diabetes mellitus who received urine protein screening or medical attention for nephropathy during at least one office visit within 12 months.	Physician Quality Reporting System Measure #119 EHR Incentive Program – Clinical Quality Measure NQF #62	Group Practice Reporting Option (GPRO) Data Collection Tool	Process

	Domain	Measure Title & Description	CMS Program, NQF Measure Number, Measure Steward	Method of Data Submission	Measure Type
43.	At Risk Population - Diabetes	**Diabetes Mellitus: Dilated Eye Exam in Diabetic Patients** Percentage of patients aged 18 through 75 years with a diagnosis of diabetes mellitus who had a dilated eye exam.	Physician Quality Reporting System Measure #117 EHR Incentive Program – Clinical Quality Measure NQF #55	Group Practice Reporting Option (GPRO) Data Collection Tool	Process
44.	At Risk Population - Diabetes	**Diabetes Mellitus: Foot Exam** The percentage of patients aged 18 through 75 years with diabetes who had a foot examination.	Physician Quality Reporting System Measure #163 EHR Incentive Program – Clinical Quality Measure NQF #56	Group Practice Reporting Option (GPRO) Data Collection Tool	Process
45.	At Risk Population - Heart Failure	**Heart Failure: Left Ventricular Function (LVF) Assessment** Percentage of patients aged 18 years and older with a diagnosis of heart failure who have quantitative or qualitative results of LVF assessment recorded.	Physician Quality Reporting System Measure #198 NQF # 79	Group Practice Reporting Option (GPRO) Data Collection Tool	Process

	Domain	Measure Title & Description	CMS Program, NQF Measure Number, Measure Steward	Method of Data Submission	Measure Type
46.	At Risk Population - Heart Failure	**Heart Failure: Left Ventricular Function (LVF) Testing** Percentage of patients with LVF testing during the current year for patients hospitalized with a principal diagnosis of heart failure (HF) during the measurement period.	Physician Quality Reporting System Measure #228 CMS	Group Practice Reporting Option (GPRO) Data Collection Tool	Process
47.	At Risk Population - Heart Failure	**Heart Failure: Weight Measurement** Percentage of patient visits for patients aged 18 years and older with a diagnosis of heart failure with weight measurement recorded.	Physician Quality Reporting System #227 NQF # 85	Group Practice Reporting Option (GPRO) Data Collection Tool	Process
48.	At Risk Population - Heart Failure	**Heart Failure: Patient Education** Percentage of patients aged 18 years and older with a diagnosis of heart failure who were provided with patient education on disease management and health behavior changes during one or more visit(s) within 12 months.	Physician Quality Reporting System #199 NQF # 82	Group Practice Reporting Option (GPRO) Data Collection Tool	Process
49.	At Risk Population - Heart Failure	**Heart Failure: Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD)** Percentage of patients aged 18 years and older with a diagnosis of heart failure who also have LVSD (LVEF < 40%) and who were prescribed beta-blocker therapy.	Physician Quality Reporting System Measure # 8 EHR Incentive Program – Clinical Quality Measure NQF #83	Group Practice Reporting Option (GPRO) Data Collection Tool	Process

	Domain	Measure Title & Description	CMS Program, NQF Measure Number, Measure Steward	Method of Data Submission	Measure Type
50.	At Risk Population - Heart Failure	**Heart Failure: Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy for Left Ventricular Systolic Dysfunction (LVSD)** Percentage of patients aged 18 years and older with a diagnosis of heart failure and LVSD (LVEF < 40%) who were prescribed ACE inhibitor or ARB therapy.	Physician Quality Reporting System Measure #5 EHR Incentive Program – Clinical Quality Measure NQF #81	Group Practice Reporting Option (GPRO) Data Collection Tool	Process
51.	At Risk Population - Heart Failure	**Heart Failure: Warfarin Therapy for Patients with Atrial Fibrillation** Percentage of all patients aged 18 and older with a diagnosis of heart failure and paroxysmal or chronic atrial fibrillation who were prescribed warfarin therapy.	Physician Quality Reporting System Measure #200 EHR Incentive Program – Clinical Quality Measure NQF #84	Group Practice Reporting Option (GPRO) Data Collection Tool	Process

	Domain	Measure Title & Description	CMS Program, NQF Measure Number, Measure Steward	Method of Data Submission	Measure Type
52.	At Risk Population – Coronary Artery Disease	**Coronary Artery Disease (CAD) Composite: All or Nothing Scoring** • Oral Antiplatelet Therapy Prescribed for Patients with CAD • Drug Therapy for Lowering LDL-Cholesterol • Beta-Blocker Therapy for CAD Patients with Prior Myocardial Infarction (MI) • LDL Level <100 mg/dl • Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy for Patients with CAD and Diabetes and/or Left Ventricular Systolic Dysfunction (LVSD)	NQF #67, 74, 70, 64, 66	Group Practice Reporting Option (GPRO) Data Collection Tool	Process & Outcome
53.	At Risk Population – Coronary Artery Disease	**Coronary Artery Disease (CAD): Oral Antiplatelet Therapy Prescribed for Patients with CAD** Percentage of patients aged 18 years and older with a diagnosis of CAD who were prescribed oral antiplatelet therapy.	Physician Quality Reporting System Measure # 6 EHR Incentive Program – Clinical Quality Measure NQF #67	Group Practice Reporting Option (GPRO) Data Collection Tool	Process

	Domain	Measure Title & Description	CMS Program, NQF Measure Number, Measure Steward	Method of Data Submission	Measure Type
54.	At Risk Population – Coronary Artery Disease	**Coronary Artery Disease (CAD): Drug Therapy for Lowering LDL-Cholesterol** Percentage of patients aged 18 years and older with a diagnosis of CAD who were prescribed a lipid-lowering therapy (based on current ACC/AHA guidelines). The LDL-C treatment goal is <100 mg/dl. Persons with established coronary heart disease (CHD) who have a baseline LDL-C 130 mg/dl should be started on a cholesterol-lowering drug simultaneously with therapeutic lifestyle changes and control of nonlipid risk factors (National Cholesterol Education Program (NCEP).	Physician Quality Reporting System #197 EHR Incentive Program – Clinical Quality Measure NQF #74	Group Practice Reporting Option (GPRO) Data Collection Tool	Process
55.	At Risk Population – Coronary Artery Disease	**Coronary Artery Disease (CAD): Beta-Blocker Therapy for CAD Patients with Prior Myocardial Infarction (MI)** Percentage of patients aged 18 years and older with a diagnosis of CAD and prior MI who were prescribed beta-blocker therapy.	Physician Quality Reporting System Measure # 7 EHR Incentive Program – Clinical Quality Measure NQF #70	Group Practice Reporting Option (GPRO) Data Collection Tool	Process
56.	At Risk Population – Coronary Artery Disease	**Coronary Artery Disease (CAD): LDL level < 100 mg/dl**	CMS	Group Practice Reporting Option (GPRO) Data Collection Tool	Outcome

	Domain	Measure Title & Description	CMS Program, NQF Measure Number, Measure Steward	Method of Data Submission	Measure Type
57.	At Risk Population – Coronary Artery Disease	**Coronary Artery Disease (CAD): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy for Patients with CAD and Diabetes and/or Left Ventricular Systolic Dysfunction (LVSD)** Percentage of patients aged 18 years and older with a diagnosis of CAD who also have diabetes mellitus and/or LVSD (LVEF < 40%) who were prescribed ACE inhibitor or ARB therapy.	Physician Quality Reporting System Measure #118 NQF #66	Group Practice Reporting Option (GPRO) Data Collection Tool	Process
58.	At Risk Population – Hypertension	**Hypertension (HTN): Blood Pressure Control** Percentage of patients with last BP < 140/90 mmHg	Physician Quality Reporting System #TBD EHR Incentive Program – Clinical Quality Measure NQF #18	Group Practice Reporting Option (GPRO) Data Collection Tool	Outcome
59.	At Risk Population – Hypertension	**Hypertension (HTN): Plan of Care** Percentage of patient visits for patients aged 18 years and older with a diagnosis of HTN with either systolic blood pressure ≥ 140 mmHg or diastolic blood pressure ≥ 90 mmHg with documented plan of care for hypertension.	Physician Quality Reporting System #TBD NQF # 17	Group Practice Reporting Option (GPRO) Data Collection Tool	Process

	Domain	Measure Title & Description	CMS Program, NQF Measure Number, Measure Steward	Method of Data Submission	Measure Type
60.	At Risk Population – COPD	**Chronic Obstructive Pulmonary Disease (COPD): Spirometry Evaluation** Percentage of patients aged 18 years and older with a diagnosis of COPD who had spirometry evaluation results documented.	Physician Quality Reporting System Measure # 51 NQF #91	Group Practice Reporting Option (GPRO) Data Collection Tool	Process
61.	At Risk Population – COPD	**Chronic Obstructive Pulmonary Disease (COPD): Smoking Cessation Counseling Received**	CMS	Group Practice Reporting Option (GPRO) Data Collection Tool	Process
62.	At Risk Population – COPD	**Chronic Obstructive Pulmonary Disease (COPD): Bronchodilator Therapy based on FEV1** Percentage of patients aged 18 years and older with a diagnosis of COPD and who have an FEV1/FVC less than 70% and have symptoms who were prescribed an inhaled bronchodilator.	Physician Quality Reporting System Measure # 52 NQF #102	Group Practice Reporting Option (GPRO) Data Collection Tool	Process
63.	At Risk Population – Frail Elderly	**Falls: Screening for Fall Risk** Percentage of patients aged 65 years and older who were screened for fall risk at least once within 12 months	NQF #101	Group Practice Reporting Option (GPRO) Data Collection Tool	Process

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	Domain	Measure Title & Description	CMS Program, NQF Measure Number, Measure Steward	Method of Data Submission	Measure Type
64.	At Risk Population – Frail Elderly	**Osteoporosis Management in Women Who had a Fracture** Percentage of women 65 years and older who suffered a fracture and who had either a bone mineral density (BMD) test or prescription for a drug to treat or prevent osteoporosis in the 6 months after the date of fracture	NQF #53	Group Practice Reporting Option (GPRO) Data Collection Tool	Process
65.	At Risk Population – Frail Elderly	**Monthly INR for Beneficiaries on Warfarin** Average percentage of monthly intervals in which Part D beneficiaries with claims for warfarin do not receive an INR test during the measurement period	NQF #555	Claims	Process

*Individual measure within composite measure is used in the EHR Incentive Program.

Information on Physician Quality Reporting System measures are available at: *http://www.cms.gov/pqri/*. Information on EHR Incentive Program measures are available at: *https://www.cms.gov/EHRIncentivePrograms/*. Information on quality measures used by the Hospital Inpatient Quality Reporting Program are available at: *http://www.cms.gov/HospitalQualityInits/08_HospitalRHQDAPU.asp*.

As illustrated in the "Method of Data Submission" column of Table 1, we propose to calculate results for the first program year measures via claims, the Group Practice Reporting Option (GPRO) data collection tool, as discussed in section II.E.4. of this proposed rule, and survey instruments. The ACO GPRO tool would be a new tool based on the data collection tool currently used in the Physician Quality Reporting System (formerly known as the Physician Quality Reporting Initiative) group practice reporting option (GPRO) and Physician Group Practice (PGP) demonstration.

In subsequent program years through additional rulemaking, we would expect to refine and expand the ACO measures to enhance our ability to assess the quality of care furnished by ACOs participating in the Shared Savings Program and expand measures reporting mechanisms to include those that are directly EHR-based. Specifically, we expect to expand the measures through future rulemaking to include other highly prevalent conditions and areas of interest, such as frailty, as well as measures of caregiver experience. In addition to ambulatory measures, we would expect to add measures of hospital-based care and quality measures for care furnished in other settings, such as home health services and nursing homes. To the extent consistent with the Shared Savings Program requirements under section 1899 of the Act, we also anticipate the ACO quality measures will evolve over time in an effort to achieve our quality program alignment goal of developing a single quality measure set that could be used by ACOs operating across a wide variety of payers, including those dealing with Medicaid, the Children's Health Insurance Program (CHIP), and Special Needs Plans.

We invite comments on the implication of including or excluding any proposed measure or measures in the calculation of the ACO Quality Performance Standard. Commenters may suggest variations or substitutions that are substantially equivalent to the proposed measures. However, without future rulemaking, we cannot consider measures that do not substantially cover the same patient populations, processes, or outcomes addressed by the existing measures outlined in this proposed rule. We invite comment on whether the list of proposed measures should be narrowed, and also invite comments on whether any of the measures we proposed in Table 1 for calculating the ACO Quality Performance Standard should be excluded for scoring purposes and/or instead be considered for quality monitoring purposes only. Finally, we also seek comment on a process for retiring or adjusting the weights of domains, modules, or measures over time.

3. Requirements for Quality Measures Data Submission by ACOs

a. General

Under section 1899(b)(3)(B) of the Act, ACOs are required to submit data in a form and manner specified by the Secretary on measures the Secretary determines necessary for the ACO to report in order to evaluate the quality of care furnished by the ACO. Most of the proposed measures identified in Table 1 can be derived from CMS systems and calculated for the assigned patient population the ACO serves. Most of the measures are consistent with those reported for the Physician Quality Reporting System, others will rely on eRx and HITECH program data, and some may rely on Hospital Compare or the Centers for Disease Control and Prevention National Healthcare Safety Network data. However, we recognize that there are a number of limitations associated with claims-based reporting, since the claims processing system was designed for billing purposes and not for the submission of quality data. For instance, measures dealing with laboratory results are not conducive to claims-based reporting, since claims typically include diagnosis and procedure codes but not specific test results. For this reason, we propose to make available a CMS-specified data collection tool and a survey tool for certain proposed measures (that is, those measures in Table 1 where the proposed method of data submission is listed as "GPRO").

We also propose that for some measures ACOs collect data via survey instruments. As noted previously, we plan to continually align the ACO reporting requirements with those required for the EHR Incentive Program and leverage the infrastructure and measures specifications being developed for that program. We propose that during the year following the first performance period, each ACO would be required to report via the GPRO tool, as applicable, the proposed quality measures listed in Table 1 with respect to services furnished during the performance period. We propose that we would derive the claims-based measures from claims submitted for services furnished during the first performance period, which therefore would not require any additional reporting on the part of ACO professionals. Survey data would also reflect care received during the first performance period. For future performance periods, we intend to use rulemaking to update the quality measure requirements and mechanisms.

We welcome comments on the proposed data submission requirements. We also seek comment on whether alternative data submission methods should be required or considered, such as limiting the measures to claims-based and survey-based reporting only.

b. GPRO Tool

In 2010, 36 large group practices and integrated delivery systems used the GPRO tool to report 26 quality measures for an assigned patient population under the Physician Quality Reporting System. The GPRO tool affords a key advantage in that it is a mechanism through which beneficiary laboratory results and other measures requiring clinical information can be reported to us. The tool would allow ACOs to submit clinical information from EHRs, registries, and administrative data sources required for measurement reporting. The tool reduces the administrative burden on health care providers participating in ACOs by allowing them to tap into their existing Information Technology (IT) tools that support data collection and health care provider feedback, including at the point of care. We propose that the existing GPRO tool be built out, refined, and upgraded to support clinical data collection and measurement reporting and feedback to ACOs under the Shared Savings Program.

For the measures with "GPRO" listed as the method of data collection in Table 1, we plan to determine a sample for each domain or measure set within the domain using a sampling methodology modeled after the methodology currently used in the 2011 Physician Quality Reporting System GPRO I, as described later in the document. Assigned beneficiaries, for purposes of the GPRO tool, would be limited to those Medicare FFS beneficiaries assigned to the ACO, as discussed in Section II.D.

For the measures with "GPRO" listed as the method of data collection in

Table 1, we also plan to provide each ACO with access to a database (that is, the GPRO data collection tool) that will include a sample of its assigned beneficiary population and the GPRO quality measures listed in Table 1. We plan to pre-populate the data collection tool with the beneficiaries' demographic and utilization information based on their Medicare claims data. The ACO would be required to populate the remaining data fields necessary for capturing quality measure information on each of the beneficiaries.

Identical to the sampling method used in the 2011 Physician Quality Reporting System GPRO I, we plan to require that the random sample for measures reported via ACO GPRO must consist of at least 411 assigned beneficiaries per measure set/domain. If the pool of eligible, GPRO assigned beneficiaries is less than 411 for any measure set/domain, then we plan to require the ACO to report on 100 percent, or all, of the assigned beneficiaries. For each measure set/domain within the GPRO tool, the ACO would be required to report information on the assigned beneficiaries in the order in which they appear consecutively in the ACO's sample.

Some GPRO measures will not rely on beneficiary data but rather on ACO attestation. GPRO measures relying on attestation include those in the Care Coordination domain that pertain to HITECH Meaningful Use, the Electronic Prescribing Incentive Program, and patient registry use. We plan to validate GPRO attestations through CMS data from the EHR Incentive Program and Electronic Prescribing Incentive Program.

For the other measures, that we propose be reported via the GPRO tool, we propose to retain the right to validate the data entered into the tool. In the event we were to audit the data entered into the GPRO tool, we propose to do so via a data validation process based on the one used in phase I of the PGP demonstration, as described later in the document.

In the GPRO audit process, we plan to abstract a random sample of 30 beneficiaries previously abstracted for each of the quality measure domains/measure sets. The audit process would include up to three phases, depending on the results of the first two phases. Although each sample would include 30 beneficiaries per domain, only the first eight beneficiaries' medical records would be audited for mismatches during the first phase of the audit. A mismatch represents a discrepancy between the numerator inclusions or denominator exclusions in the data submitted by the ACO and our determination of their appropriateness based on supporting medical records information submitted by the ACO. If there are no mismatches, the remaining 22 of the 30 beneficiaries' records would not be audited. If there are mismatches, the second phase of the audit would occur, and the other 22 beneficiaries' records would be audited. A third phase would only be undertaken if mismatches are found in more than 10 percent of the medical records in phase two. If a specific error is identified and the audit process goes to Phase 3, which involves corrective action, we propose to first provide education to the ACO on the correct specification process and provide the opportunity to correct and resubmit the measure(s) in question. If, at the conclusion of the third audit process the mismatch rate is more than 10 percent, we propose that the ACO will not be given credit for meeting the quality target for any measures for which this mismatch rate still exists. We note that the failure to report quality measure data accurately, completely and timely (or to timely correct such data) may subject the ACO to termination or other sanctions, per the Monitoring section of this proposed rule.

We invite comment on the proposed quality data submission requirements and on the administrative burden associated with reporting.

c. Certified EHR Technology

In July 2010, HHS published final rules for the EHR Incentive Programs. Included within the final regulations were certain clinical quality measures for which eligible professionals and eligible hospitals are responsible. We have noted in Table 1, the proposed Shared Savings Program quality measures currently included in the EHR Incentive Programs and will continue to further align the measures between the two programs. Given that we have proposed in Section II.E.6 that at least 50 percent of an ACO's PCPs are "meaningful EHR users" as that term is defined in 42 CFR 495.4 by the start of the second Shared Savings Program performance year in order to continue participation in the Shared Savings Program, our intent is to develop the capability of the GPRO web-based tool to interface with EHR technology, such that EHR data could directly populate the ACO GPRO tool with the required quality data. As we intend to further align both the Shared Savings Program and EHR incentive program through subsequent rulemaking, we anticipate that certified EHR technology (including certified EHR modules capable of reporting clinical quality measures) will be an additional measures reporting mechanism used by ACOs under the Shared Savings Program for future program years.

4. Quality Performance Standards

a. General

Before an ACO can share in any savings created, it must demonstrate that it is delivering high quality care. Thus, a calculation of the quality performance standard will indicate whether an ACO has met the quality performance goals that would deem it eligible for shared savings. As discussed previously in section II.E.3 of this proposed rule, we propose to use the 65 measures in Table 1 to establish the quality performance standards that ACOs must meet in order to be eligible for shared savings.

We considered two alternative options for establishing quality standards: Rewards for better performance, and a minimum quality threshold for shared savings. The performance score approach rewards ACOs for better quality with larger percentages of shared savings. The threshold approach ensures that ACOs exceed minimum standards for the quality of care, but allows full shared savings if ACOs meet the minimum. We propose the performance score approach and seek comment on the threshold approach.

b. Option 1—Performance Scoring

Under the first option, we would use quality performance standards to arrive at a total performance score for an ACO. We would organize the measures by domain, as discussed in section II.E.5.b. of this proposed rule. The performance on each measure will be scored, as discussed in section II.E.5.c. of this proposed rule. The scores for the measures will be rolled up into a score by each domain as discussed in section II.E.5.d. of this proposed rule. ACOs will receive performance feedback at both the individual measure and domain level. The percentage of points earned for each domain will be aggregated using the weighting method discussed in section II.E.5.d. of this proposed rule to arrive at a single percentage that will be applied to determine the quality sharing rate for which the ACO is eligible. The aggregated domain scores will determine the ACO's eligibility for sharing up to 50 percent of the total savings generated by the ACO under the one-sided model or 60 percent of the total savings generated by the ACO under the two-sided risk model discussed in Section II. G, Two-Side

Model. We also discuss our proposal to set the quality performance standard in the first year of the Shared Savings Program at the reporting level and set the standard at a higher level in subsequent years in section II.E.5.e. of this proposed rule.

(1) Measure Domains and Measures Included in the Domains

The 65 quality performance standard measures in Table 1 are subdivided into 5 domains, as discussed in section II.E.3.c. of this proposed rule. The domains include: (1) Patient/Caregiver Experience; (2) Care Coordination; (3) Patient Safety; (4) Preventive Health; (5) At-Risk Population/Frail Elderly Health. The At-Risk Population Care domain would include the following chronic diseases: Diabetes mellitus (DM); heart failure (HF); coronary artery disease (CAD); hypertension; and chronic obstructive pulmonary disorder (COPD). The measures from Table 1 that are included in each domain are as indicated in Table 2.

Table 2: Five Measure Domains for Quality Performance Standard

Domain	Category	Table 1 Measures (Total)
1. Patient/Caregiver Experience		1-7 (7 measures)
2. Care Coordination		8-23 (16 measures)
3. Patient Safety		24-25 (2 measures)
4. Preventive Health		26-34 (9 measures)
5. At-Risk Population/Frail Elderly Health	Diabetes	35-65 (31 measures)
	Heart Failure	
	Coronary Artery Disease	
	Hypertension	
	Chronic Obstructive Pulmonary Disorder	
	Frail Elderly	

(2) Methodology for Calculating a Performance Score for Each Measure Within a Domain

We propose that an ACO will receive a performance score on each measure included in Table 1. For the first year of the Shared Savings Program, these scores would be for informational purposes, since we propose to set the quality performance standard at the reporting level. We propose setting benchmarks for each measure using Medicare FFS claims data, MA quality performance rates, or, where appropriate, the corresponding percent performance rates that an ACO will be required to demonstrate. For each measure, we propose to set a performance benchmark and a minimum attainment level as defined in Table 3. The benchmarks would be established using the most currently available data source and most recent available year of benchmark data prior to the start of the Shared Savings Program annual agreement periods. We would determine Medicare FFS rates by pulling a data sample and modeling the measures. For MA rates, we would check the distribution from annual MA quality performance data and set the benchmark accordingly. Furthermore, since MA quality performance rates utilize both claims and clinical data, we propose to use those rates when they are available.

Benchmark levels for each of the measures included in the quality performance standard would be made available to ACOs, prior to the start of the Shared Savings Program and each annual performance period thereafter, so ACOs will be aware of the benchmarks they must achieve to receive the maximum quality score. In future program years, we anticipate that actual ACO performance will be used to update the benchmarks. As discussed in section II.H of this proposed rule, if an ACO fails to meet quality performance standard during a performance year (that is, fails to meet, the minimum attainment level for one or more domain(s)), we propose to give the ACO a warning, provide an opportunity to resubmit, and reevaluate the ACO's performance the following year. If the ACO continues to significantly under-perform, the agreement may be terminated. We further propose that ACOs that exhibit a pattern of inaccurate or incomplete reporting or fail to make timely corrections following notice to resubmit may be terminated from the program.

Table 3: Sliding Scale Measure Scoring Approach

ACO Performance Level	Quality Points
90+ percentile FFS/MA Rate or 90+ percent	2 points
80+ percentile FFS/MA Rate or 80+ percent	1.85 points
70+ percentile FFS/MA Rate or 70+ percent	1.7 points
60+ percentile FFS/MA Rate or 60+ percent	1.55 points
50+ percentile FFS/MA Rate or 50+ percent	1.4 points
40+ percentile FFS/MA Rate or 40+ percent	1.25 points
30+ percentile FFS/MA Rate or 30+ percent	1.10 point
<30 percentile FFS/MA Rate or <30 percent	No points

We propose that performance below the minimum attainment level would earn zero points for that measure under both the one-sided and two-sided risk models. Performance equal to or greater than the minimum attainment level but less than the performance benchmark shall receive points on a sliding scale based on the level of performance, for those measures in which the points scale applies. Table 3 represents the approach that we are currently considering. We also are considering setting the initial minimum attainment level for both the one-sided and two-sided shared savings models at 30 percent or the 30th percentile of Medicare FFS or the MA rate, depending on what performance data are available.

Measures 35 and 52 in Table 1 include diabetes and coronary artery disease composite measures in which we propose "all or nothing" scoring. We propose that measures designated as all or nothing measures receive the maximum available points if all criteria are met and zero points if at least one of the criteria are not met. We define "all or nothing" scoring to mean all of the care process steps and expected outcomes for a particular beneficiary with the target condition must be achieved to score positively. This means all 5 submeasures within the diabetes composite and all 5 submeasures within the CAD composite would need to be reported in order to earn points for these 2 composite measures. The intent of all or nothing scoring is to signal to providers that failing to perform any element of a process is unacceptable and will result in a "zero" score for quality for that measure. We believe that incorporating all or nothing scoring concepts into the ACO quality performance standard would provide greater insight into the use of these methodologies, drive ACOs to aggressively improve their population's health, and encourage future development of composite measures.

However, we also recognize that all or nothing scoring implies that all beneficiaries can and should receive the indicated care process, which may not necessarily be appropriate for all beneficiaries in the Medicare population given the difficulty in attaining targets for individuals with multiple chronic conditions and complications that may not be adequately addressed in denominator exclusions. Therefore, in addition to scoring the diabetes and CAD composites, we also propose scoring the sub measures within the diabetes and CAD composites individually.

Measure #24 is a hospital acquired conditions (HACs) composite, in which we propose a summation of the events included within the measure and attributing the rate to the same scale used for other measures described in Table 3. We do not propose all or nothing scoring for this composite, since the HACs are rare events. Because the HACs are rare events, we believe that grouping them into one measure will make the measure more meaningful for ACOs, which will have smaller populations and, therefore, should have even fewer HAC events than a hospital would experience for its total population outside of the Shared Savings Program. We also believe grouping the HACs into one measure reduces the HACs' impact on the ACO's overall quality performance score. We intend to post performance rates for the final measures set, including the applicable benchmarks, on the CMS Web site prior to the start of the first performance period.

(3) Methodology for Calculating a Performance Score for Each Domain

Similar to our proposal for setting a quality standard for each individual measure at the reporting level in the first program year, we also propose setting a quality standard for each domain at the reporting level. For subsequent program years, we plan to calculate the percentage of points an ACO earns for each domain after determining the points earned for each measure. We plan to divide the points earned by the ACO across all measures in the domain by the total points available in that particular domain. Each domain would be worth a pre-defined number of points based on the number of individual measures in the domain, as shown in Table 4.

Table 4: Total Points for Each Domain within the Quality Performance Standard

Domain	Category	Table 1 Measures (Total)	One-Sided Model – Total Potential Points Per Domain	Two-Sided Risk Model – Total Potential Points Per Domain
1. Patient/Caregiver Experience		1-7 (7 measures)	14	14
2. Care Coordination		8-23 (16 measures)	32	32
3. Patient Safety		24-25 (2 measures)	4	4
4. Preventive Health		26-34 (9 measures)	18	18
5. At-Risk Population/Frail Elderly Health	Diabetes	35-65 (31 measures)	62	62
	Heart Failure			
	Coronary Artery Disease			
	Hypertension			
	Chronic Obstructive Pulmonary Disorder			
	Frail Elderly			
Total Quality Points Available			130	130
Total Potential Shared Savings			**50%**	**60%**

As illustrated in Table 4, a maximum of 2 points per measure could be earned under both the one-sided and two-sided model based on the ACO's performance. However, the total potential for shared savings will be higher under the two-sided model, since the maximum potential shareable savings based on quality performance is 60 percent of the savings generated, compared to 50 percent under the one-sided model. That is, full and accurate reporting of the quality measures in the first year of the Shared Savings Program will result in an ACO earning 60 or 50 percent of shareable savings, depending on whether the ACO is in the two-sided or one-sided model. For future program years, the percent of potential shareable savings will vary on the ACO's performance on the measures as compared with the measure benchmarks.

For example, the preventive health domain has 9 measures and would be worth a maximum of 18 points (that is, 9 measures $\times$ 2 points equals 18 quality points). We propose the sliding scale in Table 3 for determining points earned for each measure. As mentioned previously, we propose calculating the percentage of points an ACO earns for each domain by dividing the points earned by the total points available, yielding a percentage. For example, if an ACO earns 16.2 out of 18 points in the preventive health domain, the ACO earned 90 percent of the points for the preventive health domain (16.2 divided by 18 equals .90). Assuming the ACO is operating under the two-sided shared savings model and earns 90 percent of the quality performance points across all five domains and generates shared savings, it would receive 90 percent of the ACO's share of the savings or 54 percent of the total savings generated. That is, achieving 90 percent of the potential 60 percent of shared savings an ACO can earn under the two-sided model, means the ACO could earn 54 percent of the total savings generated. Under the one-sided model, achieving 90 percent of the potential 50 percent of shared savings, means the ACO could earn 45 percent of the shareable savings generated.

Under both the one-sided and two-sided shared savings models, the quality measures domain scoring methodology treats all domains equally regardless of the number of measures within the domain. We believe the key benefit of weighting the domains equally is that it does not create a preference for any one domain, which we believe is important as we expect ACOs to vary in composition, and, as a result, to place more emphasis on different domains. We also considered weighting the domains to emphasize priority conditions or areas in order to emphasize (or de-emphasize) certain measures that are more difficult (or easy) to achieve without needing to change the scoring methodology. This method would require judgment about which domains are more important than others, which may not be appropriate. Equal weighting contains an implicit judgment that domains such as patient/caregiver experience of care and patient safety are equally important to the quality of care. Accordingly, we believe ACOs should seek to address all aspects of patient care in order to improve the overall quality of care under the Medicare program. Furthermore, we want to encourage a diverse set of ACOs and believe that emphasizing certain domains over others would encourage a certain type of ACO to participate but discourage other types from participating.

We propose aggregating the quality domain scores into a single overall ACO score which would be used to calculate the ACOs final sharing rate for purposes of determining shared savings or shared losses as described in section II.F. of this proposed rule. All domain scores for an ACO would be averaged together equally to calculate the overall quality score that would be used to calculate the ACO's final sharing rate.

We also propose that ACOs must report completely and accurately on all measures within all domains to be deemed eligible for shared savings consideration. We believe this is important as it requires ACOs to address all domains and be accountable across the continuum of care. If the ACO demonstrates sufficient cost savings in addition to meeting the quality performance requirements, the ACO would be deemed eligible for shared savings. We believe that this methodology provides a sufficient incentive for quality improvement targeted to specific domains and allows ACOs of varying compositions, which may be stronger in some domains than others, to receive some level of shared savings. In addition to this proposed domain-based scoring methodology, we considered several other options for assessing the quality performance of ACOs. We considered scoring measures individually under a method that would weight all measures equally. Each measure would be worth the maximum points available as described previously for a total maximum possible points for each ACO. This system would avoid overweighting or underweighting measures due to the number of measures in a domain. We also considered weighting quality measures by their clinical importance. More important quality measures would account for a greater proportion of shared savings. Outcome measures such as hospital-acquired infections and readmissions would be worth more than process measures. This would avoid overweighting or underweighting measures due to their domain, and account for clinical importance.

However, we did not think either of these approaches would be consistent with a larger measurement strategy of driving better health for populations and better care for individuals overall for the ACO beneficiary population, since we believe population health is better assessed across domains that encompass a variety of measures that apply to beneficiaries with different needs.

(4) The Quality Performance Standard Level

We propose to set the quality performance standard of the first year of the Shared Savings Program at the reporting level. That is, under the one-sided model, we propose that an ACO would receive 50 percent of shared savings (provided that the ACO realizes sufficient cost savings under the methodology described in the Shared Savings Determination section of this proposed rule) based on 100 percent complete and accurate reporting on all quality measures. Similarly, we propose that under the two-sided risk model, ACOs would receive 60 percent of shared savings (provided that the ACO realizes sufficient cost savings under the methodology described in the section II.G. of this proposed rule) based on 100 percent complete and accurate reporting on all quality measures. We believe setting the quality performance standard for the first year of the Shared Savings Program at full and accurate reporting allows ACOs to ramp up, invest in their infrastructure, engage ACO providers/suppliers, and redesign care processes to capture and provide data back to their ACO providers/suppliers to transform care at the point of care. It also would provide CMS with the opportunity to learn about the process, establish and refine benchmarks on ACO reported data, and establish improvement targets using data reporting for the first performance year. Setting the quality performance standard at the reporting level is also consistent with other value-based purchasing programs that have started out initially as pay for reporting programs.

Via future rulemaking, we plan to raise the quality performance standard requirements beginning in the second program year, when actual performance on the reported measures would be considered in determining whether an ACO is eligible to receive any shared savings (provided, that the ACO realizes cost savings under the methodology described in the Shared Savings Determination section of this proposed rule). We believe this approach is consistent with section 1899(b)(3)(C) of the Act, which requires that the Secretary "seek to improve the quality of care furnished by ACOs over time by specifying higher standards, new measures, or both for the purposes of assessing such quality of care."

c. Option 2: Quality Threshold

Under the second option, we would establish a minimum quality threshold for participating ACOs. If an ACO exceeded the quality threshold, it would retain the full shared savings percentage attributable to quality under this proposed rule (50 percent for one-sided risk, and 60 percent for two-sided risk). If an ACO did not meet the minimum quality standards in a performance year, it would not be eligible for shared savings. Furthermore, as discussed in section II.H. of this proposed rule and with respect to the performance standards option, if an ACO that fails to meet the minimum threshold during a performance year, we propose to give the ACO a warning, an opportunity for correction, and follow the termination process described in the Monitoring section if the ACO continues to underperform.

(1) Minimum Quality Threshold

Alternatively, we could establish the minimum quality threshold using the same set of quality measures and domains outlined in Table 1. We would also use the benchmarks for performance described in Table 3, established using claims data from FFS Medicare or the Medicare Advantage program. The minimum quality threshold would be performance at or above the 50th percentile (on the performance standards described in Table 3) for each domain: patient/caregiver experience; care coordination; patient safety; preventive health; and at-risk population/frail elderly. If an ACO meets these thresholds, it would be eligible for the full 50 percent of shared savings attributable to quality for those participating in the one-sided model, and the full 60 percent for those participating in the two-sided model. If an ACO failed to meet this threshold, it would not be eligible for shared savings. We expect that the quality threshold will increase over time in future rulemaking, under the requirement to improve the quality of care furnished by the ACO under section 1899(b)(3)(C) of the Act. We solicit comment on this approach and the appropriate threshold level, and on the pros and cons of the minimum threshold approach.

(2) Considerations in Establishing a Quality Threshold

The quality threshold option has advantages and disadvantages compared with the performance standard option. Under the performance standard option, an ACO could receive rewards for higher quality based on outcomes in one or two domains (for example, patient/caregiver experience and preventive care), while having very low quality in others (for example, patient safety). This is true for individual measures (for example, healthcare-acquired infections) as well. Setting a minimum threshold ensures that all ACOs meet basic standards on all quality measures, with a special emphasis on patient safety. An ACO's quality outcomes may vary from year to year due to factors outside of its control, meaning that performance-based standards could reward ACOs due to random variability. A threshold established at a basic level of quality acknowledged to be minimally necessary presents less of a risk of being triggered due to random variation, as opposed to truly poor performance. Finally, for ACOs meeting

the threshold, their shared savings percentage attributable to quality would be fixed and certain. This would increase incentives, achieve savings, and present more certainty on potential investment returns for organizations considering whether or not to become ACOs.

A quality threshold also presents disadvantages. Under this model, once an ACO is certain that it has met the minimum threshold, there is no incentive to continue improving quality; in effect, the quality incentives would be the same as under traditional FFS. ACOs may even have an incentive to reduce quality to just above the minimum. Additionally, an ACO would not be rewarded for improving quality outcomes on specific measures once it was confident that the minimum was exceeded.

In addition to proposing these two options, we also considered establishing performance standards for the overarching goals (of improving health care for individuals and populations) or a single performance standard to measure overall ACO performance. However, we believe that such aggregated scores may not be meaningful or useful for the ACO, since the general goals of improving health for individuals and populations are not as actionable as, for instance, a specific goal of lowering patients' LDL cholesterol levels. For the patient experience domain measures, we also considered weighting more heavily the responses of beneficiaries who have sought care with the ACO providers longer than the responses of those who are newer to the ACO providers. Finally, we considered an option that would permit the ACO to satisfy the quality performance standards based on peer to peer benchmarking. Under this approach the quality measure benchmarks would be set based on all ACOs' performance during the year. However, the main reason we did not propose this option is that, for measures in which most ACOs achieve high performance levels, minor changes in performance could determine whether an ACO achieves the performance benchmark. Thus, there would be little incentive to improve quality beyond the level necessary to share in savings. Additionally, our proposed approach enables us to reward improvement over the minimum attainment level by allowing the ACO to share in greater savings as they improve over time.

We also considered permitting ACOs to report a subset of the measures in Table 1, based on their level of readiness to participate in the Shared Savings Program. ACOs seeking to participate in the Shared Savings Program may vary with respect to their readiness to function in the Shared Savings Program, with respect to their organizational and systems capacity and structure. Accordingly, some ACOs might more quickly be able to demonstrate quality improvements and savings than will others. However, consistent with the overall goals of the Shared Savings Program discussed in section I. of this proposed rule, we believe that ACOs participating in the Shared Savings Program should seek to improve quality across a variety of measures addressing a range of domains, not only for those areas in which they are currently able or comfortable to report, hence our proposal to require 100 percent reporting for the measures in Table 1 to satisfactorily meet the quality performance requirements under the Shared Savings Program

We propose the performance scoring option and invite comment on this option as well as the quality threshold option. Within these options, we seek comment on the appropriateness of weighting all domains equally in determining an ACO's quality performance or whether certain domains and/or specific measures should be weighted more heavily. We also invite comment on alternatives that would blend these two approaches. For example, under the two-sided model, allowing ACOs that generate savings to increase their share of savings with higher quality scores (Option 1) but using a threshold approach (Option 2) when calculating losses so that higher quality does not reduce an ACO's share of any losses. Such an approach would have the effect of essentially applying a minimum sharing rate for losses (for example, 50 percent) and could appropriately reflect the goal of the Shared Savings Program to reward high quality and efficient care, by providing a greater reward when high quality care is also efficient and less relief for high quality care that is not efficient. Alternatively, the threshold option could be utilized in the two-sided model so that if the threshold score for the two-sided model resulted in 60% shared savings, it would also result in 60 percent shared losses, creating a symmetrical two-sided model. Another example of a blended approach would be to use the threshold approach (Option 2) for the first 3 years of the Shared Savings Program and then, as experience is gained and measures are further aligned, transition to performance scoring (Option 1). We also invite comment on the proposal to set the quality performance standard of the first program year at the reporting level and to raise the standard to reflect performance in subsequent years. We also invite comment on the proposed quality measures scoring methodologies under the one-sided and two-sided risk models. In addition, we invite comment on our proposal to have all quality measures listed in Table 1 required of all ACOs, and the alternative under which ACOs would be required to only report a subset of the measures in Table 1, based on their level of readiness for the Shared Savings Program.

5. Incorporation of Other Reporting Requirements Related to the Physician Quality Reporting System and Electronic Health Records Technology Under Section 1848 of the Act

Medicare provides multiple incentive payment options for providers to report and use clinical information more proactively in their practices. The Affordable Care Act gives the Secretary authority to incorporate reporting requirements and incentive payments from these programs into the Shared Savings Program, and to use alternative criteria to determine if payments are warranted. Specifically, section 1899(b)(3)(D) of the Act affords the Secretary discretion to "* * * incorporate reporting requirements and incentive payments related to the physician quality reporting initiative (PQRI), under section 1848, including such requirements and such payments related to electronic prescribing, electronic health records, and other similar initiatives under section 1848 * * *" and permits the Secretary to "use alternative criteria than would otherwise apply under section 1848 for determining whether to make such payments." Under this authority, we propose to incorporate certain reporting requirements and payments related to the Physician Quality Reporting System into the Shared Savings Program for "eligible professionals" within an ACO. Under section 1848(k)(3)(B) of the Act, the term "eligible professional" means any of the following: (1) A physician; (2) a practitioner described in section 1842(b)(18)(C) of the Act; (3) a physical or occupational therapist or a qualified speech-language pathologist; or (4) a qualified audiologist.

We propose to incorporate a Physician Quality Reporting System group practice reporting option (GPRO) under the Shared Savings Program and further propose that the eligible professionals that are ACO participant providers/suppliers would constitute a group practice for purposes of qualifying for a Physician Quality

Reporting System incentive under the Shared Savings Program. Specifically, eligible professionals would be required to submit data through the ACO on the quality measures proposed in Table 1 using the GPRO tool and methodology described in section II.E.3. of this proposed rule to qualify for the Physician Quality Reporting System incentive under the Shared Savings Program. We propose that the ACO would report and submit data on behalf of the eligible professionals in an effort to qualify for the Physician Quality Reporting System incentive as a group practice; that is, eligible professionals within an ACO would qualify for the Physician Quality Reporting System incentive as a group practice, and not as individuals. In addition, we propose a calendar year reporting period from January 1 through December 31, for purposes of the Physician Quality Reporting System incentive under the Shared Savings Program.

With regard to the requirements for satisfactory reporting for purposes of earning the Physician Quality Reporting System incentive under the Shared Savings Program, we propose to incorporate certain aspects of the criteria for satisfactory reporting under the 2011 Physician Quality Reporting System GPRO I option (75 FR 73506), with a few modifications. In particular, we propose the following criteria for satisfactory reporting for purposes of the Physician Quality Reporting System incentive for the first performance period under the Shared Savings Program:

- ACOs, on behalf of its EPs, would need to report on all measures included in the data collection tool;
- Beneficiaries will be assigned to the ACO using the methodology described in the Assignment section of this proposed rule. As a result, the GPRO tool would be populated based on a sample of the ACO-assigned beneficiary population. ACOs would need to complete the tool for the first 411 consecutively ranked and assigned beneficiaries in the order in which they appear in the group's sample for each domain, measure set, or individual measure if a separate denominator is required such as in the case of preventive care measures which may be specific to one sex. If the pool of eligible assigned beneficiaries is less than 411, the ACO would report on 100 percent of assigned beneficiaries for the domain, measure set, or individual measure.
- The GPRO tool will need to be completed for all domains, measure sets, and measures described in Table 1.

Accordingly, eligible professionals within an ACO that satisfactorily report the measures proposed in Table 1 during the reporting period would qualify under the Shared Savings Program for a Physician Quality Reporting System incentive equal to 0.5 percent of the ACO's eligible professionals' total estimated Medicare Part B PFS allowed charges for covered professional services furnished during the first performance period. "Covered professional services" are services for which payment is made under, or based on, the physician fee schedule and which are furnished under the ACO participant's TINs.

We plan to align the incorporated Physician Quality Reporting System requirements with the general Shared Savings Program reporting requirements, such that no extra reporting is actually required in order for eligible professionals or the ACO to earn the Physician Quality Reporting System incentive under the Shared Savings Program. Thus, for ACOs that meet the quality performance standard under the Shared Savings Program for the first performance period, the Physician Quality Reporting System eligible professionals within such ACOs will be considered eligible for the Physician Quality Reporting System incentive under the Shared Savings Program for that year. This means ACOs will need to report on all measures proposed in Table 1 in order to receive both the Shared Savings Program shared savings and Physician Quality Reporting System incentive. Failure to meet the Shared Savings Program quality performance standard would result in failure to be considered eligible for shared savings, as well as failure for the EPs within the ACO to receive a Physician Quality Reporting System incentive under the Shared Savings Program for that year. ACO participant provider/suppliers who meet the quality performance standard but do not generate shareable savings would still be eligible for PQRS incentive payments. We intend to discuss the policy for incorporating the Physician Quality Reporting System incentive under the Shared Savings Program for subsequent years in future rulemaking.

We note that ACOs will be eligible for the Physician Quality Reporting System incentive under the Shared Savings Program to the extent that they contain eligible professionals as defined under § 414.90(b). As a result, not all ACOs will necessarily be eligible for the Physician Quality Reporting System incentive under the Shared Savings Program. A complete list of Physician Quality Reporting System eligible professionals (EP) is available at: *http://www.cms.gov/PQRI/Downloads/EligibleProfessionals.pdf.* In addition, similar to traditional Physician Quality Reporting System, an EP could not qualify for the Physician Quality Reporting System incentive as both a group that is part of an ACO and as an individual. Furthermore, EPs could not qualify for a Physician Quality Reporting System incentive under both the Physician Quality Reporting System under the Shared Savings Program and the traditional Physician Quality Reporting System. For purposes of analysis and payment, we intend to use TINs and National Provider Identification numbers similar to what we have done in the traditional Physician Quality Reporting System (75 FR 40169), and we will provide such details in guidance.

At this time, we are not proposing to incorporate such payments for the EHR Incentive Program or Electronic Prescribing Incentive Program under the Shared Savings Program. Professionals in ACOs may still separately participate in those other incentive programs. However, we propose to require in the Shared Savings Program measures also included in the EHR Incentive Program and metrics related to successful participation in the Medicare and Medicaid EHR Incentive Programs for eligible professionals and hospitals and the eRx Incentive Program, as illustrated in Table 1. Metrics related to successful participation in the EHR Incentive Program and the eRx Incentive Program includes scoring the percentage of "meaningful users" of certified EHR technology, as defined in our regulations, and the percentage of those professionals that meet the criteria for the eRx incentive, as measures that are part of the quality performance standard. These measures would be subject to the same points scale and 30 percent or 30th percentile minimum attainment level previously described in table D3. We note that including metrics based on EHR Incentive Program and eRx Incentive Program data does not in any way duplicate or replace specific program measures within each of the two respective programs or allow eligible professionals to satisfy the requirements of either of the two programs through the Shared Savings Program. To receive incentive payments under the EHR incentive or eRx programs (or to avoid payment adjustments), eligible professionals will be required to meet all the requirements of the respective EHR and eRx programs. In addition, as a Shared Savings Program requirement separate from the quality measures reporting discussed previously, we propose

requiring that at least 50 percent of an ACO's primary care physicians are determined to be "meaningful EHR users" as that term is defined in 42 CFR 495.4 as defined in the HITECH Act and subsequent Medicare regulations by the start of the second performance year in order to continue participation in the Shared Savings Program. The EHR Incentive regulations, including the definition of meaningful EHR user and certified EHR technology can be found at 42 CFR part 495, as published on July 28, 2010 (75 FR 44314). The preamble to the July 28, 2010 final rule also describes the stages of meaningful use. We believe these approaches would foster incentives for improving and delivering high quality care by engaging providers in performance based quality incentive programs; and encourage adoption of EHRs. The requirement that at least 50 percent of ACO primary care physicians be meaningful users represents a first step towards achieving our objective of incenting full participation of ACOs' providers in the EHR Incentive Program over time. For subsequent years, we anticipate proposing greater alignment between the Shared Savings Program and the EHR Incentive program through future rulemaking. We considered several other options for incorporating other program reporting requirements into the Shared Savings Program. One option was to incorporate Physician Quality Reporting System into the Shared Savings Program via a scaled approach, in which how the ACO performs on the quality measures under the Shared Savings Program would determine the amount of Physician Quality Reporting System incentive an ACO could earn. However, we thought this approach would be burdensome and confusing to providers who are used to a different approach under the traditional Physician Quality Reporting System. We also considered proposing to limit incorporation of the Physician Quality Reporting System incentive under the Shared Savings Program to the ACO's group practices that were used for beneficiary assignment rather than to all group practices associated with an ACO. However, we thought expanding the Physician Quality Reporting System incentive under the Shared Savings Program to all participant TINs within an ACO would be more efficient for EPs participating in both traditional Physician Quality Reporting System and the Physician Quality Reporting System and the Physician Quality Reporting System incentive under the Shared Savings Program. This way ACOs would report one way for the Physician Quality Reporting System for all of its ACO providers/suppliers who are eligible professionals; that is, for purposes of qualifying for the Physician Quality Reporting System incentive, the ACO would not need to report one way for the TINs used for beneficiary assignment and another way for the TINs not used for assignment. Another option we considered was to incorporate the eRx Incentive Program's incentive requirements and payments into the Shared Savings Program. However, we are not proposing to incorporate the eRx incentive requirements and payments under the Shared Savings Program since the eRx incentive ends after 2013. We believe it would be burdensome to require ACOs to incorporate the eRx incentive requirements for only a 2-year period.

In concert with the proposal for 50 percent of primary care physicians to be meaningful EHR users by the second performance year, we seek comment on whether we should also specify a percentage-based requirement for hospitals. Such a requirement would be similar to the previous proposal for primary care physicians and would require 50 percent of eligible hospitals that are ACO providers/suppliers achieve meaningful use of certified EHR technology by the start of the second performance year in order for the ACO to continue participation in the Shared Savings Program. We also request public comment related to circumstances where the ACO may only include one eligible hospital or no hospital and whether we would need to provide an exclusion or exemption in such a circumstance.

We also considered limiting the metrics related to percentage of meaningful users to be applicable to the Medicare EHR Incentive Program only, since presumably ACO providers/suppliers may see a high proportion of Medicare FFS patients. However, we realize that ACO providers/suppliers eligible for the EHR incentive may seek to qualify for the EHR incentive through any of the EHR Incentive Programs available to Medicare and Medicaid eligible professionals and hospitals. Finally, we considered incorporating EHR Incentive Program's incentive requirements into the Shared Savings Program, however, per the previous discussion, we did not believe the program was ready for incorporation at this time. Furthermore, we are proposing that ACOs report quality measures as a group, and the EHR Incentive program does not include a group reporting option at this time.

We invite comment on our proposal to incorporate Physician Quality Reporting System requirements and payments and certain metrics related to under the Shared Savings Program, as well as the options discussed previously that we considered.

6. Public Reporting

Increasingly, transparency of information in the health care sector is seen as a means to facilitate more informed patient choice, offer incentives, and feedback that help improve the quality and lower the cost of care, and improve oversight with respect to program integrity. Examples of existing efforts that improve transparency include Hospital Compare, which enables patients along with their family and health care providers to compare the quality of care provided in the hospitals that agree to submit data on the quality of certain services they provide for certain conditions. Hospital Compare displays the following kinds of information:

- Rates for process of care measures that show whether or not hospitals provide some of the care that is recommended for patients being treated for a heart attack, heart failure, pneumonia, asthma (children only) or patients having surgery.
- Information on hospital outcome of care measures, including 30-day risk adjusted death (mortality) and readmission rates.
- Data collected from the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) Survey, reflecting patients' hospital experiences.
- Medicare inpatient hospital payment information.
- The number of Medicare patients treated for certain illnesses or diagnoses (as reported by Medicare severity-diagnosis related groups (MS–DRGs)).

(For more information, see the Hospital Compare Web site at *http://www.hospitalcompare.hhs.gov/hospital-search.aspx?AspxAutoDetectCookieSupport=1.*)

Similarly, Nursing Home Compare reports detailed information about every Medicare and Medicaid-certified nursing home in the country. Nursing Home Compare includes comparative information on health inspection results such as: (1) An assessment of the care of residents; (2) the process of care; (3) staff and resident interactions; and (4) the nursing home environment; (5) nursing home staffing; and quality measures. (For more information, see the Nursing Home Compare Web site at *http://www.medicare.gov/NHCompare/Include/DataSection/Questions/SearchCriteriaNEW.asp?version=default&browser=*

IE%7C6%7CWinXP&language=English&defaultstatus=0&pagelist=Home&CookiesEnabledStatus=True.)

The Affordable Care Act included several new initiatives that will expand transparency in the Medicare program. Among these, section 3003 of the Affordable Care Act will make aggregate information on physician resource use publicly available; section 3004 of the Affordable Care Act will make quality data relating to long-term care hospitals, inpatient rehabilitation facilities, and hospices publicly available; and section 3005 of the Affordable Care Act will make quality data for certain cancer hospitals publicly available. Similarly, section 10331 of the Affordable Care Act requires the Secretary to develop a Physician Compare Internet Web site by January 1, 2011 with information on physicians enrolled in the Medicare program and other eligible professionals who participate in the Physician Quality Reporting Initiative. Not later than January 1, 2013, the Secretary must also implement a plan for making information on quality and patient experience measures publicly available. Further, in developing this plan and as determined appropriate, the Secretary must consider the plan to transition to a value-based purchasing program for physicians and other practitioners developed under section 131 of the Medicare Improvements for Patients and Providers Act of 2008 (Pub. L. 110–275). Section 10332 of the Affordable Care Act requires the Secretary to make certain standardized claims data under Medicare Parts A, B, and D available to entities qualified by the Secretary to use these data to evaluate the performance of providers of services and suppliers on measures of quality, efficiency, effectiveness, and resource use.

While the Act did not include a specific requirement for public reporting and transparency related to the Shared Savings Program, improved transparency would support a number of program requirements. In particular, increased transparency would be consistent with and support the requirement under section 1899(b)(2)(A) of the Act for ACOs to be willing to "become accountable for the quality, cost, and overall care" of the Medicare beneficiaries assigned to it.

Public reporting of ACO cost and quality measure data would improve a beneficiary's ability to make informed health care choices, and facilitate an ACO's ability to improve the quality and efficiency of its care by making available information that enables ACO professionals to assess their performance relative to their peers, and creates incentives for those professionals to improve their performance. For example, the transparency of outcomes that results when consumers have access to publicly reported performance information could be an important catalyst for providers to continually seek to improve their performance. Further, many other stakeholders, including health plans, employers, and policy makers have an interest in knowing the degree to which different health care delivery models are effective in improving quality and reducing costs. Timely dissemination of reports on ACO quality and cost performance will contribute to the dialogue, at the national, regional and local level, on how to drive improvement and innovation in health care.

Therefore, we believe it is desirable and consistent with section 1899(b)(2)(A) of the Act for several aspects of an ACO's operation and performance to be transparent to the public—specifically, information regarding: (1) Providers and suppliers participating in the ACO; (2) parties sharing in the governance of the ACO; (3) quality performance standard scores; and (4) general information on how an ACO shares savings with its members. We are proposing that certain information regarding the operations of the ACO would be subject to public reporting to the extent administratively feasible and permitted by law. Specifically, we propose that the following information regarding the ACO be publicly reported:

- Name and location.
- Primary contact.
- Organizational information including—

++ ACO participants;

++ Identification of ACO participants in joint ventures between ACO professionals and hospitals;

++ Identification of the ACO participant representatives on its governing body; and

++ Associated committees and committee leadership.

- Shared savings information including—

++ Shared savings performance payment received by ACOs or shared losses payable to us; and

++ Total proportion of shared savings invested in infrastructure, redesigned care processes and other resources required to support the three-part aim goals of better health for populations, better care for individuals and lower growth in expenditures, including the proportion distributed among ACO participants.

- Quality performance standard scores.

In the interest of transparency, it is important that the ACO make available to the public information on its accountability for the quality, cost, and the overall care furnished to its assigned beneficiary population. We are proposing that each ACO be responsible for making this information available to the public in a standardized format that we will make available through subregulatory guidance. This requirement would be included in each ACO's 3-year agreement.

We seek comments on our proposals, including whether the proposed list includes elements that should not be required, or excludes elements that are important for achieving transparency or meaningful public disclosure within the Shared Savings Program and whether we should standardize the format or allow ACOs the flexibility to try different and innovative approaches for providing this information to beneficiaries. We welcome comment on these requirements and new reporting requirement recommendations that could be considered for future program years through future rulemaking. Also, we seek comment on whether ACOs themselves should be required to make this information publicly available or whether ACOs should report this information to us, and we would then make this information publicly available.

7. Aligning ACO Quality Measures With Other Laws and Regulations

The standards for Accountable Care Organizations proposed in this rule are among the first quality standards for doctors and health care organizations established under the Affordable Care Act. As such, we believe that they represent an opportunity to continue a robust discussion between the Federal government, affected parties such as physicians, hospitals, and patients, and all other stakeholders on developing and aligning the best possible framework for ensuring quality care. The Act directs the Department to promulgate quality standards and require accountability or reporting in several sections. It calls for a National Quality Strategy that was released on March 21, 2011. We have already proposed standards for inpatient hospitals and the Medicaid program through rulemaking, as well as the standards for ACOs outlined in this rule. These standards affect different constituencies, including physicians, hospitals, other providers, and patients and their families. As such, we have proposed distinct domains and

categories of quality measures, and different frameworks for rewarding performance, under each Affordable Care Act program as illustrated in Table 5.

Table 5: Quality Frameworks for Affordable Care Act Programs

Domain
Proposed for Medicare Shared Savings Program: Accountable Care Organizations
Patient/Caregiver Experience
Care Coordination
Patient Safety
Preventive Health
At-Risk Population/Frail Elderly Health
Proposed for Initial Core Set of Health Quality Measures for Medicaid-Eligible Adults
Prevention and health promotion
Management of Acute Conditions
Management of Chronic Conditions
Family Experiences of Care
Availability
Proposed for Hospital Inpatient Value-Based Purchasing Program
Process Measures
Outcome Measures
Survey Measures
National Health Care Quality Strategy and Plan
Patient-centeredness and family engagement
Eliminating disparities in care
Better care
Affordable care
Healthy communities

While these quality domains and categories—and the parties that they affect—overlap in a number of areas, each set of standards has different domains, categories, and specific measures. We recognize that different quality frameworks and rewards may add to confusion and administrative burdens for affected parties, and mitigate efforts to focus on the highest-quality care. We seek comment from affected parties and other stakeholders on the best and most appropriate way to align quality domains, categories, specific measures, and rewards across these and other Federal healthcare programs, to ensure the highest-possible quality of care. Specifically, we seek comment on whether quality standards in different Affordable Care Act programs should use the same definition of domains, categories, specific measures, and rewards for performance across all programs to the greatest extent possible, taking into account meaningful differences in affected parties.

F. Shared Savings Determination

1. Background

Section 1899 of the Act, as added by section 3022 of the Affordable Care Act, establishes the general requirements for payments to participating ACOs. Specifically, section 1899(d)(1)(A) of the Act provides that ACO participants will continue to receive payment "under the original Medicare fee-for-service program under Parts A and B in the same manner as they would otherwise be made." However, section 1899(d)(1)(A) of the Act also provides for ACOs to receive payment for shared Medicare savings provided that the ACO meets both the quality performance standards established by the Secretary, as discussed in section II.E. of proposed rule, and demonstrates that it has achieved savings against a benchmark of expected average per capita Medicare FFS expenditures. Additionally, section 1899(i) of the Act authorizes the Secretary to use other payment models in the place of the one-sided model outlined in section 1899(d) of the Act. This provision authorizes the Secretary to select a partial capitation model or any other payment model that the Secretary determines will improve the quality and efficiency of items and services furnished to Medicare beneficiaries without additional program expenditures.

In the November 17, 2010 **Federal Register**, we solicited public comment on a number of issues regarding ACOs and the Shared Savings Program, including the types of additional payment models we should consider in addition to the model laid out in section 1899(d) of the Act, either under the authority provided in 1899(i) of the Act or using the Innovation Center authority under section 1115A of the Act. We

further asked about the relative advantages and disadvantages of any such payment models.

We considered several options for structuring the Shared Savings Program. One option we considered was to offer a pure one-sided shared savings approach using the calculation and payment methodology under 1899(d) of the Act. This option would have the potential to attract a large number of participants to the program and introduce value-based purchasing broadly to providers and suppliers, many of whom may never have participated in a value-based purchasing initiative. Another reason we considered this option was that a one-sided model with no downside risk might be more accessible and attract smaller group participation. However, as some commenters suggest, while such a model may provide incentive for participants to improve quality, it may not be enough of an incentive for participants to improve the efficiency of health care delivery and cost. Therefore, we considered whether we should instead focus on our authority under section 1899(i) of the Act to create a risk-based option in the Shared Savings Program. Such a model would have the advantage of providing an opportunity for more experienced ACOs that are ready to share in losses to enter a sharing arrangement that provides greater reward for greater responsibility.

Another option would be to offer a hybrid approach. A hybrid approach would combine many of the elements of the one-sided model under section 1899(d) of the Act with a risk-based approach under section 1899(i) of the Act. The hybrid approach would have the advantage of providing an entry point for organizations with less experience with risk models, such as some physician-driven organizations or smaller ACOs, to gain experience with population management before transitioning to a risk-based model while also providing an opportunity for more experienced ACOs that are ready to share in losses to enter a sharing arrangement that provides greater reward for greater responsibility.

Based on the input of commenters on the November 17, 2010 RFI, other stakeholders and policy experts we are proposing to implement a hybrid approach. Specifically, we are proposing that ACOs participating in the Shared Savings Program will have an option between two tracks:

Track 1: Under Track 1, shared savings would be reconciled annually for the first 2 years of the 3-year agreement using a one-sided shared savings approach, with ACOs not being responsible for any portion of the losses above the expenditure target. However, for the third year of the 3-year agreement, we will use our authority under section 1899(i) of the Act to establish an alternative two-sided payment model. Under this model, an ACO would be required to agree to share any losses that may be generated as well as savings. The portion of shared losses that the ACO would be at risk for in the third year of the agreement is further described in section II.G. of this proposed rule. ACOs that enter the Shared Savings Program under Track 1 would be automatically transitioned to the two-sided model in the third year of their agreement period. In that year, the ACO's payments would be reconciled as if it was in the first year of the two-sided model. However quality scoring would still be based on the methods for the third year (that is, it would not revert back to the first year standard of full and accurate reporting). Thereafter, those ACOs that wish to continue participating in the Shared Savings Program would only have the option of participating in Track 2, that is, under the two-sided model.

Track 2: More experienced ACOs that are ready to share in losses with greater opportunity for reward may elect to immediately enter the two-sided model (as discussed in section II.G. of this proposed rule). An ACO participating in Track 2 would be under the two-sided model for all three years of its agreement period. Under this model, the ACO would be eligible for higher sharing rates than would be available under the one-sided model.

Unless specifically noted, the elements discussed in the rest of this section will apply to both the one-sided and two-sided models. Section II.G. of this proposed rule provides additional detail regarding aspects of the two-sided model that are not discussed in this section.

We seek comment on our proposal and the alternatives discussed previously.

2. Overview of Shared Savings Determination

The basic requirements for establishing and updating the benchmark, as well as determining whether an ACO has achieved savings against the benchmark, are outlined in section 1899(d)(1)(B) of the Act. Section 1899(d)(1)(B)(i) of the Act establishes that an ACO shall be eligible for payment of shared savings "only if the estimated average per capita Medicare expenditures under the ACO for Medicare FFS beneficiaries for Parts A and B services, adjusted for beneficiary characteristics, is at least the percent specified by the Secretary below the applicable benchmark * * * ." We will take into account payments made from the Medicare Trust Fund for Parts A and B services, for assigned Medicare FFS beneficiaries, including payments made under a demonstration, pilot or time limited program when computing average per capita Medicare expenditures under the ACO. The statute further requires the Secretary to establish the percentage that expenditures must be below the applicable benchmark "to account for normal variation in expenditures under this title, based upon the number of Medicare fee-for-service beneficiaries assigned to an ACO." We will refer to this percentage as the "minimum savings rate" (MSR).

Section 1899(d)(1)(B)(ii) of the Act requires the Secretary to establish and update the "benchmark for each agreement period using the most recent available 3 years of per-beneficiary expenditures for parts A and B services for Medicare fee-for-service beneficiaries assigned to the ACO." This section also requires the benchmark to "be adjusted for beneficiary characteristics and such other factors as the Secretary determines appropriate and updated by the projected absolute amount of growth in national per capita expenditures for Parts A and B services under the original Medicare fee-for-service service program, as estimated by the Secretary." A new benchmark is to be established consistent with these requirements at the beginning of each new agreement period.

Section 1899(d)(2) of the Act provides that, if the ACO meets the quality performance standards established by the Secretary, as discussed in section II.E. of this proposed rule "a percent (as determined appropriate by the Secretary) of the difference between such estimated average per capita Medicare expenditures in a year, adjusted for beneficiary characteristics, under the ACO and such benchmark for the ACO may be paid to the ACO as shared savings and the remainder of such difference shall be retained by the program under this title." We will refer to this percentage as the "sharing rate." This section also requires the Secretary to "establish limits on the total amount of shared savings that may be paid to an ACO." We will refer to this limit as the "sharing cap".

Thus, in order to implement the provisions of section 1899(d) of the Act for determining and appropriately sharing savings, we must make a number of determinations about the specific design of the shared savings

methodology described by the statute. First, we must establish an expenditure benchmark, which involves determining: (1) The patient population (that is, assigning patients to ACOs for purposes of quality and financial performance measurement) for whom the benchmark is calculated; (2) appropriate adjustments for beneficiary characteristics such as demographic factors and/or health status that should be taken into account in the benchmark; (3) whether any other adjustments to the 3-year benchmark are warranted, such as to avoid potentially disadvantaging various types of providers (for example, hospitals that receive Medicare disproportionate share hospital payments (DSH hospitals) or teaching hospitals that receive indirect graduate medical education (IME) payments) or ACOs located in high cost, or low cost, areas; and (4) appropriate methods for trending the 3-year benchmark forward to the start of the agreement period, and subsequently for updating the benchmark for each of the 3 performance years of the agreement period with the ACO.

Second, we must compare the benchmark to the assigned beneficiary per capita Medicare expenditures in each performance year under the agreement period in order to determine the amount of any savings.

Third, we must establish the appropriate MSR, as required by the statute "to account for normal variation in expenditures * * * based upon the number of Medicare fee-for-service beneficiaries assigned to an ACO" and we must determine the appropriate sharing rate for ACOs that have realized savings against the benchmark above the MSR. Finally, we must determine the required sharing cap on the total amount of shared savings that may be paid to an ACO. We discuss all these issues, and our proposals for addressing them, in this section.

3. Establishing an Expenditure Benchmark

a. Background

Section 1899(d)(1)(B)(ii) of the Act specifies several requirements with regard to establishing an ACO's benchmark.

- First, the law requires the Secretary "to estimate a benchmark for each agreement period for each ACO using the most recent available 3 years of per-beneficiary expenditures for parts A and B services for Medicare fee-for-service beneficiaries assigned to the ACO."
- Second, the law requires that "[s]uch benchmark shall be adjusted for beneficiary characteristics and such other factors as the Secretary determines appropriate."
- Third, the law requires that the benchmark be "updated by the projected absolute amount of growth in national per capita expenditures for parts A and B services under the original Medicare fee-for-service program, as estimated by the Secretary."
- Finally, the law requires that "[s]uch benchmark shall be reset at the start of each agreement period."

A useful way to view the benchmark is as a surrogate measure of what the Medicare FFS Parts A and B expenditures would otherwise have been in the absence of the ACO. Once the savings realized by the ACO exceed a margin for normal variation in expenditures from year-to-year (what we call the MSR described in more detail later in this proposed rule), the difference between actual expenditures of the ACO's assigned beneficiaries during each year of the agreement period and its benchmark (updated, according to statute as described in more detail later in the document) should reflect how well the ACO is coordinating care for these beneficiaries and improving the overall efficiency of their care.

An accurate benchmark estimate is important in order to ensure that an ACO that successfully coordinates care and achieves real savings is rewarded with shared savings. Similarly, an accurate benchmark estimate helps to ensure that shared savings are not inadvertently paid to an ACO that does not successfully coordinate care well or that has not achieved savings in excess of normal variation in annual expenditures.

We have considered two legally permissible approaches to meeting the statutory language for estimating the benchmark, which we will call Option 1 and Option 2 in this proposed rule. Both approaches involve benchmarks that are derived from prior expenditures of assigned beneficiaries and adjusted for certain beneficiary characteristics, and other factors, the Secretary determines appropriate and updated by the projected absolute amount of growth in national per capita expenditures. Under both approaches, the benchmark would also be reset at the start of each agreement period. However, a key difference between these two approaches is the beneficiary population used to determine expenditures for purposes of the benchmark. Specifically, under Option 1, we would estimate an ACO's benchmark based on the Parts A and B FFS expenditures of beneficiaries who would have been assigned to the ACO in each of the 3 years prior to the start of an ACO's agreement period using the ACO participants' TINs. In contrast, under Option 2, the benchmark would be based on the Parts A and B FFS expenditures of beneficiaries, who are actually assigned to the ACO during each performance year, with the expenditures being those incurred in the 3 years immediately preceding the ACO's agreement period for those assigned beneficiaries. We describe these two options later in this document. In this proposed rule, we are proposing Option 1 to establish each ACO's benchmark; however, we solicit comments on both options.

b. Option 1

Under Option 1, we would estimate the benchmark for an ACO for an agreement period starting with the TINs of ACO participants identified at the start of the agreement period. The same rules that will be used to determine assignment of beneficiaries to ACOs during the agreement period would be applied to these data. Accordingly, consistent with the assignment methodology proposed in section II.D. of this proposed rule, we would use the claim records of these ACO participants to determine a list of beneficiaries who received a plurality of their primary care services from primary care physicians participating in the ACO in each of the prior 3 most recent available years.

Using the per capita Parts A and B FFS expenditures for beneficiaries that would have been assigned to the ACO in each of these 3 prior years, we will estimate a fixed benchmark that is adjusted for overall growth and beneficiary characteristics, including health status using prospective HCC adjustments (as discussed in section 3 later in this document). This benchmark would then be updated annually during the agreement period, according to statute, based on the absolute amount of growth in national per capita expenditures for Parts A and B services under the original Medicare FFS program.

- The first step in this process is to calculate annual Parts A and B FFS per capita expenditures for the beneficiaries who would have been assigned for each of the benchmark years. To minimize variation from catastrophically large claims, we would truncate an assigned beneficiary's total annual Parts A and B FFS per capita expenditures at the 99th percentile as determined for each benchmark year (for example roughly $100,000 in 2008). We would also truncate an assigned beneficiary's total annual Parts A and B FFS per capita expenditures at the 99th percentile as

determined for each subsequent performance year.

• Next, using our Office of the Actuary national Medicare expenditure data for each of the years making up the benchmark, we would determine an appropriate growth index and trend them to benchmark year 3 (BY3) dollars. Our proposed method for trending expenditures is discussed in section II.F.7.of this proposed rule.

• Using health status measures for the beneficiary population in each of the years making up the benchmark, we would establish health status indices for each year and adjust so they are restated to reflect BY3 risk. Our approach to account for health status is discussed section II.F.3. of this proposed rule.

• Next, we would compute a 3-year risk-and growth-trend adjusted per capita expenditure amount for the patient populations in each of the 3 benchmark years by combining the initial per capita expenditures for each year with the respective growth and health status indices. This yields risk adjusted per capita expenditures for beneficiaries historically assigned to the ACO in each of the 3 years used to establish the benchmark stated in BY3 risk and expenditure amounts.

• We propose to weight the most recent year of the benchmark, BY3 at 60 percent, BY2 at 30 percent and BY1 at 10 percent so that we can ensure the benchmark reflects more accurately the latest expenditure and health status of the ACO's assigned beneficiary population. This weighting allows us to establish lower MSRs since the weighting results in a more accurate benchmark.

• Last, as required by statute, for each performance year we would update this fixed benchmark by the projected absolute amount of growth in national per capita expenditures for Parts A and B services under the original Medicare FFS program using data from our Office of the Actuary. This approach for updating the benchmark avoids current law issues associated with Medicare expenditure projections since it uses the actual claims and expenditure experience for Medicare patients to calculate the factor used to update the benchmark for purposes of annual reconciliation. Consistent with the statutory requirement, the benchmark and its associated computations would only be rebased at the start of a new agreement period.

As described in section II.C. of this proposed rule, if requested by the ACO, we are proposing to provide the ACO with aggregated data and information on beneficiaries that would historically have been assigned to the ACO and, as a result, have a likelihood of being assigned during the agreement period.

It is possible that to the extent that an ACO's population or its composition of ACO providers/suppliers change over time, the assigned population could diverge from the benchmark population, potentially affecting the comparability of performance measurement. Modeling the PGP demonstration data using the proposed primary care based assignment methodology revealed that assignment of beneficiaries varies from year-to-year, with about 25 percent of those assigned in one year not being assigned in the subsequent year (due to relocation, death, participation in MA, or changes in their choice of care professionals). This was consistent across organizations participating in the demonstration which were also geographically diverse. We believe the approach to establishing the benchmark described previously would provide a relatively accurate reflection of the average population of Medicare FFS beneficiaries that receive their care from the ACO participants during the ACO agreement period. However, because the FFS population served by the ACO changes from year to year, some of the beneficiaries whose expenditures would be included in the benchmark with this approach would not be reflected in the population assigned to the ACO during the years of the ACO agreement period. It is also possible that this benchmark approach could provide unwanted incentives to seek and/or avoid specific beneficiaries during the agreement period so that average expenditures would more likely be less than for their historical beneficiaries included in the benchmark. Therefore we also considered a second option that relies on developing a benchmark based on the populations of specific beneficiaries who are actually assigned to the ACO during the agreement period.

c. Option 2

Under this option, for each beneficiary assigned to the ACO during the agreement period, we would calculate their per capita Parts A and B FFS expenditures during each of the 3 years immediately preceding the first year of the agreement period. These amounts would be trended to the start of the agreement period as was described for Option 1, that is, since Option 2 also requires risk adjustment, we will adjust the benchmark for health status using the same prospective CMS–Hierarchal Condition Category (CMS–HCC) risk adjuster and apply it to calculate the benchmark in the same manner as described for Option 1.

To meet the statutory requirement to adjust the benchmark for "beneficiary characteristics" we would adjust the annual per capita expenditures to account for changes in health status.

For beneficiaries without 3 full years of immediately-prior Medicare eligibility (such as beneficiaries who were not 68 in their first year assigned to the ACO), a further adjustment would be necessary under this option.

• For those beneficiaries with less than one full year of prior Medicare experience, we would either—

++ Use a substitute for their own expenditures in the update amount within the benchmark, that is, substitute the average per capita FFS expenditures for all Medicare beneficiaries during the year they are first assigned to the ACO, adjusted for health status (as described later in the document in section 3); or

++ Exclude their experience from the shared savings computations.

• For those assigned beneficiaries with more than 12 months prior Medicare experience but less than 36 months we also have two choices:

++ Compute a weighted-average (using number of months as the weight) that blends.

—Their prior expenditure experience and

—The average per capita Parts A and B FFS expenditures for all Medicare beneficiaries during the year before the first year they are assigned to the ACO, adjusted for health status; or

++ Use only their prior expenditure experience.

We seek comments about these adjustment approaches and solicit other approaches we might consider.

After the benchmark is adjusted for beneficiary health status, the benchmark would also be updated by the applicable projected amount of growth in national per capita expenditures for Parts A and B services under the original Medicare FFS program as was described for Option 1.

For the second and third year of the agreement period, we would make no further adjustments for assigned beneficiaries who were also assigned in the first year of the ACO agreement period. However, in the second and third year of the agreement, there will also be newly-assigned beneficiaries as well as previously-assigned beneficiaries who are no longer assigned to the ACO. The benchmark would be adjusted to account for these changes. We would adjust the benchmark by adding the experience of the newly-assigned beneficiaries (as discussed previously for the first year) for the 3 years prior to the agreement period, and

by removing the prior experience of the no-longer assigned beneficiaries. In the case of a beneficiary who was assigned during the first year, not assigned during the second year, and then again assigned during the third year of the ACO's agreement period, the prior expenditure experience that would be used to adjust the benchmark in the third year would be the same amount initially used for their first year of assignment. These adjustments would yield a benchmark for each ACO that is estimated using beneficiary expenditures for the three years prior to the agreement period for only those beneficiaries that were actually assigned to the ACO during that year of the agreement period.

Additionally, Option 2 would require an adjustment for assigned beneficiaries who die during an agreement year. We know that approximately 5 percent of all Medicare beneficiaries die in a single year, and that their average monthly expenditures are often higher during this last year of life compared to the immediately preceding years. For these beneficiaries, the benchmark might therefore not be a fair basis for comparison with actual expenditures for purposes of determining shared savings, which could create incentives for ACOs to avoid assignment of beneficiaries who may be in their last year of life or treat such beneficiaries differently. This would not be the case for Option 1 as that benchmark approach would include the average per capita costs of beneficiaries who died during the benchmark period. We are therefore considering one of two methods to adjust for this beneficiary characteristic within Option 2.

Under the first method for adjusting for decedents, we would propose to exclude the expenditures of deceased beneficiaries from actual expenditures during the agreement period. We believe this approach would best avoid concerns about creating incentives for ACOs to avoid assignment of beneficiaries in their last year of life or treat such beneficiaries differently. In a second method for adjusting for decedents, we would compare average expenditures for each deceased beneficiary during the agreement year to the average expenditures for beneficiaries included in the benchmark.

- If the agreement year's expenditures were 5 percent or less above the benchmark, we would make no adjustment;
- If the agreement year's expenditures were greater than 5 percent above the benchmark, we would need to decide upon an acceptable method to adjust the accumulated expenditures for deceased beneficiaries.

Of these two methods for adjusting for decedents during the course of the performance year under Option 2, our preference is for the first method. However, we invite comments on both of these methods, and any others that might be suggested for adjusting for decedents during the course of the performance year under Option 2.

The second method is intended to address the implications of changes to an ACO's population over time, but this option would require additional data adjustments and computations that are not required under the first method.

However, to the extent that average per capita expenditures for all beneficiaries differs from the average for the geographic area in which an ACO operates, the first method previously discussed would effectively be imputing a value that is likely to be somewhat higher or lower than would actually be expected for that ACO. Alternatively, excluding the experience of beneficiaries with less than 1 full year of experience from the shared savings computations as contemplated in the second method previously discussed, would reduce the size of an ACO's beneficiary population, increasing the MSR that would be needed before an ACO would be eligible to share savings. This could have the effect of discouraging participation among smaller ACOs, for example, in rural areas. Likewise, we would expect a similar impact on an ACO's MSR if deceased beneficiaries were excluded from the shared savings computations as is previously proposed.

d. Summary

We believe both Option 1 and Option 2 are legally permissible approaches to setting the expenditure benchmark, adjusting for beneficiary characteristics, and updating by the projected absolute amount of growth in national per capita expenditures. We also believe that both approaches can establish viable benchmarks to measure ACO performance over time and provide incentives for ACOs to improve their processes and outcomes during the agreement period.

We are proposing to adopt Option 1 for establishing ACO benchmarks, but seek comments on the merits and limitations of both options, particularly with respect to how each approach might affect the willingness of ACOs or particular types of ACO to participate in the Shared Savings Program, create incentives for ACOs to seek or avoid certain kinds of beneficiaries, and impact Medicare expenditures. Moreover, we will continue to examine the merits and potential effects of both options over the next several months. If, based on our findings and the comments received in response to this proposal, we determine that Option 2 would be a more appropriate method for establishing a benchmark, we would expect to adopt that option in the final rule.

4. Adjusting the Benchmark and Average per Capita Expenditures for Beneficiary Characteristics

Section 1899(d)(1)(B)(i) of the Act stipulates that an ACO is eligible for shared savings "only if the estimated average per capita Medicare expenditures under the ACO for Medicare fee-for-service beneficiaries for Parts A and B services, adjusted for beneficiary characteristics" is below the applicable benchmark. Likewise, section 1899(d)(1)(B)(ii) of the Act specifies that the benchmark "shall be adjusted for beneficiary characteristics and such other factors as the Secretary determines appropriate * * *." This requirement to adjust for "beneficiary characteristics" implicitly recognizes that, under a shared savings model, the realization of savings against a benchmark could be a function of two factors. One factor is reduced expenditure growth as a result of greater quality and efficiency in the delivery of health care services. The other factor could be changes in the characteristics of the beneficiaries who are under the care of the ACO. Thus, in the absence of risk adjustment, some organizations may realize savings merely because of treating a patient mix with better health status than the patient population reflected in the benchmark. On the other hand, some organizations may share in savings on a risk adjusted basis but would not have shared in savings if expenditures were not risk adjusted.

Beneficiary health status can be measured using various tools, under which beneficiaries are typically assigned "risk scores" that reflect their demographic and diagnostic conditions and offer an estimate of the relative extent to which they are likely to utilize medical services compared to other beneficiaries. Performance payments are a function of the ACO's success in controlling expenditure growth and changes in the health status of the assigned population, thus they are sensitive to changes in risk scores. However, an ACO's ability to share in savings can be affected not only by changes in the health status of a population but also by changes in coding intensity and changes in the mix of specialists and other providers within

an ACO, which in turn could affect the characteristics of its assigned beneficiary population, relative to the benchmark period. Our goal is to measure improvements in care delivery of an ACO and to make appropriate adjustments to reflect the health status of assigned patients as well as changes in the ACOs organizational structure that would affect the case mix of assigned patients rather than apparent changes arising from the manner in which ACO providers/suppliers code diagnoses. Thus, when applying a risk adjustment model, it is necessary to guard against changes that result from more specific or comprehensive coding as opposed to improvements in the coordination and quality of health care.

The statute clearly calls for the characteristics of the beneficiaries assigned to an ACO to be taken into account in estimating both an ACO's benchmark and its expenditures during the agreement period. This requirement helps to ensure that quality and efficiency in the delivery of health care services are the basis for realizing and sharing savings under the Shared Savings Program. Because we want to create an environment where ACOs are encouraged to effectively coordinate care for beneficiaries with complex illnesses, and not create an environment where ACOs have incentive to avoid these types of beneficiaries, we believe that relative health status is one such beneficiary characteristic that should be reflected in the calculation of average per capita expenditures for purposes of both the benchmark and actual expenditures during the agreement period. We have considered two basic options for risk adjusting the average per capita expenditures in order to reflect beneficiary characteristics.

One option is to employ a method that considers only patient demographic factors, such as age, sex, Medicaid status, and the basis for Medicare entitlement (that is, age, disability or ESRD), without incorporating diagnostic information. The second option is to employ a methodology that incorporates diagnostic information, specifically the CMS–HCC prospective risk adjustment model that has been used under the MA program. In addition to demographic variables, the CMS–HCC prospective risk adjustment model uses beneficiaries' prior year diagnoses to develop risk scores that are then applied to their current year expenditures. The model is widely accepted by payers and providers, and risk scores are annually calculated for all Medicare beneficiaries by us, so readily available data can be incorporated into the Shared Savings Program. Additional information on the CMS–HCC model can be found in the Advance Notice of Methodological Changes for Calendar Year (CY) 2011 for Medicare Advantage (MA) Capitation Rates, Part C and Part D Payment Policies and 2011 Call Letter, which can be found at *http://www.cms.gov/MedicareAdvtgSpecRateStats/Downloads/Advance2011.pdf* and *http://www.cms.gov/MedicareAdvtgSpecRateStats/Downloads/Announcement2011.pdf*.

As discussed previously, a key issue when using a risk adjustment model that incorporates diagnosis data is that risk scores can be affected not just by changes in the health status of the population but also by changes in coding intensity and by the mix of specialists and providers furnishing services. The experience in MA clearly shows that health plans can significantly increase the HCC score of their populations by focusing on more complete coding. Similarly, our experience with the PGP demonstration shows that participating sites have an incentive to code more fully or intensely because of the potential impact on performance payments, to provide more accurate measurement and reporting of quality measures, as well as to provide for more complete and accurate information that can be used for population management.

If we adopt a risk adjustment methodology in the Shared Savings Program that incorporates diagnostic data, we expect that ACOs would have a similar incentive to code more fully for purposes of population management, quality reporting and to optimize their risk scores for the purpose of achieving shared savings. Because they are responsible for the delivery of care, and can control the information included in Parts A and B claims, the ACO providers/suppliers could potentially increase the risk scores for their FFS patients by more completely reporting diagnoses. The practical effect of increasing risk scores would be to decrease the actual annual expenditures compared to the benchmark, because the benchmark would be increased to reflect changes in the ACO's risk score, while actual expenditures would not change. As a result, the ACO's chances of demonstrating savings and receiving a shared savings payment would improve. Behaviors such as these could allow an ACO to achieve apparent savings by coding changes alone and without improved methods of beneficiary care.

We have made adjustments to account for the upward trend in risk scores in other programs. For example, for the MA program we make adjustments to account for the upward trend in FFS diagnostic coding and CMS–HCC model changes through normalization factors and coding intensity adjustments. Another approach to addressing this upward trend in diagnostic coding would be to incorporate an annual cap in the amount of risk score growth we would allow for each ACO. One option for setting the annual cap could be setting a fixed growth percentage for all ACOs, and any increase in risk score growth above the cap would be negated. A challenge to this approach would be determining a generally acceptable sized cap. A second option would be to establish a risk score for the ACO's assigned population during the agreement period based on the calculated risk score of beneficiaries who were used to calculate the ACO's benchmark. This would establish an annual cap, that is based on experience specific to each individual ACO and would thus result in an individually calculated cap for each ACO. Yet another alternative we considered for addressing the upward trend in coding intensity would be to use a methodology similar to the MA methodology that would reduce the amount of growth in the risk scores for beneficiaries assigned to the ACOs, but continue to allow increases. However, modeling this approach showed that it would reward those organizations with exceptionally high risk score growth while penalizing organizations that do not engage in efforts to more completely and accurately code since their risk score growth could go negative if they did not code sufficiently intensively.

A model that uses beneficiary demographic factors alone would avoid this issue, and may be simpler administratively precisely because it employs a more restricted range of factors. We have therefore also considered implementing the MA "new enrollee" demographic risk adjustment model. This model includes adjustments for age, sex, Medicaid enrollment status and originally disabled status. Such a model, however, would not take into account the health status of the assigned beneficiaries which could have a particularly adverse effect on ACOs that include providers and suppliers that typically treat a comparatively sick beneficiary population, including academic medical centers and tertiary care centers. Therefore, we are proposing to adjust Medicare expenditure amounts by employing the CMS–HCC model used in the MA program.

The CMS–HCC model more accurately predicts health care expenditures than the demographic-

only model as it accounts for variation in case complexity and severity. In addition, incorporating diagnosis data in the risk adjustment model will encourage ACOs to maintain complete and accurate medical documentation which could result in better information for population management, care coordination, and quality improvement. ACOs will have an incentive to code more completely and accurately, as is the case with MA plans, and behaviors such as these could allow an ACO to achieve apparent savings by coding changes alone and without improved methods of beneficiary care. We do not want to create an environment that rewards ACOs for achieving apparent savings by coding changes alone. Additionally, we expect the ACO's average population risk scores to be stable over time, given that there is stability in ACO participants and therefore case mix and we will have calculated the benchmark risk adjustment score for the ACO's historically assigned beneficiary population under conditions when the ACO providers/suppliers would not have an incentive to increase coding. As a result, we believe the benchmark risk adjustment score for the ACO's historically assigned beneficiary population will be a reasonable approximation of the actual risk score for the beneficiary population assigned to the ACO during the agreement period, while avoiding any distortion due to changes in coding practices. Therefore, we propose to calculate a single benchmark risk score for each ACO. The same risk score will then be applied throughout the agreement period to the annual assigned patient populations per capita expenditures for assigned beneficiaries. The benchmark risk score will be calculated by applying the CMS–HCC model to the assigned beneficiary population attributed in each year of the 3-year benchmark. However, changes in the assigned beneficiary population risk score from the 3-year benchmark period during the performance year will not be incorporated. By not incorporating the effects of changes in coding intensity during the performance years (versus the benchmark), we will protect the program from costs due to greater diagnosis coding intensity in ACOs.

We welcome comments on this proposal including comments on alternative approaches such as using the MA "new enrollee" demographic risk adjustment model for risk adjusting in the Shared Savings Program or applying a coding intensity cap on annual growth in the risk scores of an ACO's assigned beneficiary population.

We intend to monitor and evaluate the issue of more complete and accurate coding as we gain experience with the Shared Savings Program, and would consider making revisions and adaptations to the final risk adjustment model through future rulemaking if they are warranted. Further, to assure the appropriateness of ACO coding practices and our methodology for risk adjusting, we are also proposing to retain our option to audit ACOs especially those ACOs with high levels of risk score growth relative to their peers and adjust the risk scores used for purposes of establishing the 3-year benchmark accordingly. We seek comment on this proposal.

5. Technical Adjustments to the Benchmark: Impact of IME and DSH

Section 1899(d)(1)(B)(ii) of the Act states that "Such benchmark shall be adjusted for beneficiary characteristics and such other factors as the Secretary determines appropriate * * *." Several factors in the Medicare FFS payment systems can affect an ACO's ability to realize savings by adjusting payment rates and thus affecting both expenditures during the benchmark period and each subsequent performance year. Additionally, changes in these payment factors, between the benchmark and performance years can also influence whether an ACO realizes savings or incurs losses under the program.

Teaching hospitals receive additional payment to support medical education through an indirect medical education (IME) adjustment. In addition, hospitals that serve a disproportionate share of low-income beneficiaries also receive additional payments, referred to as the Medicare disproportionate share hospital (DSH) adjustment. Many hospitals, especially academic medical centers, receive both these adjustments, which can provide substantial increases in their Medicare payments compared to hospitals that do not qualify for these adjustments. The higher payments provided to these types of hospitals could provide ACOs with a strong incentive to realize savings simply by avoiding referrals to hospitals that receive IME and DSH payments.

We have considered whether it would be appropriate to remove IME and DSH payments or a portion of these payments from the benchmark and the calculation of actual expenditures for an ACO. However, section 1899(d)(1)(B)(i) of the Act only provides authority to adjust expenditures in the performance period for beneficiary characteristics and does not provide authority to adjust for "other factors". Therefore, while we may adjust the benchmark under this provision by removing IME and DSH payments, we could not also do so in our calculation of performance year expenditures. If we were to remove IME and DSH payments from the benchmark, the benchmark would be set artificially lower relative to the performance period, thus making it more difficult for an ACO to overcome and achieve savings under this program. In addition, excluding these payments would result in an artificial and incomplete representation of actual spending of Medicare Trust Fund dollars. Further, section 1899(d)(1)(B)(ii) of the Act requires that we update an ACO's benchmark during each year of the agreement period based on a national standard ("the projected absolute amount of growth in national per capita expenditures for parts A and B under the original Medicare fee-for-service program"), which would necessarily include the effects of these payments. Additionally, we believe all relevant Medicare costs should be included in an ACO's benchmark to maintain sufficient incentives for ACOs to ensure their assigned beneficiaries receive care in the most appropriate settings. For example, ACOs that include teaching and/or DSH hospitals in their network might be more interested in joining the program if we do not remove these payments from the calculations. This is because including these payments would result in higher benchmarks against which such ACOs would work to achieve savings, and such ACOs may be able to earn back a portion of forgone IME/DSH payments in the form of shared savings in cases where a referral to a less intensive setting is most appropriate for the beneficiary.

Thus, we are not proposing to remove IME and DSH payments from the per capita costs included in the benchmark for an ACO. However, we invite comments on this issue, especially on how including or excluding these payments in the benchmark could likely affect access to medically necessary services provided at teaching/DSH hospitals. We will consider comments on this issue carefully, and in the light of these comments, we could adopt a policy in the final rule of adjusting the benchmark calculation in order to prevent any adverse effects on access to services at these hospitals.

6. Technical Adjustments to the Benchmark: Impact of Geographic Payment Adjustments on the Calculation of the Benchmark

Similarly, another factor in the Medicare FFS payment systems that could affect an ACO's ability to realize savings is the geographic payment adjustment (for example, the IPPS wage index adjustments and the physician fee schedule geographic practice cost index (GPCI) adjustments) that is generally made to payments under these systems. These adjustments increase and decrease payments under these systems to account for the different costs of providing care in different areas of the country. Further, there have been a number of temporary legislative adjustments to the wage indexes for various parts of the country during recent years. In some cases these have been extended on virtually an annual basis while others have been updated more intermittently. The timing of these adjustments could result in changes being made during an ACO's agreement period and between the benchmark and the performance years, thus influencing an ACO's ability to realize savings under the program.

As in the case of IME and DSH adjustments, we have considered removing these geographic payment adjustments from the calculation of the benchmark and actual expenditures. However, as with IME and DSH payments, we only have statutory authority under section 1899(d)(1)(B) of the Act to remove them from the benchmark and thus we cannot remove them from performance period expenditure calculations. Consistent with our proposed treatment of IME and DSH payments, we are not proposing to remove geographic payment adjustments from the calculation of benchmark expenditures. Again, we welcome comments on this issue and will especially consider comments on the likely impact of this proposal in areas that are affected by temporary geographic adjustments. After consideration of the comments, we could adopt a policy in the final rule of adjusting the benchmark calculation to remove the effects of these geographic payment adjustments.

7. Technical Adjustments to the Benchmark: Impact of Bonus Payments and Penalties on the Calculation of the Benchmark and Actual Expenditures

Medicare bonus payments are available and penalties may be imposed through value-based purchasing initiatives such as the Physician Quality Reporting System and the Health Information Technology for Economic and Clinical Health (HITECH) Act, which encourages hospital and physician adoption of electronic health records (EHR), and provides for penalties in subsequent years for those that do not demonstrate meaningful use of EHR. Incentive payments for programs such as these can affect actual expenditures and the benchmark, and thus an ACO's ability to realize savings. For example, an ACO's chances to share in savings or the level of savings that would be shared with the ACO would be reduced when an ACO professional or hospital participating in the ACO fails to receive an incentive payment (or is penalized with a payment reduction) under one of these programs during a benchmark year and subsequently receives an incentive payment from that program in an ACO performance year. This is because, all else being equal—(1) the ACO's expenditures in the performance year would be higher than they would have been in the absence of the incentive; and (2) the ACO's expenditures during the benchmark year would be relatively lower than they would have been had an incentive been received. Conversely, an ACO would be more likely to share in savings if it received an incentive payment under one of these other programs in a benchmark year and received no incentive or was penalized during a performance year. As such, the effect of including these incentive payments in the calculation of the benchmark and actual expenditures could create perverse incentives with the result that participation in the Shared Savings Program has the potential to adversely affect the performance of providers of services and suppliers with respect to other important Medicare efforts, such as the value-based purchasing and HITECH initiatives.

Section 1899(b)(3)(D) of the Act provides authority for the Secretary to incorporate, as the Secretary determines appropriate, the reporting requirements and incentive payments related to the Physician Quality Reporting System, eRx, EHR, and other similar initiatives under section 1848 of the Act. The statute provides that these incentive payments "shall not be taken into consideration when calculating any payments otherwise made under subsection (d)." Additionally, we believe it is important to ensure that these various programs' incentives are properly aligned so that their interactions support rather than impede each of the programs' goals.

Thus, consistent with our statutory authority, we are proposing to exclude Medicare expenditures or savings for incentive payments and penalties under section 1848 of the Act for value-based purchasing initiatives such as Physician Quality Reporting System, eRx, and the EHR incentives for eligible professionals under the HITECH Act from the computations of both benchmark and actual expenditures during the agreement period. We believe that excluding these costs and savings will reduce the chances that incentives that were intended to encourage and reward participation in one Medicare program would discourage full participation in another. We seek comments on this proposal.

Section 1899(b)(3)(D) of the Act does not, however, provide authority for the Secretary to exclude Medicare expenditures or savings for incentive payments and penalties not under section 1848 of the Act from benchmark and actual expenditures. Therefore, payments that are reflected in Part A and B claims for services furnished to assigned FFS beneficiaries, such as EHR incentive payments to hospitals and the Hospital Inpatient Value-Based Purchasing Program, which are made under section 1886 of the Act, and EHR incentive payments to CAHs, which are made under section 1814 of the Act, (or any incentive payments not made under section 1848 of the Act) would be counted in both the computation of actual expenditures and benchmark expenditures for Part A and B costs.

8. Trending Forward Prior Years' Experience To Obtain an Initial Benchmark

Section 1899(d)(1)(B)(ii) of the Act requires the use of "the most recent 3 years of per-beneficiary expenditures for parts A and B services" to estimate a benchmark for each ACO. As the statute requires the use of historical expenditures, the per capita costs for each year must be trended forward to current year dollars and then averaged using the weights previously described to obtain the benchmark for the first agreement period. This benchmark is subsequently updated for each year of the agreement period based on the "projected absolute amount of growth in national per capita expenditures for parts A and B services" under the FFS program as estimated by the Secretary.

a. Flat Dollar vs Growth Rate as a Benchmark Trending Factor

The statute does not specify the trending factor to be used in estimating the initial benchmark. Typically, prior years would be increased using a percentage growth factor. We considered two options for trending forward the most recent 3 years of per

beneficiary expenditures for Parts A and B services in order to estimate the benchmark for each ACO. The first option is to trend these expenditures forward using growth rates in expenditures for Parts A and B services for FFS beneficiaries. The second option is to trend these expenditures forward using a flat dollar amount equivalent to the absolute amount of growth in per capita expenditures for Medicare Parts A and B under the FFS program.

An advantage of the first option is that the use of a growth rate, as opposed to a flat dollar amount, would more accurately reflect each ACO's historical experience. That is, in contrast to a flat dollar amount, this option would neither raise the bar for ACOs in historically higher growth rate areas nor lower it for ACOs in lower growth areas. At the same time, it could be argued that this option perpetuates current regional differences in medical expenditures. An advantage of the second option, using the flat dollar amount equivalent to the absolute amount of growth in per capita expenditures for Medicare Parts A and B under the FFS program, is that it is more consistent with the method designated by the under section 1899(d)(1)(B)(ii) of the statute for updating the benchmark (as described later in this proposed rule) during the agreement period. This option also provides a stronger incentive for ACO development in areas with historically lower expenditures and growth rates. Conversely, potential ACOs in areas with historically higher growth rates could be reluctant to participate in the program because the challenge to reduce their growth rate would be greater in these areas relative to low expenditure, low growth ones.

On balance, we believe that for purposes of establishing an initial expenditure benchmark, expenditures should be trended forward in a relatively neutral and comparable way across geographic areas. Therefore, we are proposing to trend forward the most recent 3 years of per-beneficiary expenditures using growth rates in per beneficiary expenditures for Parts A and B services. For example, we would use 2011, 2012 and 2013 claims year data to set the benchmark for an ACO starting its agreement period in 2014. The 2011 and 2012 data would be trended forward using the factor described later in this proposed rule so that all benchmark dollars would be in 2013 dollars. We welcome comments on this proposal, and especially on whether the other option that we considered to trend the benchmark by the flat dollar amount would be more consistent with our proposal to update the benchmark as specified under section 1899(d)(1)(B)(ii), as discussed in the next section.

b. National vs Local Growth Rate as a Benchmark Trending Factor

Under the option described previously, we could trend per beneficiary expenditures forward using national or local growth factors. Using the national growth rate in Medicare A and B FFS expenditures would appear to be more consistent with the methodology that, as specified in section 1899(d)(1)(B)(ii) of the Act incorporates the absolute amount of growth in per capita expenditures for Medicare Parts A and B nationwide under the FFS program in updating each ACO's benchmark. A national growth rate would allow a single growth factor to be applied to all ACOs regardless of their size or geographic area. However, a national rate could also disproportionately encourage the development of ACOs in areas with historical growth rates later in this proposed rule the national average that would benefit from having a relatively higher base, which increases the chances for shared saving, while relatively discouraging development of ACOs in areas with historically higher growth rates above the national average that would have a relatively lower base.

In contrast, trending expenditures based on State or local area growth rates in Medicare A and B expenditures may more accurately reflect the experience in an ACO area and mitigate differential incentives for participation based on location. Therefore, we considered an option to trend the benchmark by the lower of the national projected growth rate or the State or the local growth rate. This option would balance providing a more accurate reflection of local experience with not rewarding historical growth higher than the average. This method also instills strong saving incentives for ACOs in both high-cost growth and low-cost growth areas.

After considering both of these alternatives, we are proposing to employ the national growth rate in Medicare Parts A and B expenditures for FFS beneficiaries for trending forward the fixed benchmark. We believe this approach will help to ensure that ACOs in both high spending, high growth and low spending, low growth areas will have appropriate incentives to participate in the Shared Savings Program, while also moving toward establishing a national standard for calculating and measuring ACO financial performance. We seek comment on this proposal and on the alternatives to using a national growth rate as outlined previously.

9. Updating the Benchmark During the Agreement Period

Section 1899(d)(1)(B)(ii) states that the benchmark shall be "updated by the projected absolute amount of growth in national per capita expenditures". We believe that Congress demonstrated an interest in mitigating some of the regional differences in Medicare spending among ACOs by requiring the use of a flat dollar amount equivalent of the absolute amount of growth in national FFS expenditures to update the benchmark for the agreement period. In effect, in the second and third years of an agreement period, using a flat dollar increase, which would be the same for all ACOs, provides a relatively higher expenditure benchmark for low growth low spending ACOs and a relatively lower benchmark for high growth high spending ACOs. All else being equal, an ACO can more likely share in savings when its actual expenditures are judged against a higher, rather than a lower benchmark. Thus, with a flat dollar increase to the benchmark, ACOs in high cost high growth areas must reduce their rate of growth more to bring their costs more in line with the national average.

However, we also considered our authority under Section 1899(i) for an alternative option. Specifically, we considered an option to update the benchmark by the lower of the national projected absolute amount of growth in national per capita expenditures or the local/State projected absolute amount of growth in per capita expenditures. Incorporating more localized growth factors reflects the expenditure and growth patterns within the geographic area served by ACO participants and ACO providers/suppliers, potentially providing a more accurate estimate of the updated benchmark based on the area from which the ACO derives its patient population. Capping the update at the projected absolute amount of growth in national per capita expenditures prevents the update from disproportionately allowing relatively larger dollar-amount updates for high-spending areas that potentially have a stronger ability to improve care coordination and efficiency from current levels. Not using the national flat-dollar update for low-spending, low-growth areas ensures that the Medicare Shared Savings Program instills strong saving incentives for ACOs in low-cost areas, as well as for those in high-cost areas. Also, as noted in section V.C.1. of this proposed rule, using the national flat-dollar update as specified in section 1899(d)(1)(B)(ii) for all ACOs could contribute to selective

program participation that could result in Medicare costs due to an increase in the amount of bonus payments for unearned savings.

In keeping with section 1899(d)(1)(B)(ii) of the Act, we are proposing to update the benchmark by the projected absolute amount of growth in national per capita expenditures. We believe this approach will help to ensure that ACOs in both high spending, high growth and low spending, low growth areas will have appropriate incentives to participate in the Shared Savings Program. We seek comment on this proposal and on the alternative to update by the lower of the national projected absolute amount of growth in national per capita expenditures or the local/State projected absolute amount of growth in per capita expenditures under section 1899(i) of the Act.

10. Minimum Savings Rate (MSR) and Sharing Rate

Section 1899(d)(1)(B)(i) of the Act provides that "an ACO shall be eligible to receive payment for shared savings under paragraph (2) only if the estimated average per capita Medicare expenditures under the ACO for Medicare fee-for-service beneficiaries for parts A and B services, adjusted for beneficiary characteristics, is at least the percent specified by the Secretary below the applicable benchmark * * *." That provision further states that the "Secretary shall determine the appropriate percent * * * to account for normal variation in expenditures under this title, based upon the number of Medicare fee-for-service beneficiaries assigned to an ACO." Section 1899(d)(1)(B)(ii) of the Act provides that, if an ACO has savings in excess of the MSR and meets the quality standards established by the Secretary, "a percent (as determined appropriate by the Secretary) of the difference between such estimated average per capita Medicare expenditures in a year, adjusted for beneficiary characteristics, under the ACO and such benchmark for the ACO may be paid to the ACO as shared savings and the remainder of such difference shall be retained by the program under this title."

A goal of the Shared Savings Program is to use a portion of the savings (the difference between the ACO's actual expenditures and the benchmark) to encourage and reward participating ACOs for coordinating the care for an assigned beneficiary population in a way that controls the growth in Medicare expenditures for that patient population while also meeting the established quality performance standards. However, observed savings can also occur as a result of normal year-to-year variations in Medicare beneficiaries' claims expenditures in addition to the ACO's activities. Thus, even if an ACO engages in no activities to improve the quality and efficiency of the services it delivers, in certain cases, differences between the benchmark expenditures (updated according to statute) and assigned patients' expenditures would be observed during some performance periods merely because of such normal variation. Consequently, the statute requires us to specify a MSR to account for the normal variations in expenditures, based upon the number of Medicare FFS beneficiaries assigned to the ACO. The MSR should be set in a way that gives us some assurance that the ACO's performance is a result of its interventions, not normal variation. However, we also do not want an outcome where savings that have been earned are not recognized.

Establishing an MSR on the basis of standard inferential statistics that take into account the size of an ACO's beneficiary population provides confidence that, once the savings achieved by the ACO exceed the MSR, the change in expenditures represents actual performance improvements by the ACO as opposed to normal variations.

Under the PGP demonstration, the MSR was initially set at a flat 2 percent of the benchmark, regardless of number of assigned beneficiaries, and PGP practices received back 80 percent of the savings achieved in excess of the MSR. However, in establishing a MSR, section 1899(d)(1)(b)(i) of the Act calls on us to take into account "the number of fee-for-service beneficiaries assigned to an ACO." As such, we would need to apply statistical sampling techniques to determine a MSR based on the number of assigned beneficiaries with some level of statistical confidence.

The MSR in combination with the savings rate will determine the amount of shared savings that an ACO can receive. For example, fewer savings would be shared if the MSR were set at a higher percentage. Conversely, shared savings would be higher if the MSR were set at a lower percentage. There are several policy implications associated with the methodology used to set the MSR. A higher MSR would provide greater confidence that the shared savings amounts reflect the real quality and efficiency gains, and offer greater protection to the Medicare Trust Funds. However, due to the larger barrier to achieve savings, a higher MSR could also discourage potentially successful ACOs, especially physician organized ACOs and smaller ACOs in rural areas, from participating in the program. In contrast, a lower MSR would encourage more potential ACOs to participate in the program, but would also provide less confidence that savings are a result of improvements in quality and efficiency made by an ACO.

We believe that the most appropriate policy concerning determination of the "appropriate percent" for the MSR would achieve a balance between the advantages of making incentives and rewards available to successful ACOs and prudent stewardship of the Medicare Trust Funds. For the one-sided model we are proposing a sliding scale confidence interval (CI) based on the number of assigned beneficiaries. The MSR would be established for each ACO based on increasing nominal confidence intervals for larger ACOs so that an ACO with the minimum 5,000 assigned beneficiaries would have an MSR based on a 90 percent CI; an ACO with 20,000 assigned beneficiaries would have a MSR based on a 95 percent CI and an ACO with 50,000 assigned beneficiaries would have an MSR based on a 99 percent CI. In addition, the MSR would not be allowed to fall below 2 percent for larger ACOs.

An ACO that exceeds its MSR would be eligible to share up to 50 percent of the savings in the one-sided model (based on quality performance), as discussed in section II.E. of this proposed rule. Table 6 displays the minimum savings rate an ACO would have to achieve before savings could be shared based on the number of its assigned beneficiaries.

In order to improve the opportunity for groups of solo and small practices to participate in the Shared Savings Program, we are proposing to vary confidence intervals by the size of the ACO, which is determined based on the number of assigned beneficiaries. In response to our November 17, 2010 RFI, many commenters recognized the prevalence of solo and small practices and the importance of these providers for rural areas and for the treatment of specific patient populations, for example, individuals with mental health and substance abuse disorders or beneficiaries residing in skill nursing facilities. Many of these commenters urged us to consider policies and models that encourage the participation of solo and small practices and to address barriers they face in forming ACOs such as access to up-front capital to invest in the infrastructure and resources required to redesign care. One option that would help accomplish this would be to vary the confidence

intervals used to establish MSRs so that smaller practices would have relatively lower MSRs. Conversely, in recognition that they are likely to be already established, possess prior experience, and thus better able to achieve savings, larger ACOs would have their MSRs based on a higher confidence interval, resulting in a relatively higher MSR.

The MSRs are estimated to provide confidence that an ACO with a given number of beneficiaries and assumed to be of average national baseline per-capita expenditure and expenditure growth rate would be unlikely to achieve a shared savings payment by random chance alone. A specific MSR is a function of both the number of assigned beneficiaries and a chosen confidence interval. Recognizing the higher uncertainty regarding expenditures for smaller ACOs and the desire to encourage participation by smaller ACOs, for the one-sided model, we propose to set the confidence interval to 90 percent for ACOs of 5,000 beneficiaries, resulting in an MSR of 3.9 percent. For ACOs with 20,000 and 50,000 beneficiaries, we propose to set the confidence interval to 95 percent and 99 percent, respectively, resulting in MSRs of 2.5 percent and 2.2 percent. As ACO size increases from 5,000 to 20,000 (or similarly from 20,000 to 50,000), we propose blending the MSRs between the two neighboring confidence intervals, resulting in the MSRs as shown in Table 6. We specify an MSR at both the high and low end of each range of ACO population size. A particular ACO would be assigned a linearly-interpolated MSR given their exact number of beneficiaries. For example, an ACO with 7,500 beneficiaries would be assigned an MSR of 3.3 percent because it lies at the midpoint between 7,000 and 7,999 beneficiaries, sizes at which the MSR would be 3.4 percent and 3.2 percent, respectively. For ACOs serving more than 60,000 aligned beneficiaries, we propose that the MSR would not be allowed to fall below 2 percent. This lower bound is designed to protect the shared savings formula from expenditure reduction due to random chance that can occur in group claims due to factors that persist regardless of a group's size. This lower bound is also consistent with the flat 2 percent MSR we propose to use in the two-sided model and is the minimum level that was used in the PGP Demonstration for groups regardless of size which also provided a lower MSR for smaller physician groups participating in the demonstration.

We considered using a flat 95 percent confidence interval for organizations which is a recognized standard for measuring statistical differences, but as previously noted, because we believe that many smaller physician-driven and rural ACOs have the potential to improve the quality and efficiency of care, we were concerned about the impact on the ability of these ACOs to participate in the Shared Savings Program. We also wanted to protect the Medicare Trust Funds against large organizations coming together solely for purposes of aggregating their number of assigned beneficiaries in order to have smaller MSRs to be able to achieve the minimum required savings levels and share in savings with little or no actual improvement in the quality and efficiency of care provided to beneficiaries.

The proposed confidence intervals were determined assuming that the variation in the per capita expenditure growth for a particular ACO is equal to the variation in per capita expenditure growth nationally. This is not the case for the majority of ACOs, however, as regional growth rates tend to vary from the national average due to a number of variables. Therefore, the confidence intervals generated using only the national expenditure growth variation overstate the relative confidence associated with an increasing group size. This is compensated for in two ways: (1) The 2 percent floor; and (2) increasing the confidence interval as group size increases.

Table 6. Minimum Savings Rate and Confidence Intervals by Number of Assigned Beneficiaries (One-Sided Model)

Number Beneficiaries	MSR (low end of assigned beneficiaries)	MSR (high end of assigned beneficiaries)
5,000 - 5,999	3.9%	3.6%
6,000 - 6,999	3.6%	3.4%
7,000 - 7,999	3.4%	3.2%
8,000 - 8,999	3.2%	3.1%
9,000 - 9,999	3.1%	3.0%
10,000 - 14,999	3.0%	2.7%
15,000 - 19,999	2.7%	2.5%
20,000 – 49,999	2.5%	2.2%
50,000 – 59,999	2.2%	2.0%
60,000 +	2.0%	

We welcome comments on the most appropriate means to establish the MSR for an ACO, including the appropriate confidence intervals.

11. Net Sharing Rate

Section 1899(d)(2) calls for us to share "a percent (as determined appropriate by the Secretary) of the difference between such estimated average per capita Medicare expenditures in a year, adjusted for beneficiary characteristics under the ACO and such benchmark for the ACO." Section 1899(i) of the Act permits the Secretary to consider other payment models if she determines that they will "improve the quality and efficiency of items and services furnished under this title" and will not result in additional expenditures. Thus, in considering the amount of savings ACOs under the one-sided model could be eligible to receive, we considered several options in addition to the methodology outlined in section 1899(d)(2) of the Act.

The first option we considered is the one required under section 1899(d)(2) of the Act, which would permit the ACO to share on first dollar savings once the MSR was exceeded. This option would maximize the reward that an ACO could realize. This amount could provide critical financial support for ACOs that serve a smaller population (for example, less than 10,000 assigned beneficiaries), which may be physician only and/or predominantly care for underserved populations, or ACOs whose beneficiaries rely upon safety net providers for care or ACOs which serve rural areas. However, given the normal variation in expenditures, we have concerns that sharing on first dollar could result in sharing on unearned savings rather than on savings achieved by the ACO for redesigned care processes.

Therefore, we considered another alternative which would be to limit the amount of savings by requiring ACOs to exceed the MSR and then share with the ACO only those savings in excess of the MSR. As discussed in the previous section, one challenge to appropriate sharing of savings under this program is that observed savings can occur as a result of normal year-to-year variations in Medicare beneficiaries' claims expenditures in addition to the ACO's activities. This concern is heightened in the one-sided model, because absent initial accountability for losses, ACOs have less motivation to eliminate unnecessary expenses and may be more likely to be rewarded as a result of methodological requirements. Sharing only in savings which exceed the MSR is consistent with the design of the original PGP demonstration and would reduce the probability that shared savings are earned as a result of chance or lower pre-existing expenditure trends due to existing efficiencies, and not newly enhanced care coordination and/or redesigned delivery of care. Further, such a requirement would encourage ACOs to strive to generate greater levels of savings.

A third option we considered would be to require all ACOs to exceed the MSR to be eligible for savings, but only share savings in excess of a certain threshold. ACOs meeting certain criteria could be exempted from this provision and be allowed to share in first dollar savings. This option would balance the need to have assurance that savings are not a result of random variation with the need to provide critical financial support for under-funded ACOs, particularly ACOs that serve a smaller population, safety net providers, or physician-only participants. Additionally, we have experience with this model through the PGP demonstration.

We are proposing the third option, that is, we propose that once an ACO has surpassed its MSR, the ACO would share in savings beyond a certain threshold. We further propose that, unless exempted, ACOs that exceed the MSR would be eligible to share in net savings above a 2-percent threshold, calculated as 2 percent of its benchmark (updated according to statute). The sharing rate (earned quality performance sharing rate and additional increases for including FQHCs and/or RHCs) would be applied to net savings above this 2 percent threshold in order to determine the shared savings amount. We believe that this threshold protects the program from sharing unearned savings and helps to ensure that shared savings are due to enhanced care coordination and quality of care on the part of the ACO.

As previously discussed, many smaller physician-driven ACOs and ACOs caring for underserved populations have the potential to improve the quality and efficiency of care, but may be especially challenged in accessing capital to meet their needs. We hope to encourage successful participation by these ACOs in the Shared Savings Program. Additionally, we acknowledge that providers/suppliers working in these environments face additional challenges in coordinating care and creating the infrastructure necessary to create a successful ACO, and therefore may not be equipped to assume the risk right away (and be eligible for greater reward) of the two-sided model. As such, we are proposing that ACOs that meet the following criteria would be exempt from the 2 percent net savings threshold and would instead share on first dollar savings under the one-sided model. We propose to exempt ACOs with less than 10,000 assigned beneficiaries in the most recent year for which we have complete claims data (for instance, 2012 for 2014 program participation) and that meet one of the following:

- The ACO is comprised only of ACO professionals in group practice arrangements or networks of individual practices of ACO professionals.
- 75 percent or more of the ACO's assigned beneficiaries reside in counties outside a Metropolitan Statistical Area (MSA) in the most recent year for which we have complete claims data.
- 50 percent or more of the ACO's assigned beneficiaries were assigned to the ACO on the basis of primary care services received from a Method II CAH.
- 50 percent or more of the beneficiaries assigned to the ACO had at least one encounter with an ACO participant FQHC and/or RHC in the most recent year for which we have complete claims data, that is, the ACO has met criteria for receiving full potential additional payment as described later in this proposed rule.

We invite comment on these proposals and the other options considered.

12. Additional Shared Savings Payments for Including FQHCs and/or RHCs

We are also proposing that an ACO in the one-sided model can receive an increase in its shared savings rate of up to 2.5 percentage points during the first 2 years of its agreement, for including a strong FQHC and/or RHC presence within the structure of the ACO. (See section II.G. of this proposed rule for details surrounding the two-sided model which provides for a 5 percentage point increase for including FQHCs or RHCs or both.)

FQHCs and RHCs have long delivered comprehensive, high-quality primary health care to patients regardless of their ability to pay, and increase access to health care through innovative models of community-based, comprehensive primary health care that focus on outreach, disease prevention, and patient education activities. FQHCs provide high-quality care to rural and urban populations alike by focusing attention on improving public health through preventive care in addition to direct patient care. Not only do health centers provide critical, high quality primary care in the Nation's neediest areas, but reports have shown that the

health center model of care can reduce the use of costlier providers of care, such as emergency departments and hospitals. Currently, more than 1,100 such health centers operate over 7,900 service delivery sites that provide care to nearly 19 million patients in every State, the District of Columbia, Puerto Rico, the U.S. Virgin Islands, and the Pacific Basin.

Despite serving less healthy and more vulnerable populations, research indicates that these health centers have achieved considerable success in increasing access to care, improving health outcomes for patients, reducing health disparities, and containing health care costs. For example, regarding FQHCs, data show health center Medicaid patients were 11 percent less likely to be inappropriately hospitalized and 19 percent less likely to visit the emergency room inappropriately than Medicaid beneficiaries who had another provider as their usual source of care.[15]

RHCs improve access to primary care in underserved rural areas through the use of interdisciplinary team· based care. Currently, more than 3,800 such RHCs provide care to more than 1.6 million Medicare beneficiaries throughout the United States. RHCs provide critical, quality primary care to Medicare beneficiaries and others most in need in underserved areas. Research has shown that RHCs not only provide care at costs significantly less than other providers of care, such as emergency departments and hospitals, but also reduce use of those providers. Additionally, research on RHCs has shown that:

- Among older adults, the presence of an RHC in the county reduced ambulatory care sensitive (ACS) conditions admission rates, compared to counties in which an RHC was not present.[16]
- RHCs offer financially accessible care to low income individuals; 96 percent of independent RHCs surveyed offer free care, sliding fee scales, or both.[17]

Accordingly, because FQHCs and RHCs are unable to participate independently in this program, we believe providing incentives to ACOs that include FQHCs and/or RHCs as ACO participants is in the interest of the Shared Savings Program as incorporation of these types of entities will promote care coordination and the delivery of efficient, high-quality health care. Therefore, we are proposing, for the one-sided model, up to a 2.5 percentage point increase in the sharing rate for ACOs that include these entities as ACO participants. We propose establishing a sliding-scale payment, outlined in the following table, based on the number of Medicare FFS beneficiaries with one or more visit at an ACO's participant FQHC or RHC during the performance year.

Table 7: Sliding Scale Payment Based on Number of Beneficiary Visits at an ACO's Participant FQHC or RHC

Percentage of ACO Assigned Beneficiaries With 1 or More Visits to an ACO participant FQHC/RHC During the Performance Year	Percentage Point Increase in Shared Savings Rate (One-Sided Model)
1-10%	0.5
11-20%	1
21-30%	1.5
31-40%	2
41-50%	2.5

We are also proposing that ACOs specifically identify their FQHC/RHC participant TINs in their initial and annual reporting of ACO participant TINs, and disclose other provider identifiers as requested to assure proper identification of these organizations for the purpose of awarding the payment preference.

The statutory definition of FQHCs at section 1861(aa)(4) of the Act includes FQHCs receiving grant support under section 330 of the Public Health Service Act, so-called FQHC look-a-likes, and outpatient health programs/facilities operated by tribal organizations. Our regulations at 42 CFR 405.2401(b) include this statutory definition of FQHCs. Similarly, § 405.2401(b) reflects the statutory definition of RHCs in section 1861(aa)(2) of the Act. We therefore propose to define FQHCs and RHCs, for the purpose of awarding this payment preference, as these terms are defined in § 405.2401(b) of our regulations. We seek comments on alternate options for establishing a payment preference with sliding scale for ACOs that include FQHCs or RHCs as ACO participants, including suggestions for the appropriate method to measure FQHC/RHC involvement and the appropriate level of incentives.

We are also interested in encouraging providers who serve a large portion of dual eligible beneficiaries to participate in the Medicare Shared Savings Program. Medicare beneficiaries who are also eligible for Medicaid—that is, are "dually eligible" for these programs—are among the most vulnerable of Medicare beneficiaries. Dual eligible beneficiaries tend to have higher medical costs than other fee-for-service beneficiaries, and, as a result, are expected to benefit even more than other beneficiaries from improvements in the quality and efficiency of their care resulting from the greater care coordination offered by an ACO. The Affordable Care Act recognizes the unique status of dual eligible beneficiaries and includes several provisions to address their special

[15] Falik M. *et al*. Comparative Effectiveness of Health Centers as Regular Source of Care. Journal of Ambulatory Care Management 2006; 29(1): 24–35.

[16] Probst, J.C., Laditka, J., and Laditka, S. (2009). "Community Health Center and Rural Health Clinic Presence Associated With Lower County-Level Hospitalization Rates for Ambulatory Care Sensitive Conditions." South Carolina Rural Health Research Center.

[17] Hartley, D., Gale, J. Leighton, A. and Bratesman, S. (2010). "Are Rural Health Clinics Part of the Rural Safety Net?" Muskie School of Public Service; Maine Rural Health Research Center.

needs. For instance, section 2602 of the Affordable Care Act established a Federal Coordinated Health Care Office within CMS to bring together officers and employees of the Medicare and Medicaid programs at CMS to: (1) more effectively integrate benefits under the Medicare and Medicaid programs; and (2) improve the coordination between the Federal government and States for individuals eligible for benefits under both such programs in order to ensure that these individuals receive full access to the items and services to which they are entitled under titles XVIII and XIX of the Act.

Additionally section 1899(j) of the Act provides that "[t]he Secretary may give preference to ACOs who are participating in similar arrangements with other payers." The statute prescribes neither the kind of preference that the Secretary should provide to such ACOs nor what other types of arrangements should be considered "similar" for purposes of such a preference. We believe that the more patients an ACO sees for which it is eligible to receive performance-based incentives, such as shared savings, the more likely it is that the ACO will adopt substantial behavior changes conducive to improved quality and cost savings.

We are seeking comment on methods to provide preference to ACOs that serve a large dual-eligible population or that enter and maintain similar arrangements with other payers. Specifically we seek comment regarding suggestions to encourage accountability for dual-eligible beneficiaries and participation in similar arrangements with other types of payers.

13. Withholding Performance Payments To Offset Future Losses

Over the course of the program, an ACO may earn performance payments in some years and incur losses in other years. The issue is whether the full amount of shared savings payments should be paid in the year they are accrued, or whether some portion should be withheld to offset potential future losses. For example, under the PGP demonstration, a flat 25 percent withhold applied to annual earned performance payments to guard against losses in future years as well as to provide an incentive for PGPs to continue in the demonstration since the withhold was only released at the end of the demonstration period or when the PGPs were rebased. Under the two-sided model discussed in section II.G. of this proposed rule, we propose that an ACO may use a withhold of their earned shared savings payment as one option for demonstrating an adequate repayment mechanism in the event they incur shareable losses. As discussed in sections II.B. and II.I. of this proposed rule, we believe the requirement that ACOs be willing to commit to a 3-year agreement to participate in the Shared Savings Program is necessary to ensure that the program achieves its long-term goal of redesigning health care processes, and our proposal here furthers that intent. Since we want to encourage ACOs to participate for all 3 years of their agreements, protect the Medicare program against losses, and ensure ACOs have an adequate repayment mechanism in the event they incur losses under either the one-sided or two-sided model, we are proposing a flat 25 percent withholding rate will be applied annually to any earned performance payment. Under the two-sided model as discussed in Section II.G. of this proposed rule, we propose that an ACO may withhold an additional portion of its earned performance payment as a mechanism to demonstrate an adequate repayment mechanism in the event they incur shareable losses. Furthermore, we propose that at the end of each agreement period, positive balances will be returned to the ACO. However, if the ACO does not complete its 3-year agreement, the ACO would forfeit any savings withheld.

14. Performance Payment Limit

Section 1899(d)(2) of the Act requires the Secretary to "establish limits on the total amount of shared savings that may be paid to an ACO * * *." Therefore, we must propose the maximum performance payment an ACO may receive in any given performance year in this proposed rule. In determining what would constitute an appropriate limit, we believe that it should provide a significant opportunity for ACOs to receive shared savings generated from quality improvements and better coordination and management of Part A and B services, while avoiding creating incentives for excessive reductions in utilization which could be harmful to beneficiaries. Under the PGP demonstration, the limit was set at 5 percent of the organization's Part A and Part B expenditure target.

For purposes of the Shared Savings Program, we considered an option to vary the performance payment limit by the readiness of the ACO to take on greater responsibility and risk. ACOs seeking to participate in the Shared Savings Program will vary with respect to their readiness to function under a risk model with respect to their organizational and systems capacity and structure. Accordingly, some ACOs might more quickly be able to demonstrate quality improvements and savings than will others. Applying differential payment limits based on an ACO's readiness to take on risk could be another means to encourage and reward successful ACO participation.

In light of our experience with the PGP demonstration, we considered a limit of 5 percent. We also considered whether a higher limit, such as 10 percent or 15 percent, would be appropriate to provide an even stronger incentive for ACOs to develop the quality and efficiency improvements that could result in greater shared savings. Depending on an ACO's composition, shared savings payments under such higher limits could represent an even larger portion of Medicare payments to ACO participants for care furnished to assigned beneficiaries since the cap is a percentage of the ACO's benchmark for Medicare Part A and B expenditures for assigned beneficiaries, which reflects all care furnished to those beneficiaries, regardless of whether it was provided in the ACO. For example, an ACO that does not include a hospital would have the opportunity to realize a relatively higher proportion of shared savings as a percentage of its Medicare revenue by reducing Part A expenditures for its assigned beneficiaries. However, opportunities to earn greater savings could also raise questions about whether the quality of care is improving, which is a goal as important as achieving savings in the Shared Savings Program. Providing an incentive for ACOs to invest to improve quality and efficiency of care needs to be balanced against providing an overly large incentive where an ACO may be encouraged to generate savings resulting from inappropriate limitations on necessary care. A higher cap on total shared savings could provide such an incentive to limit care. While all ACOs may have this incentive to some degree, ACOs without Part A providers could have greater incentive to do so, depending on where the cap is established.

A lower limit, such as the 5 percent limit under the PGP demonstration, would reward ACOs for improving quality and efficiency and potentially generate more savings for the Medicare program without creating incentives to limit care that is appropriate and necessary. On the other hand, a lower limit might be an insufficient incentive for some potential ACOs to participate in the program. In contrast, a higher percentage limit, such as 10 or 15 percent of an ACO's Part A and B expenditure benchmark, would provide

greater incentives for organizations to participate in the program and to achieve the quality and efficiency gains that are the goals of the Shared Savings Program. Many health care researchers believe that the rate of unnecessary health care is more than the approximate 10 percent which would be implied by establishing a 5 percent cap on ACO shared savings. (Since the maximum shared savings potentially realized by an ACO under the one-sided model is 52.5 percent, a 7.5-percent limit on the ACO share implies an expectation that overall savings may be as high as approximately 14 percent; a 10-percent limit implies a savings expectation of approximately 19 percent.) On the other hand, such a higher limit may provide some incentive for ACO providers/suppliers to reduce utilization inappropriately, which could potentially be harmful to beneficiaries

We believe that the considerations in favor of both a lower (for example, 5 percent) and a higher (for example, 10 percent) limitation on shared savings with an ACO have merit. Accordingly we are proposing to establish the payment limit at 7.5 percent of an ACO's benchmark for the first 2 years of the agreement under the one-sided model. Following suggestions by MedPAC, in order to encourage ACOs to assume risk and participate in the two-sided model, as described in section II.G. of this proposed rule, we are proposing, for the two-sided model, to establish the payment limit at 10 percent of an ACO's benchmark for those ACOs that either elect the two-sided model initially for all 3 years or are transitioned from the one-sided model during the third year of their agreement period. (Since the maximum shared savings potentially realized by an ACO under the two-sided model is 65 percent, a 10-percent limit on the ACO share implies an expectation that overall savings may be as high as approximately 15 percent). We are soliciting comments on these proposed payment limits and on whether a higher limit—for example, 10 percent for all ACOs—would be more appropriate in the light of the considerations discussed previously and other considerations that commenters may wish to raise. We also seek comments on whether differential limits should be established based on an ACO's readiness, as discussed previously, including the criteria we would apply and the methods by which we would assess readiness and how differential limits should be structured. We will consider this information and the implications for a differential cap based on ACO readiness in future rulemaking cycles.

Regardless of what limit is adopted in the final rule, we plan to monitor beneficiary access and utilization of services, and the potential contribution of the performance limit to any inappropriate reductions in services. Our proposals related to monitoring and addressing ACO performance can be found in Section II.H. of this proposed rule. Furthermore, as we gain more experience with the Shared Savings Program and are able to evaluate how well the incentive structure under the Shared Savings Program is operating to generate greater quality and efficiency without inappropriately reducing utilization of services, we may undertake additional rulemaking to revise the performance payment limits we establish in the final rule.

G. Two-Sided Model

Section 1899 of the Act implements a voluntary program that provides incentives for group of providers of services and suppliers to work together to improve the quality and efficiency of care for a FFS beneficiary population in exchange for a share in any savings generated from their effort. Section 1899(i) of the Act authorizes the Secretary to use other payment models in addition to the shared savings model outlined in section 1899(d) of the Act under which we only share savings with ACOs. This provision authorizes the Secretary to select a partial capitation model or any other payment model that the Secretary determines would improve the quality and efficiency of items and services furnished to Medicare fee-for-service beneficiaries. In addition, section 1115A of the Act, as amended by 3021 of the Affordable Care Act, authorizes the Center for Medicare and Medicaid Innovation (Innovation Center) to test innovative payment and service delivery models, which could include alternative ACO payment models.

In the November 17, 2010 **Federal Register**, we solicited public comment on a number of issues including the types of alternative payment models we should consider in addition to the model laid out in section 1899(d) of the Act, either in the Shared Savings Program under the authority provided in 1899(i) of the Act or using the Innovation Center authority under section 1115A of the Act. We further asked about the relative advantages and disadvantages of any such payment models.

Most comments received in response to this question favored our use of alternative payment models. A number of commenters suggested risk-based models such as partial capitation (an up-front fixed dollar amount for a subset of Medicare services rendered by a provider per beneficiary per period of time) or global payment (an up-front fixed dollar amount for all Medicare-covered services required per beneficiary per period of time). Commenters proposed both one-sided shared savings models (to ease providers of services and suppliers into this payment model) and models that would allow ACOs to share in savings and be held accountable for losses (two-sided models).

Taking these comments into account, we are proposing that ACOs could elect the two-sided model for their initial agreement period, to become accountable for losses and in order to be eligible for higher sharing rates than would be available under the one-sided model, beginning in their first performance year. In addition, we are also proposing that ACOs that initially elect the one-sided model would be reconciled annually for the first 2 years of the 3-year agreement using the one-sided model and automatically transitioned to the two-sided model for the third year of their agreement. This approach gives ACOs an option of two tracks for their initial agreement period, thereby providing an opportunity for organizations more experienced with care coordination and risk models, that are ready to accept risk to enter a sharing arrangement that provides greater reward for greater responsibility in year 1, while also providing an entry point for organizations with less experience with risk models, such as some physician-driven organizations or smaller ACOs, to gain experience with population management before transitioning to more risk.

1. Risk-Based Payment Models

In section II.F of this proposed rule, we describe in detail the one-sided model, under which ACOs share in savings but are not accountable for repaying any losses if actual expenditures exceed the benchmark. While we believe this model holds promise for creating substantial improvement in quality and cost, many commenters on the November 17, 2010 RFI, and other stakeholders urged us to include risk-based arrangements where ACOs would also be accountable for downside risk. Policy experts have also suggested that incorporating downside risk-based models into the Shared Savings Program would provide a stronger lever than a one-sided model for encouraging ACOs to achieve

efficiencies and attain the program's transformative goals.[18]

Risk-based arrangements may take many forms. Two models considered for inclusion in the Shared Savings Program were two-sided risk arrangements (shared savings and losses) and partial capitation. Real-world examples of these models vary widely, according to the terms of specific provider-payer initiatives they encompass. Partial capitation refers to a payment system that incorporates elements of both capitation and FFS. Section 1899(i) of the Act defines partial capitation as a model "* * * in which an ACO is at financial risk for some, but not all, of the items and services covered under Parts A and B, such as at risk for some or all physicians' services or all items and services under Part B." Our intent is to design and test partial capitation models in the Innovation Center first in order to gain more experience, introduce them to providers of services and suppliers, and refine them before adopting them more widely in the Shared Savings Program.

In a two-sided model based around FFS within the Shared Savings Program, ACOs would accept the downside risk for losses once the minimum loss rate is exceeded (the equivalent of the minimum savings rate that must be exceeded in order to share in savings under the Shared Savings Program). ACOs' exposure to downside risk could also be limited by the creation of risk corridors that establish a maximum shared loss cap. We are proposing to make available a two-sided model in the Shared Savings Program to foster ACOs' accountability for greater risk with a greater opportunity for reward. ACOs may elect to enter the one-sided model (Track 1) or elect the two-sided model (Track 2). An ACO that elects Track 1 would automatically be transitioned to the two-sided model for the third year of its agreement. Thus, in the third year of the ACO's agreement under Track 1, the methodology used to reconcile ACOs under the first year of the two-sided model would apply except ACOs must meet the quality performance standard that applies in the third year (as opposed to the first year standard of full and accurate reporting). A key attribute of FFS is beneficiary freedom of choice to choose any provider they wish which will be maintained under both the one-sided and two-sided models.

There are pros and cons of risk-based arrangements. Providers of services and suppliers engaged in a risk-based payment arrangement, compared to a one-sided shared savings structure, have a stronger incentive to control spending and achieve efficiencies. This is consistent with the antitrust perspective that participants in financially integrated organizations have the incentive to cooperate in controlling costs and improving quality by managing the provision of services; such that to demonstrate financial integration, participants in a collaboration must share substantial financial risk, as discussed in section II.B of this proposed rule. Risk-based arrangements offer payers a chance to control spending, either through the recoupment of excess expenditures (losses) in two-sided risk arrangements, or through capitated payments. However, since providers of services and suppliers have an increased motivation to control spending and achieve efficiencies under a risk-based model, it would be reasonable to anticipate an increase in negative incentives such as incentives to stint on care or undersupply services, shift costs (for instance through changes in referral patterns), as well as increased incentives for providers of services and suppliers to avoid at risk beneficiaries. In the 1990's, California providers' willingness to take risk led to the rapid expansion and failure of many under-capitalized risk-bearing physician organizations. This experience illustrates that risk-bearing arrangements have broad implications for provider relationships (namely leading to the integration of providers through mergers and acquisitions); the financial solvency of provider organizations and therefore the stability of health care markets and patients' access to care; as well as leverage between providers and private payers.[19] For these reasons, risk-based arrangements require greater assurance of providers' financial solvency in order to repay Medicare for excess expenditures that may be incurred, as well as greater beneficiary protections, for example by heightened monitoring to detect inappropriate short-cutting of care and avoidance of at-risk beneficiaries. In addition, proper safeguards may be needed to address the risk of conduct violating fraud and abuse laws.

Incorporation of downside risk into the Shared Savings Program, while retaining a FFS base, has been encouraged by commenters on the November 17, 2010 RFI (including MedPAC), other stakeholders and policy experts as an entry point for moving ACOs to risk-based arrangements. MedPAC suggested offering a two-sided risk model in addition to the one-sided model, and over time, making the two-sided model the dominant or only option available to program participants. Further, to encourage ACOs to participate in the two-sided model, MedPAC recommended that it could be distinguished from the one-sided model by features such as a larger share of savings and risk corridors to protect ACOs from high levels of losses.[20]

A relevant example of a two-sided risk arrangement in a FFS setting is Blue Cross Blue Shield of Massachusetts' (BCBSMA) Alternative Quality Contract, an initiative that engages groups of providers for HMO or PPO beneficiaries. Under this contract, providers continue to be paid on a FFS basis. Each group's yearly expenditures are compared against a predetermined global budget, factoring in the level of risk the group has agreed to take on; the group is paid any surplus or repays BCBSMA for any deficit. Groups can earn bonuses based on quality performance targets, and achieved savings, and also earn significant quality bonuses.[21]

Given these considerations, we believe payment models where ACOs bear a degree of financial risk hold the potential to induce more meaningful systematic change in the behavior of groups of providers of services and suppliers compared to a one-sided model. We propose to develop an option for an ACO to either enter into a two-sided model within the Shared Savings Program initially or enter into the one-sided model within the Shared Savings Program initially and be transitioned to the two-sided model in year 3 of its initial 3-year agreement. We believe this proposal strikes a balance between stakeholders' requests for risk-based arrangements with the implications for beneficiary protections and market stability posed by capitated models and the operational complexity of creating

[18] *See e.g.,* Robert A. Berenson, "Shared Savings Program for Accountable Care Organizations: A Bridge to Nowhere?" The American Journal of Managed Care, Vol 16, No. 10 (October 2010).

[19] *See* Robert A. Berenson, Paul B. Ginsburg and Nicole Kemper, "Unchecked Provider Clout in California Foreshadows Challenges To Health Reform" Health Affairs, April 2010; James C. Robinson & Emma L. Dolan, "Accountable Care Organizations in California: Lessons for the National Debate on Delivery System Reform" Integrated Healthcare Association, White Paper (2010).

[20] Letter from Glenn M. Hackbarth, Chairman MedPAC, to Dr. Donald M. Berwick, Administrator, Centers for Medicare and Medicaid Services, November 22, 2010 (File Code CMS–1345–NC).

[21] Michael E. Chernew et al. "Private-Payer Innovation In Massachusetts: The 'Alternative Quality Contract'" Health Affairs (January 2011).

these arrangements in a FFS environment. As we develop experience with other risk-based models, for example through the Innovation Center, we expect to consider incorporating additional payment models into the Shared Savings Program through future rule making.

2. Two Tracks Provide Incremental Approach to Incorporating Risk

We considered several options about how to incorporate a two-sided model into the Shared Savings Program. The major options we considered are as follows:

- Basing the program on a two-sided model, thereby requiring all participants to accept risk from the first program year.
- Allowing applicants to choose between program tracks, either a one-sided model or two-sided model, for the duration of the agreement.
- Allowing a choice of tracks, but requiring ACOs electing the one-sided model to transition to the two-sided model during their initial agreement period.

Requiring all ACOs to initially take downside risk would likely inhibit the participation of some interested entities. Potential Shared Savings Program applicants will likely include providers and suppliers with different levels of experience with risk-based payment arrangements and with different levels of financial footing, reflecting the heterogeneity of providers and suppliers and provider arrangements that exist in the nation's health care system. The comments on the November 17, 2010 RFI reflect this diversity, but in sum, favored our adoption of a flexible approach that recognizes the different levels of ACOs' readiness to take on risk. For instance, organizations experienced with integrated care and risk-based arrangements, with available financial reserves, may be ready and willing to accept risk beginning in the first program year. Others urged against program requirements which could preclude small/solo practices and safety net providers, from entering the Shared Savings Program. These comments underscored the scenario in which ACOs, otherwise capable of meeting the program's requirements, may initially lack the experience and capital to accept significant downside risk.

However, allowing ACOs to choose from either a one-sided model or a two-sided model also creates some concerns. Some ACOs capable of taking risk may take advantage of the option that allows for gain by realizing savings without any risk for incurring added costs. We believe it important that all Shared Savings Program participants quickly move to taking on downside risk. We believe that payment models where ACOs bear a degree of financial risk have the potential to induce more meaningful systematic change in providers' and suppliers' behavior. Additionally, by introducing a risk model, we believe we will elicit applicants to the program who are more serious about their commitment to achieving the program's goals around accountability for the care of Medicare beneficiaries and the three-part aim of enhancing the quality of health care, improving patient satisfaction with their care, and better controlling the growth in health care costs.

We propose that applicants will have the option of choosing between a one-sided model and a two-sided model initially. Under Track 1, ACOs enter the program under the one-sided model and must transition to the two-sided model for the third year of their initial agreement period. Thereafter, those ACOs can only participate under the two-sided model for any subsequent agreement periods. Alternatively, under Track 2, an ACO may enter the two-sided model option immediately for a full 3-year agreement period. Those ACOs must also participate in the two-sided model thereafter in subsequent agreement periods. Thus an ACO may only participate for a maximum of two years under the one-sided model, during its first agreement period, before it must transition and participate thereafter in the Shared Savings Program under the two-sided model. We believe that this approach addresses the concerns we have identified. Incorporating both a one-sided and two-sided model into the Shared Savings Program provides a path forward for diverse organizations to gain experience with redesigning care processes and assuming accountability for the quality of care and financial outcomes of the populations they serve. Requiring those who enter the program on Track 1 to migrate to the two-sided model encourages organizations to take on greater risk with the opportunity for greater reward. We invite comments on this proposal and other options for incorporating a two-sided model into the Shared Savings Program, including mechanisms for transitioning ACOs to two-sided risk arrangements.

3. Elements of the Two-Sided Model

In developing the elements of a two-sided model under the Shared Savings Program, we propose to employ, as feasible and appropriate, the elements of the one-sided model that we have described in detail in the rest of this proposed rule. At the same time, it will be necessary to develop some policies for the two-sided model that would not be necessary under a one-sided model, for example, a methodology for determining shared losses. In addition, we believe that it is also appropriate to adapt some of the elements of the one-sided model to the somewhat different circumstances and incentives under which ACOs sharing two-sided risk would operate. Specifically, in light of the greater potential for a two-sided model to bring about positive changes in the operation of the FFS system by improving both the quality and efficiency of medical practice, we believe that it is both appropriate and essential to provide greater incentives for organizations that participate in the two-sided model. For example, as we describe below, we believe that it is appropriate to provide a higher shared savings rate for organizations participating in the Shared Savings Program under the two-sided model than for those organizations participating under the one-sided model.

In the discussion that follows, it can be assumed that the features of the one-sided model we have proposed in this rule would also apply under the two-sided model, unless we specifically state otherwise. In general, we are proposing the same eligibility requirements and methodologies for the two-sided model as we have proposed for the one-sided model. That is, we propose to use the same eligibility criteria, beneficiary assignment methodology, benchmark and update methodology, quality performance standards, data reporting requirements, data-sharing provisions, monitoring for avoidance of at-risk beneficiaries, and transparency requirements under the two-sided model that we have described under the one-sided model. However, as we discuss below, we are adding some requirements in order to provide further assurance about the ability of an ACO which will be operating under the two-sided model to repay the Medicare program in the case of incurred losses.

The following table provides a summary comparison of the program's two models:

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Table 8: Shared Savings Program Overview

Design Element	One-Sided Model (performance years 1 & 2)	Two-Sided Model
Maximum Sharing Rate	52.5 percent	65 percent
Quality Scoring	Sharing rate up to 50 percent based on quality performance.	Sharing rate up to 60 percent based on quality performance
FQHC/RHC Participation Incentives	Up to 2.5 percentage points	Up to 5 percentage points
Minimum Savings Rate	Varies by population	Flat 2 percent regardless of size.
Minimum Loss Rate	None	Flat 2 percent regardless of size
Maximum Sharing Cap	Payment capped at 7.5 percent of ACO's benchmark	Payments capped at 10 percent of ACO's benchmark
Shared Savings	Savings shared once MSR is exceeded; unless exempted, share in savings net of a 2 percent threshold; up to 52.5 percent of net savings up to cap.	Savings shared once MSR is exceeded; up to 65 percent of gross savings up to cap.
Shared Losses	None	First dollar shared losses once the minimum loss rate is exceeded. Cap on the amount of losses to be shared phased in over three years starting at 5 percent in year 1; 7.5 percent in year 2; and 10 percent in year 3. Losses in excess of the annual cap would not be shared. Actual amount of shared losses would be based on final sharing rate that reflects ACO quality performance and any additional incentives for including FQHCs and/or RHCs using the following methodology (1 minus final sharing rate).

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a. Beneficiary Notification and Protections

Because we believe participants in risk models have an increased incentive to lower costs, we also recognize there may also be an increased incentive for ACOs to avoid at-risk beneficiaries. We believe that the monitoring procedures that we are proposing as discussed in section II.H. of this proposed rule, in combination with our proposed use of a retrospective beneficiary assignment methodology and proposed beneficiary notification requirements, are sufficient to guard against the prospects that two-sided model ACOs might try to avoid at-risk beneficiaries in order to minimize the possibilities of realizing losses against their benchmarks. However, we invite comments on the sufficiency of these proposed monitoring procedures as well as additional areas and mechanisms for monitoring two-sided model ACOs.

b. Eligibility Requirements

We believe the eligibility requirements for ACOs we are proposing for the one-sided model, as discussed in section II.B. of this proposed rule, in combination with the proposed requirement that ACOs entering the two-sided model receive our approval of their repayment

mechanisms, are sufficient to ensure the ability of ACOs to pay CMS in the event they incur losses. We invite comments on whether additional eligibility requirements are necessary for ensuring that ACOs entering the two-sided model would be capable of repaying us if actual expenditures exceed their benchmark.

c. Quality Performance Measurement and Scoring

We believe that the comprehensive quality performance standards that we have proposed for the one-sided model are also appropriate for the two-sided model. However, it is worth emphasizing in this context that we place great importance on the quality aspects of the Shared Savings Program, and that the quality standards take on even greater importance for ensuring high quality of care for beneficiaries since we are proposing to incorporate a requirement that all ACOs participating in the Shared Savings Program accept risk either beginning in year 1 or year 3 of their initial agreement period. Therefore, in order to provide greater incentives for organizations to participate under the two-sided model, we are proposing higher shared savings rates under the two-sided model. Specifically, we are proposing a sharing rate of up to 60 percent (based on quality performance) under this model, compared to a sharing rate of up to 50 percent under the one-sided model, as discussed in section II.E. of this proposed rule. We propose that each of the 5 quality measure domains in Table 2 would continue to be equally weighted. Thus, each domain would be worth 12 percent of the savings generated by the ACO. That is, 5 domains $\times$ 12 percent equals 60 percent of the total savings generated by the ACO. Under this model, high performers in quality scoring would continue to earn more than lower quality performers. As discussed in section II.E. of the proposed rule, Table 3 illustrates our proposed sliding scale for determining points earned for each measure; we are proposing that under the two-sided model ACOs, like one-sided model ACOs, could earn a maximum of 2 points per measure.

As discussed in section II.E. of this proposed rule, the quality performance standard for the first year of the Shared Savings Program will be set at full and accurate reporting. For the purposes of determining the shared savings rate for Track 2 ACOs, ACOs which meet this standard will obtain the maximum savings rate for quality performance (60 percent). As previously proposed, under Track 1, ACOs will be reconciled using the methodology under the one-sided model for the first and second year of the agreement. In the third year of the ACO's agreement under Track 1, the methodology used to reconcile ACOs under the first year of the two-sided model would apply for payment purposes. With respect to the quality performance standard, Track 1 ACOs in the third year of their agreement must meet the quality performance standard that applies in the third program year, as opposed to the first year standard of full and accurate reporting.

We considered a number of alternatives to incorporating features that mirror the quality performance standard proposed for the one-sided model into determining the shared savings and shared losses under the two-sided model. That is, as proposed, under the two-sided model ACOs could increase their share of savings or decrease their amount of losses with higher quality scores. Alternatives track to the options considered for establishing the quality performance standard discussed in section II.E. of this proposed rule. An alternative is to take a threshold approach to measuring quality performance for the purpose of determining the amount of shared savings or losses. A third option is to use a blend of these two options, by allowing ACOs to increase their share of savings with higher quality scores but use a threshold approach when calculating losses, so that higher quality does not reduce an ACO's share of any losses. We seek comment on these alternate approaches.

d. Shared Savings Methodology

As discussed in Section II.F. of this proposed rule, we are proposing that ACOs choosing to participate in the one-sided model could share savings if they exceed a minimum savings rate (MSR). For those ACOs whose savings exceed the MSR in the one-sided model, we are proposing a savings sharing rate of up to 50 percent of total savings, above a 2 percent savings threshold, with a payment cap of 7.5 percent of an ACO's benchmark. We are also proposing an additional increase of up to 2.5 percentage points for including FQHCs and/or RHCs as ACO participants, as discussed in section II.F of this proposed rule. Thus, under our proposal, an ACO participating in the one-sided model could realize a maximum shared savings rate of 52.5 percent.

For purposes of the two-sided model, we are proposing to adopt the same methodology for determining shared savings, with some changes and incentives outlined below. In comparison to the one-sided model, the ACOs participating in the two-sided model would: (1) Have increased incentive payments for the same quality performance and including FQHCs and/or RHCs as ACO participants; (2) would be subject to a fixed minimum savings rate and minimum loss rate of 2 percent and would share in gross savings once the MSR is exceeded; and (3) would be responsible for a portion of the excess expenditures above the benchmark based on their quality performance and inclusion of FQHCs and/or RHCs. ACOs with excess expenditures within the minimum loss rate would not be responsible for repaying Medicare. ACOs with expenditures exceeding the minimum loss rate would be responsible for paying excess expenditures calculated by multiplying the amount of excess above the benchmark by one minus the final sharing rate. The final sharing rate is defined as the quality performance sharing rate plus the percentage points for including FQHCs and/or RHCs as ACO participants. ACOs would be responsible for paying the percentage of excess expenditures up to the annual loss cap which is measured as a percentage of the benchmark: 5 percent, 7.5 percent and 10 percent respectively across the first 3 years for Track 2 ACOs; an ACO in Track 1 who has entered the third year of its initial agreement period would be liable for an amount not to exceed the percentage of the first year of the two-sided model, that is, it would not exceed 5 percent.

(1) Minimum Savings Rate

We believe that the MSR remains important under the two-sided model to guard against normal variation in costs, so that ACOs share savings or losses with the program only under those circumstances in which we can be confident that such savings or losses are the result of the ACO's behavior rather than normal variation. At the same time, we believe that it is more appropriate to employ a fixed minimum savings rate under this model. First, the greater predictability of a fixed minimum savings rate is more likely to attract organizations to participate under this model. Second, greater protection to the Medicare trust fund is afforded by ACOs accepting the risk of paying Medicare back for losses. Therefore, based on our experience with the Physician Group Practice demonstration and consistent with the lowest applicable MSR under the one-sided model, we are proposing to adopt a fixed 2 percent MSR for organizations operating under this model, in place of the variable

minimum savings rate for organizations operating under the one-sided model.

(2) Additional Shared Savings Payments

In the one-sided model described previously in this proposed rule, we propose to increase an ACO's share in savings for including FQHCs and/or RHCs as ACO participants. To further increase the ACO's reward for taking risk, we are proposing to double this amount, awarding a sliding scale increase of up to 5 percentage points for including FQHCs and/or RHCs as ACO participants in an ACO participating in the two-sided model, compared to 2.5 percentage points available under the one-sided model.

(3) Net Sharing Rate

As discussed in section II.F. of this proposed rule, we considered several options for the amount of savings an ACO could receive under the one-sided model. These options included requiring the ACO to exceed the MSR and then sharing either on a first dollar basis or sharing with the ACO savings in excess of a threshold amount. We proposed that for the first 2 years of the agreement for the one-sided model that ACOs which exceed the MSR would be eligible to share in savings net of a 2 percent threshold, calculated as 2 percent of their benchmark. We further proposed that small ACOs under the one-sided model which meet certain criteria (namely, physician-driven ACOs, rural ACOs, and ACOs caring for underserved populations) which generate savings that exceed the MSR will be eligible to share in savings on a first dollar basis.

We considered the same options on limiting the amount of savings an ACO could receive under the two-sided model. A number of factors favored allowing two-sided model ACOs to share on first dollar savings. For one, ACOs participating in the two-sided model are assuming the risk of losses due to normal year-to-year variations in Medicare beneficiaries' claims expenditures. Second, sharing first dollar savings with two-sided model ACOs would provide greater reward for ACOs that choose to participate in the program's two-sided model as compared to the one-sided model. Therefore, we propose that two-sided model ACOs which generate savings that exceed the MSR will be eligible to share in savings on a first dollar basis. Thus, under the two-sided model, the final sharing rate (quality performance sharing rate and any additional increases for including FQHCs and/or RHCs) would be applied to an ACO's total savings that exceed its benchmark.

(4) Calculating Sharing in Losses

In addition to a methodology for determining shared savings, the two-sided model requires a methodology for determining shared losses in those cases where an ACO realizes a loss as opposed to a savings against its benchmark in any performance year. As discussed previously, we considered several options for calculating the amount of shared losses, tracking the options considered for establishing the quality performance standard. While a methodology for determining shared losses is obviously not necessary under a one-sided model, we have mirrored the structure and features of the shared savings methodology as much as possible to the determination of loss sharing. Thus, for purposes of the loss-sharing methodology, we propose adopting a similar structure of minimum loss rate (the equivalent of minimum savings rate on the savings side), shared loss cap, and adjustments to the shared loss percentage based on the ACO's quality performance and inclusion of FQHCs and/or RHCs.

As noted previously, we are proposing a minimum loss rate for purposes of computing shared losses when an ACO's actual expenditures exceed its benchmark. As in the case of shared savings, we believe that losses must exceed some minimum percentage around the benchmark in order to provide sufficient confidence that the losses experienced during a given performance year are not simply the result of random variation. Further, we are also proposing a cap on the loss sharing rate under the two-sided model, as we discuss later in this proposed rule.

In addition, as in the determination of shared savings, we are proposing to adjust the loss sharing rate by considering several factors related to performance and behavior. These factors would include: (1) Performance on quality measures; and (2) any additional adjustment for including FQHCs and/or RHCs as ACO participants. However, in order to recognize these factors appropriately in the determination of the shared loss rate, these factors must operate as decreases in the ACO's shared loss rate, rather than as the increases that they represent in the determination of the shared savings rate.

For example, a two-sided model ACO that realizes savings against its benchmark may qualify for a final sharing rate of up to 65 percent if it is eligible for the maximum adjustments. In this case, the 65 percent final sharing rate is comprised of the savings rate of up to 60 percent for quality performance, plus 5 percentage points for including FQHCs and/or RHCs as ACO participants.

On the other hand, a two-sided model ACO that experiences actual expenditures in excess of its benchmark may qualify for a shared loss rate as low as 35 percent of total losses if it is eligible for the maximum adjustments to its shared loss rate. So, for example, if the ACO obtained maximum points for its quality performance, and also received the maximum adjustment for including FQHCs and/or RHCs as ACO participants, it would have a sharing rate of 65 percent for purposes of sharing in savings. But since there are losses, the quality performance and inclusion of FQHCs and/or RHCs should be taken into consideration when calculating losses owed to the program. Accordingly, under our proposed methodology we would multiply the total losses by 1 minus the 65 percent final sharing rate, or 35 percent, making the ACO responsible for only 35 percent of the amount of losses.

As discussed in section II.E. of this proposed rule, the quality performance standard for the first year of the Shared Savings Program will be set at full and accurate reporting. Therefore, for the purposes of determining the loss sharing rate, two-sided model ACOs which meet this standard will obtain the maximum savings rate for quality performance (60 percent), making them responsible for 40 percent of any losses under the methodology previously described, absent any increases in the sharing rate for FQHC/RHC participation.

(5) Maximum Shared Savings and Shared Loss Caps

We are proposing a maximum shared loss cap, so that the shared losses that an ACO might be required to return to the Medicare program under this model could not exceed a designated percentage of an ACO's benchmark in any performance year. However, in order to provide a greater incentive for organizations to participate in the Shared Savings Program under the two-sided model, we are proposing to phase in this shared loss cap over a 3-year period. Specifically, we are proposing a shared loss cap of 5 percent of the benchmark in the first year of the Shared Savings Program, 7.5 percent in the second year, and 10 percent in the third year.

ACOs electing the one-sided model that are transitioned to the two-sided model in the third year of their agreement would be subject to the 5 percent cap on losses since they would be considered to be in their first year under the two-sided model.

Additionally, as discussed previously, we are proposing a higher maximum shared savings cap under the two-sided model, so that shared savings payment under this model could not exceed 10 percent of an ACO's benchmark, compared to 7.5 percent under the one-sided model.

An example of estimating an ACO's maximum potential downside risk and estimating the ACO's yearly losses is as follows. If the ACO's annual average per capita benchmark for assigned beneficiaries is $8,000 the maximum amount of losses an ACO would be responsible for the first year is 5 percent of its benchmark, 7.5 percent the second year, and 10 percent the third year. Therefore, the ACO's maximum per capita liability could range from $400 to $800 per assigned beneficiary. Actual liability depends on the ACO's actual final sharing rate which incorporates its quality performance and any increases for inclusion of FQHCs and/or RHCs.

Continuing this example, if an ACO with a benchmark of $8,000 per capita has actual costs for its assigned beneficiaries of $8,800, it would have a per capita loss of $800. The following table presents how much of the loss the ACO would be responsible to pay back under the program based on its final sharing rate, as determined by its quality performance, and assuming no additional increases for FQHC/RHC participation.

Table 9: Examples of Loss Estimates in Dollars Per Beneficiary

Final Sharing Rate	Annual Per Capita Loss	First Year Cap (5% of benchmark)	Payment Due CMS
40%	$800 (1-0.4) = $480	$400	$400
50%	$800 (1-0.5) = $400	$400	$400
60%	$800 (1-0.6) = $320	$400	$320

(e) Ensuring ACO Repayment of Shared Losses

Ensuring that ACOs entering the two-sided model will be capable of repaying us for costs that exceed their benchmark is a critical program requirement. Financial protection requirements for other entities with which CMS does business provide examples of potential mechanisms for recouping payment. In order to enroll in and bill the Medicare program, some Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) suppliers are required to obtain a surety bond. Home Health Agencies (HHA) entering into the Medicare program must have available sufficient "initial reserve operating funds" at the time of application submission—and at all times during the enrollment process up to the expiration of the 3-month period following the conveyance of Medicare billing privileges. CMS, through an intermediary, determines the amount of the HHA's required initial reserve operating funds using reported cost and visit data from submitted cost reports for the first full year of operation from at least three HHAs that the intermediary serves that are comparable to the HHA.

As discussed in section II.F. of this proposed rule, we propose a flat 25 percent withholding rate will be applied annually to an ACO's earned performance payment. We propose that this withholding serve as a component of the repayment mechanism ACOs will need to establish to ensure their ability to repay Medicare for incurred losses. We propose that we would apply the withheld amount towards repayment of an ACO's losses. However, we recognize that the 25 percent withholding of shared savings may be inadequate to cover the total amount of shared losses, particularly if a Track 2 ACO experiences losses in its first year. In order to more fully ensure that the Medicare program is paid back in the event that an ACO incurs losses, we have considered a number of options, including the following:

- Recoup funds from the ACO and require the ACO to obtain reinsurance, place ACO funds in escrow, obtain surety bonds, or establish a line of credit as evidenced by a letter of credit that the Medicare program can draw upon.
- Recoup funds from an ACO via the ACO's participants. We would require the ACO to disclose on its application the percentage of shared losses that each ACO participant would be responsible for, and the ACO would provide copies of signed agreements with its ACO participants, establishing their liability. We would require ACO participants to agree to have their future Medicare payments reduced by the amount reflected in the agreement. We note that such arrangements, to the extent they involve remuneration between referral sources and those seeking referrals, may raise liability issues under the physician self-referral law and anti-kickback statute. CMS and the OIG have solicited comments on how best to approach this issue in the Medicare Program; Waiver Designs in Connection with the Medicare Shared Savings Program and the Innovation Center, also released today.
- Withhold an additional portion of any annual shared savings payments (on top of the proposed flat 25 percent withhold discussed in section II.F. of this proposed rule in order to guard against losses in subsequent years. This could be done in combination with other alternatives in order to guard against any losses incurred by ACOs that have not previously received shared savings sufficient to offset such losses.
- Permit ACOs to specify how they would repay us, for example through one or more of the previously noted recoupment options.

We further considered requiring an ACO to establish a self-executing method of repaying losses, using one or more of the aforementioned options, to demonstrate its ability to repay a prescribed portion of its possible losses. Another option we considered was to require ACOs to use only one of these repayment mechanisms. In that regard, we considered requiring ACOs to obtain a letter of credit in an amount not less than the maximum potential downside exposure for the ACO in any given performance year (for example 5 percent of the benchmark in the first performance year for an ACO entering Track 2, or for a Track 1 ACO entering its third performance year of its initial agreement period).

After considering these options, we propose to require that an ACO establish a self-executing method for repaying losses to the Medicare program by indicating that funds may be recouped from Medicare payments to the ACO's participants, obtaining reinsurance, placing funds in escrow, obtaining

surety bonds, establishing a line of credit as evidenced by a letter of credit that the Medicare program can draw upon, or establishing another repayment mechanism, such as those previously discussed. This proposal assures operational simplicity without establishing eligibility requirements that might discourage ACOs with limited risk-bearing experience from entering Track 2.

We considered several options for determining the adequacy of an ACO's recoupment mechanism. One option would be to require ACOs to demonstrate an ability to repay the maximum amount of possible losses, for example 5 percent of the benchmark in the first performance year for an ACO entering Track 2, or for a Track 1 ACO entering its third performance year of its initial agreement period. Such a requirement could be prohibitively burdensome given that ACOs may need to demonstrate their ability to repay a large amount of capital and potentially excessive given that ACOs' loss rates would be reduced to account for quality performance and inclusion of FQHCs and/or RHCs and ACOs have a limited probability of incurring the maximum possible losses. Another option, potentially equally as effective as the first but less onerous, would be to require ACOs to demonstrate their ability to repay losses, defined as a percentage of the benchmark but below the annual loss cap. Either option would require the ACO to estimate anticipated losses, and for CMS to confirm this amount against the ACO's benchmark (once available). Given the anticipated variation in ACO composition and regional variations in cost, there may be numerous ways of accurately estimating an ACO's maximum potential downside risk. We further recognize that an ACO's assigned number of beneficiaries may vary from year to year. Given the potential for fluctuation in the size of an ACO's assigned population, and the increase in the cap on shared losses in the second and third years under Track 2, the sufficiency of the ACO's repayment mechanism would need to be periodically reassessed to ensure its adequacy.

We propose that an ACO must demonstrate having established a repayment mechanism, using one or more of the recoupment methods proposed previously, sufficient to ensure repayment of losses equal to at least 1 percent of per capita expenditures for its assigned beneficiaries from the most recent year available. We further propose that we will determine the adequacy of an ACO's repayment mechanism prior to its entrance into a period of participation in the Shared Savings Program. We also propose that an ACO must demonstrate the adequacy of this repayment mechanism annually, prior to the start of each performance year in which it takes risk, to ensure that it is adequate to cover the anticipated number of assigned Medicare beneficiaries. An ACO must maintain this repayment mechanism, ensuring adequate capitalization of funds in the case of some recoupment methods (such as adequately funded escrow accounts or reinsurance coverage), for the duration of the performance year and up until the time when we would need to be reimbursed for the ACO's losses. We would ensure that an ACO maintains an adequate repayment mechanism through monitoring activities. We invite comments on this proposal and on the other options we have considered, as well as alternate suggestions for assuring risk-bearing ACOs have an appropriate amount of available funds to repay potential losses.

We further propose that an ACO would be required, as part of its application, to submit documentation of such a repayment mechanism for approval by us. This documentation would include details supporting the adequacy of the mechanism for repaying the ACO's maximum potential downside risk exposure. An ACO applying for Track 2 would be required to submit this documentation as part of its initial application. An ACO applying for Track 1 would also be required to submit this documentation as part of its Shared Savings Program application since Track 1 ACOs will be required to transition to the two-sided model in the third year. We believe it is important that ACOs electing Track 1 can demonstrate that they can fulfill the requirements for the full three year agreement period and that we do not create an incentive for ACOs to terminate their agreements prior to the start of the third year under Track 1. As a result, it is important to ensure that prior to entry into the Shared Savings Program, the ACO has an appropriate plan for how it will repay any losses incurred during the third year of its agreement when it is automatically transitioned to the two-sided model.

To the extent that an ACO's repayment mechanism does not enable us to fully recoup the losses for a given performance year, we propose to carry forward unpaid losses into subsequent performance years (to be recouped either against additional financial reserves, or by offsetting shared savings earned by the ACO). We invite comments on this proposal and on other options that we have considered, as well as alternate suggestions for assuring that any losses by ACOs participating in the two-sided model can be recouped, the processes for recouping losses from these ACOs and/or their ACO participants, and the appropriate amount of available funds a risk-bearing ACO should be required to have.

(f) Future Participation of Under-Performing Organizations

As discussed in section II.C. of this proposed rule, we propose that an ACO which experiences a net loss during its first 3-year agreement period may not reapply to participate in the Shared Savings Program because it has been unsuccessful in lowering the growth in Medicare expenditures and/or its activities contributed in increases in Medicare expenditure growth. We believe this proposal is a means for ensuring that under-performing organizations do not continue to increase Medicare expenditure growth. We seek comment on this proposal and whether denying continued participation in the Shared Savings Program for ACOs that under-perform would create disincentives for the formation of ACOs. We are specifically interested in whether this requirement will create disincentives for participation among smaller ACOs.

(g) Public Reporting

We believe that the public reporting requirements proposed under the one-sided model should also apply to the two-sided model. One such proposed requirement is for ACOs to report publicly on the shared savings received by ACOs. Given that the purpose of this proposed requirement is to enhance transparency of the program we further propose that ACOs under the two-sided model publicly report on their amount of losses, if any. We invite comments on this proposed public reporting requirement and whether, for the purpose of ensuring transparency, there is any additional information that would be important for two-sided model ACOs to publicly report.

(h) Impact on States

Finally, we emphasize that, under our proposal for a two-sided model under the Shared Savings Program, the Medicare program retains the insurance risk and responsibility for paying claims for the services furnished to Medicare beneficiaries, and that the agreement to share risk against the benchmark would be solely between the Medicare program and the ACO. We do not intend that any of our proposals concerning the Shared Savings Program would render States

responsible for bearing any costs resulting from the operation of this program. However, we note that each State has its own insurance and risk oversight programs and that some States may regulate risk bearing entities, such as the ACOs participating in the two-sided model under the Shared Savings Program. Accordingly, we seek comment on whether any of our proposals for the two-sided model in particular, or the Shared Savings Program in general, would trigger the application of any State insurance laws, the adequacy of those provisions that we have set forth, and the ways that we can work with ACOs and States to minimize the burden of any additional regulation.

4. Verification of Savings and Losses

We will notify an ACO in writing regarding whether the ACO qualifies for a shared savings payment, and if so, the amount of the payment due. Similarly, we will provide written notification to an ACO of the amount of shared losses, if any, that it must pay to the program. We propose that an ACO must make payment in full to CMS of any shared losses within 30 days of receipt of notification. Because we will calculate amounts due to, or owed by, the ACO on the basis of information submitted by the ACO, we propose that the ACO must certify the accuracy, completeness, and truthfulness of such information. We propose that, as a condition of receiving a shared savings payment, the ACO must submit to us a written request for the shared savings payment amount. The written request must certify the ACO's compliance with program requirements for the relevant performance period as well as the accuracy, completeness, and truthfulness of any information submitted to us by the ACO, or its ACO participants, or the ACO providers/suppliers, or another entity, including the accuracy, completeness, and truthfulness of TINs used to assign patients, any quality data or other information or data relied upon by us in determining the ACO's eligibility for, and the amount of, the shared savings payment. In the case of an ACO participating in the two-sided model that has incurred shared losses, we propose to require submission of a similar certification at such time that would provide us with assurance of the ACO's compliance with program requirements for the relevant performance period and the accuracy, completeness, and truthfulness of any data or other information submitted by the ACO upon which we rely in calculating the amount of shared losses.

H. Monitoring and Termination of ACOs

Section 1899(d)(3) of the Act, as added by section 3022 of the Affordable Care Act, authorizes the Secretary to "impose an appropriate sanction" on an ACO, including "termination from the program," if the Secretary determines an ACO "has taken steps to avoid patients at risk in order to reduce the likelihood of increasing costs to the ACO." We discuss later in the document our proposal to monitor ACOs for avoidance of at-risk beneficiaries and to take appropriate corrective actions when ACOs are found to have engaged in this prohibited conduct, including termination where necessary.

Section 1899(d)(4) of the Act authorizes the Secretary to terminate an agreement with an ACO that does not meet the established quality performance standards. As discussed later in the document, we propose to monitor ACO performance with respect to our proposed quality standards. Subsequently, we discuss our proposal to terminate ACOs that fail to meet quality performance standards which are described in section II.E. of this proposed rule.

Section 1899 of the Act sets forth a number of requirements for ACOs, and authorizes the Secretary to promulgate additional criteria that ACOs must satisfy in order to be eligible to participate in the Shared Savings Program. The statute does not prescribe procedures for monitoring nor what factors we should consider in imposing sanctions against an ACO, including termination of its 3-year agreement for reasons beyond avoiding patients at risk and not meeting established quality standards. Based on our experience with other Medicare programs, as discussed this proposed rule, we believe it is important for patient protection and to effectuate the Shared Savings Program that we monitor an ACO to determine if it meets additional Shared Savings Program requirements not set forth in section 1899 of the Act and take actions such as termination with ACOs that are not in compliance with additional Shared Savings Program requirements that are not set forth in section 1899 of the Act. We discuss our proposal to monitor ACO performance with respect to these requirements and to terminate or otherwise sanction ACOs that are not in compliance with the requirements of the Shared Savings Program.

In implementing other Medicare programs, including the MA and the Medicare Prescription Drug programs, we have gained extensive experience in monitoring organizational, provider, and supplier behavior with respect to compliance with Medicare program and program integrity requirements, quality measurement, and avoidance of particular types of beneficiaries. For purposes of the Shared Savings Program, we propose to employ many of the methods we have developed for purposes of the MA and Medicare prescription drug programs to monitor and assess ACOs and their participating providers and suppliers. In general, the methods we could use to monitor ACO performance may include, but are not limited to the following:

- Analysis of specific financial and quality data as well as aggregated annual and quarterly reports.
- Site visits.
- Assessment and following up investigation of beneficiary and provider complaints.
- Audits (including, for example, analysis of claims, chart review, beneficiary surveys, coding audits).

If based upon the monitoring activities described previously we conclude that an ACO's performance may subject the ACO to termination from the Shared Savings Program, we are proposing that CMS in its sole discretion, may take any or all of the following actions prior to termination of the ACO from the Shared Savings Program:

- Provide a warning notice to the ACO of the specific performance at issue.
- Request a corrective action plan (CAP) from the ACO.
- Place the ACO on a special monitoring plan.

We are seeking comment on additional actions that may be appropriate prior to termination.

A number of factors may trigger heightened oversight of ACOs by us, including conditions specified as the bases for terminating the agreement described in this proposed rule. Further, we anticipate close examination of ACOs that incur large losses to the Medicare program.

In order to ensure that we have the information necessary to conduct appropriate monitoring and oversight of ACOs, it will be necessary for ACOs, ACO participants, and ACO providers/suppliers, and other contracted entities performing services and functions on behalf of the ACO to retain records of their activities under the Shared Savings Program for a sufficient period of time to allow the government to conduct the appropriate audits, evaluations, and inspections of their activities. A "contracted entity performing services or functions on behalf of the ACO" would include any party that enters into

an arrangement with an ACO to provide services (including administrative, management, or clinical services) to the ACO or health care services to the beneficiaries assigned to the ACO. It also includes any party that enters into an arrangement with an entity is in an arrangement with the ACO down to the level of the ultimate provider of services.

We are proposing that an ACO, ACO participant, ACO providers/suppliers, and contracted entities performing services and functions on behalf of the ACO, will be required to maintain and give us, the Department of Health and Human Services (DHHS), the Comptroller General, the Federal Government or their designees, the right to inspect all books, contracts, records, documents, and other evidence (including data related to Medicare utilization and costs, quality performance measures, shared savings distributions, and other financial arrangements related to ACO activities) sufficient to enable the audit, evaluation, and inspection of the ACO's compliance with Shared Savings Program requirements and the ACO's right to any shared savings payment. We propose that such books, contracts, records, documents, and other evidence be maintained by the ACO for a period of 10 years from the end of the agreement period or from the date of completion of any audit, evaluation, or inspection, whichever is later, unless we determine there is a special need to retain a particular record or group of records for a longer period and notify the ACO organization at least 30 days before the normal disposition date. If there has been a termination, dispute, or allegation of fraud or similar fault by the ACO organization or its members, we propose that the retention may be extended to 6 years from the date of any resulting final resolution of the termination, dispute, fraud, or similar fault. We further propose that if we determine that there is a reasonable possibility of fraud or similar fault, we may inspect, evaluate, and audit the ACO organization at any time. If as a result of any inspection, evaluation, or audit, we determine that the amount of shared savings due to the ACO or the amount of shared losses owed by the ACO has been determined in error, we reserve the right to reopen the initial determination and issue a revised initial determination.

We further propose that ACOs include terms in their agreements with ACO participants, ACO providers/suppliers, and the ACO and contracted entities performing services and functions on behalf of the ACO requiring them to comply with the same record retention requirements and to make such books, contracts, records, documents, and other evidence available to the government upon request. Notwithstanding any arrangements between or among an ACO, ACO participants, ACO providers/suppliers, and contracted entities performing services and functions on behalf of the ACO, the ACO shall have ultimate responsibility for adhering to and otherwise fully complying with all terms and conditions of its agreement with CMS, including the record retention requirement.

1. Monitoring Avoidance of At-Risk Beneficiaries

As noted previously, section 1899(d)(3) of the Act authorizes the Secretary to "impose an appropriate sanction" on an ACO, including "termination from the program," if the Secretary determines an ACO "has taken steps to avoid patients at risk in order to reduce the likelihood of increasing costs to the ACO." While the statute does not define what constitutes "patients at-risk", we believe such patients are those beneficiaries who have a high risk score on the CMS–HCC risk adjustment model, are considered high cost due to having two or more hospitalizations or emergency room visits each year, are dually eligible for Medicare and Medicaid, have a high utilization pattern, have one or more chronic conditions (such as, for example, diabetes, heart failure, coronary artery disease, chronic obstructive pulmonary disease, depression, dementia, end stage renal disease) or beneficiaries who have a recent diagnosis (for example, newly diagnosed cancer) that is expected to result in an increased cost.

Such beneficiaries might be appropriately targeted by an ACO to implement care improvement strategies to coordinate their care more efficiently. However, high-cost beneficiaries are also potentially at-risk for inappropriate avoidance by an ACO because the ACO may believe that it will be more likely to realize shared savings against its benchmark costs if it can avoid having higher-cost patients assigned to it during a performance year. We seek comment on this definition of "at-risk beneficiary" and whether other beneficiary characteristics should be considered in determining whether a beneficiary is "at-risk."

To identify ACOs that could be avoiding at-risk beneficiaries, we propose to use a combination of methods that would begin with an analysis of claims and examination of other beneficiary-level documentation (for example, beneficiary satisfaction surveys, medical record audits, beneficiary and provider complaints) to identify trends and patterns suggestive of avoidance of at-risk beneficiaries. The results of these analyses could lead to further investigation and follow-up with the beneficiary or the ACO (including ACO participants and ACO providers/suppliers) in order to determine whether avoidance of at-risk beneficiaries has occurred. If as a result of our analysis we conclude that an ACO has been avoiding at-risk beneficiaries during a performance year, we propose to notify the ACO of our determination and to require the ACO to submit a corrective action plan (CAP) for our approval. The CAP must address actions the ACO will take to ensure that the ACO, ACO participants, and ACO providers/suppliers cease avoidance of at-risk beneficiaries and must be implemented as approved. In addition, we propose that the ACO will be re-evaluated both during and at the end of the CAP. If we determine that the ACO has continued to avoid at-risk beneficiaries, the ACO would be terminated from the Shared Savings Program. We also propose that the ACO would not receive shared savings payments while it is under the CAP regardless of the period of performance in question and that the ACO would not be eligible to earn any shared savings for the period during which it is under the CAP for avoiding at-risk beneficiaries.

We solicit comments on whether lesser sanctions may be appropriate when an ACO avoids at-risk beneficiaries, such as the cessation of, or a reduction in, the assignment of new beneficiaries to the ACO, a reduction in the amount of the shared savings payment, or a fine for each instance of at-risk beneficiary avoidance.

2. Monitoring Compliance With Quality Performance Standards

Section 1899(d)(4) of the Act further authorizes the Secretary to terminate an agreement with an ACO that does not meet the established quality performance standards. To identify ACOs that are not meeting the quality performance standards, we will review the ACO's submission of quality measurement data. We may request additional documentation from an ACO or its ACO participants or ACO providers/supplier, as appropriate. In those instances where an ACO fails to meet the minimum attainment level for one or more domains, we propose to give the ACO a warning and to re-evaluate the following year. If the ACO continues to underperform on the quality performance standards in the

following year, the agreement will be terminated. We also propose that if an ACO fails to report one or more measures, we would send the ACO a written request to submit the required data by a specified date and to provide a reasonable written explanation for its delay in reporting the required information. If the ACO fails to report by the requested deadline and does not provide a reasonable explanation for delayed reporting, we would immediately terminate the ACO for failing to report quality measures. We further propose that ACOs that exhibit a pattern of inaccurate or incomplete reporting or fail to make timely corrections following notice to resubmit may be terminated from the program. We note that since meeting the quality standard is a condition for sharing in savings, the ACO would be disqualified from sharing in savings in each year in which it underperforms.

3. Terminating an ACO Agreement

There are a number of important program requirements that ACOs must satisfy in order to be eligible to participate in the Shared Savings Program. As a result, in addition to the statutory provisions at section 1899(d)(3) and (d)(4) of the Act regarding termination for avoidance of at-risk beneficiaries and for failure to meet the quality standards, we believe the agreement with an ACO should be contingent upon that ACO continuing to meet the requirements for eligibility to participate in the Shared Savings Program. Accordingly, we propose that an ACO's failure to continue to meet the eligibility requirements for participation in the Shared Savings Program should also result in an ACO's termination from the Shared Savings Program. As described in section II.F. of this proposed rule, termination of an ACO from the Shared Savings Program by us or at the ACOs request for any reason will result in loss of the mandatory 25 percent withhold of shared savings.

Therefore, we are proposing that based upon monitoring and assessing ACO operations (including ACO participants and ACO providers/suppliers), we may terminate an agreement with an ACO before the end of the 3-year agreement period for any of the following reasons:

- Avoidance of at-risk beneficiaries as described previously.
- Failure to meet the Shared Savings Program's quality performance standard as described previously.
- Any material change impacting ability to meet eligibility requirements, including but not limited to the following:

++ Changes in ACO participants that are the basis for beneficiary assignment.

++ Increase in ACO provider/supplier composition that results in a reviewing Antitrust Agency to state it is likely to challenge or recommend challenging the ACO.

++ Changes in the ACO's leadership and management structure that result in an inability to perform the functions discussed in section II.B. of this proposed rule.

++ Sanctions or other actions taken against the ACO, its ACO participants, and ACO providers/suppliers, or contracted entities performing services or functions on behalf of the ACO, by an accrediting organization, or by a State, Federal or local government agency.

- Failure of the ACO to effectuate required regulatory changes during the agreement period after given the opportunity for a CAP.
- Failure of an ACO to demonstrate that it has adequate resources in place to repay losses and to maintain those resources for the agreement period.
- Noncompliance with requirements regarding beneficiary notification of provider/supplier participation in an ACO.
- Failure to completely and accurately report or failure to make timely corrections.
- Material noncompliance, or a pattern of noncompliance, with public reporting and other CMS reporting requirements.
- Limiting or restricting internally compiled beneficiary summary of care or medical records from providers and suppliers both within and outside of the ACO, to the extent permitted by law (for example, not sharing beneficiary medical records with providers or suppliers not participating in the ACO from whom the beneficiary chooses to receive care).
- Failure to offer beneficiaries the option to opt out of sharing claims information.
- Improper use or disclosure of claims information received from us in violation of the HIPAA Privacy Rule, Medicare Part D Data Rule, Privacy Act, the data use agreement, or other applicable laws or regulations.
- Violation of physician self-referral prohibition, civil monetary penalty laws, anti-kickback statute, other antifraud laws, antitrust laws, or other applicable Medicare laws, rules, or regulations that are relevant to ACO operations.
- Submission to us of false, inaccurate, or incomplete data and or information, including but not limited to, information provided in the Shared Savings Program application, quality data, financial data, and information regarding the distribution of shared savings.
- Failure to submit payment due to us in a timely manner.
- Use of marketing materials or activities or other beneficiary communications subject to approval that have not been approved by us as discussed in section II.B.11.of this proposed rule.

Furthermore, we believe it is appropriate that an ACO should provide notice if it elects to terminate its participation in the Shared Savings Program. Accordingly, we are proposing to require an ACO to provide us with a 60-day notice if it chooses to terminate its agreement. The ACO would be required to notify us of its decision to terminate its participation in the Shared Savings Program and would also be required to notify all of its ACO participants and ACO providers/suppliers, who would in turn be required to notify beneficiaries in a timely manner of the ACO's decision to withdraw from the Shared Savings Program. As described in section II.F.of this proposed rule, the ACO would forfeit its mandatory 25 percent withhold of shared savings.

Finally, we propose that an ACO that has been terminated from the Shared Savings Program may apply to participate in the Shared Savings Program again at the end of the original 3-year agreement period. To be eligible to participate in the Shared Savings Program, the ACO must demonstrate in its application that it has corrected the deficiencies that caused it to be terminated from the Shared Savings Program and has processes in place to ensure that it will remain in compliance with the terms of the new participation agreement. We have proposed in section II.G. of this proposed rule, that ACOs may only have one agreement period involving the one-sided model, thus ACOs with corrected deficiencies that wish to reenter the program only have the option to do so under the two-sided model.

For violations that we consider minor in nature and pose no immediate risk or harm to beneficiaries or impact on care, we propose to allow ACOs the opportunity to submit a corrective action plan (CAP) before termination. We further propose that the ACO must submit a CAP for our approval by the deadline indicated on the notice of violation. The CAP must address what actions the ACO will take to ensure that the ACO, ACO participants, ACO providers/suppliers, and entities performing services or functions on

behalf of the ACO will correct any deficiencies to remain in compliance with Shared Savings Program requirements. The CAP must be implemented as approved. The ACO's performance will be monitored during the CAP process. Failure of the ACO to submit, obtain approval for, or implement a CAP may result in termination of the agreement. Failure of the ACO to demonstrate improved performance upon completion of the CAP may result in termination. We seek comments on our proposal, including any additional conditions that could merit the termination of an ACO agreement.

4. Reconsideration Review Process

Section 1899(g) of the Act, as added by section 3022 of the Affordable Care Act, states that there shall be no administrative or judicial review of the following actions:

- Specification of criteria for meeting quality performance standards under section 1899(a)(1)(B) of the Act.
- Assessment of quality of care furnished by an ACO and the establishment of quality performance standards under section 1899(b)(3) of the Act.
- Assignment of Medicare FFS beneficiaries to an ACO under section 1899(c) of the Act.
- Determination of whether an ACO is eligible for shared savings under section 1899(d)(2) of the Act), the amount of shared savings, including the determination of the estimated average per capita Medicare expenditures under the ACO for Medicare FFS beneficiaries assigned to the ACO and the average benchmark for the ACO under section 1899(d)(1)(B) of the Act.
- Percent of shared savings specified by the Secretary under section 1899(d)(2) of the Act and any limit on the total amount of shared savings.
- Termination of an ACO under section 1899(d)(4) of the Act for failure to meet quality performance standards.

The statute is otherwise silent regarding an ACO's right to contest decisions on such matters as eligibility to participate in the Shared Savings Program or termination for avoidance of at-risk beneficiaries. Accordingly, we believe it is important to establish a fair administrative process by which ACOs may request review of decisions, such as the denial of an ACO application or the termination of an existing ACO agreement for reasons other than those exempted by statute. An administrative reconsideration process provides an opportunity to resolve disputes quickly and efficiently, and creates an administrative record that can serve as the basis for any further review of the agency's decision.

Based on our experiences with the Medicare durable medical equipment prosthetics orthotics and supplies (DMEPOS) competitive bidding program and the MA Part C and D programs, we are proposing to implement reconsideration review procedure similar to the review process used by those programs for initial determinations that are not precluded from administrative or judicial review by statute. These initial determinations would include the denial of an ACO application or the termination of an ACO participation agreement. Under this proposal, if we deny a Shared Savings Program application, the applicant would be able to request reconsideration of our determination from a CMS reconsideration official. This process would not apply to applicants who are rejected on the grounds that their certified application was not submitted by the required deadline, because in this situation no valid application would have been submitted. In the case where an ACO has entered a 3-year agreement and subsequently met criteria for termination, we will give the ACO notification of our initial determination to terminate the agreement. The ACO would be able to request an independent review from a CMS reconsideration official who will reconsider the initial determination.

We propose that if an ACO or ACO applicant wants to request a review by a CMS reconsideration official of an adverse initial determination, it must submit a written request by an authorized official for receipt by CMS within 15 days of the adverse initial determination. If the 15th day is a weekend or a Federal holiday, then the timeframe is extended until the end of the next business day. Failure to submit a request for a reconsideration review within 15 days will result in denial of the request for a review.

Reconsideration reviews are scheduled at the discretion of the review official and may be held orally (that is, in person, by telephone or other electronic means) or on the record (review submitted documentation). The ACO or ACO applicant will receive acknowledgement of the reconsideration request that will outline the review procedures. The burden of proof would be on the ACO or ACO applicant to demonstrate to the reconsideration official with convincing evidence that the termination or application denial is not consistent with CMS' regulations or statutory authority. The ACO or ACO applicant may not use the reconsideration process to submit required documentation as evidence for the record that was not previously submitted to CMS by the applicable deadline. Furthermore, the reconsideration official will only consider evidence for the record that is submitted in the required format and in the timeframes indicated in the acknowledgement notification, unless additional information is requested by the official. Following the review, the reconsideration official will issue a recommended decision.

We further propose that if the ACO or ACO applicant disagrees with the recommendation of the reconsideration official, it will have an opportunity to request a record review of the initial determination and recommendation of the reconsideration official by an independent CMS official who was not involved in the initial determination or the reconsideration review process. An ACO or ACO applicant that wishes to request an on the record review of the reconsideration official's recommendation must submit an explanation of why it disagrees with the recommendation in the timeframe and in the format indicated in the recommendation letter. The CMS official may also review the recommendation of the reconsideration official on his or her own motion. The on the record review process will be based only on evidence presented for the reconsideration review. The CMS official will review the recommendation of the reconsideration official and the supporting materials and make a final agency determination.

If an ACO applicant requests a review of a decision to deny its application, and our initial determination is upheld, the application will be considered to have been denied based on the effective date of the original notice of denial. An ACO that requests a reconsideration review of an initial determination to terminate its participation in the Shared Savings Program will be permitted to continue to participate during the review process. However, if our initial determination to terminate the agreement with the ACO is upheld, the decision to terminate the agreement is effective as of the date indicated in the initial notice of termination.

An ACO whose Shared Savings Program application has been denied or whose Shared Savings Program agreement has been terminated due to a determination made by a reviewing antitrust agency may not contest the merits of the antitrust agency's determination through the reconsideration review process proposed in this rule. Furthermore, the

reconsideration review process proposed in this rule shall not be construed to negate, diminish, or otherwise alter the applicability of existing laws, rules, and regulations or determinations made by other government agencies.

We invite public comment, in general, on the structures and procedure of an appropriate review process for ACOs terminated for avoidance of at-risk beneficiaries or other reasons not exempted from review by statute.

I. Coordination With Other Agencies

As mentioned previously, in developing the Shared Savings Program, and in response to stakeholder concerns, we have worked very closely with agencies across the Federal Government to facilitate participation in the Shared Savings Program and to ensure a coordinated and aligned inter- and intra-agency effort in the implementation of the program. The result of this effort is the release of three documents with which potential participants are strongly encouraged to become familiar. These documents include: (1) A joint CMS and DHHS Office of Inspector General (OIG) Medicare Program; Waiver Designs in Connection with the Medicare Shared Savings Program and the Innovation Center addressing proposed waivers of the civil monetary penalties (CMP) law, Federal anti-kickback statute, and the physician self-referral law; (2) an Internal Revenue Service (IRS) notice soliciting comments regarding the need for additional tax guidance for tax-exempt organizations, including tax-exempt hospitals, participating in the Shared Savings Program; (3) a proposed Antitrust Policy Statement issued by the FTC and DOJ (collectively, the Antitrust Agencies). In addition, we are proposing to preserve the benefits of competition for Medicare beneficiaries by precluding newly formed ACOs with market power from participating in the Shared Savings Program.

1. Waivers of CMP, Anti-Kickback, and Physician Self-Referral Laws

Certain arrangements between and among ACOs, ACO participants, other owners, ACO providers/suppliers, and third parties may implicate the CMP law (section 1128A(b)(1) and (2) of the Act), the Federal anti-kickback statute (section 1128B(b)(1) and (2) of the Act), and/or the physician self-referral prohibition (section 1877 of the Act). Section 1899(f) of the Act authorizes the Secretary to waive certain fraud and abuse laws as necessary to carry out the provisions of the Shared Savings Program. Accordingly, pursuant to section 1899(f) of the Act, CMS and OIG have jointly published elsewhere in this **Federal Register** a Medicare Program, Waiver Designs in Connection with the Medicare Shared Savings Program and the Innovation Center, which describes and solicits public input regarding possible waivers of the application of certain CMP law provisions, the Federal anti-kickback statute, and the physician self-referral law to specified financial arrangements involving ACOs under the Shared Savings Program. In addition, section 1115A(d)(1) of the Act, as added by section 3021 of the Affordable Care Act, authorizes the Secretary to waive the same fraud and abuse laws, among others, as necessary solely for the purposes of carrying out the provisions of section 1115A of the Act with respect to the testing of certain innovative payment and service delivery models by the Innovation Center. The notice with comment period published elsewhere in this **Federal Register** also solicits public input regarding that separate waiver authority.

We expect that the waivers applicable to ACOs participating in the Shared Savings Program will be issued concurrently with our publication of the Shared Savings Program final rule. The requirements of the Shared Savings Program final rule will bear on the scope of any waivers granted for the Shared Savings Program. Because of the close nexus between the final regulations governing the structure and operation of ACOs under the Shared Savings Program and the development of waivers necessary to carry out the provisions of the Shared Savings Program, CMS and OIG may, when crafting waivers applicable to the Shared Savings Program, consider comments submitted in response to this Shared Savings Program proposed rule and the provisions of the Shared Savings Program final rule. Conversely, we may consider comments received in response to the joint notice with comment period when drafting the Shared Savings Program final rule. Members of the public submitting comment on this proposed regulation should consider commenting on the proposed waivers, as well.

2. IRS Guidance Relating to Tax-Exempt Organizations

Nonprofit hospitals and other health care organizations recognized by the IRS as tax-exempt organizations are likely to participate in the development and operation of ACOs in the Shared Savings Program. Accordingly, the IRS intends to solicit public comment on whether existing guidance relating to the Internal Revenue Code provisions governing tax exempt organizations is sufficient for those tax-exempt organizations planning to participate in the Shared Savings Program through ACOs, and if not, what additional guidance is needed. The IRS also intends to solicit comments concerning what guidance, if any, is necessary for tax-exempt organizations participating in ACOs that conduct activities unrelated to the Shared Savings Program.

We plan to continue to work with the IRS to ensure a coordinated and aligned interagency effort in the implementation of the program. Nothing in this proposed rule should be construed to modify, impair, or supersede the applicability of any of the Federal tax laws. For further guidance, tax-exempt organizations and ACOs should review the IRS notice and solicitation of public comment.

3. Antitrust Policy Statement

Concurrently with the issuance of this Shared Savings Program proposed rule, the Antitrust Agencies have issued a proposed Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations Participating in the Medicare Shared Savings Program (Antitrust Policy Statement). The Antitrust Policy Statement applies to collaborations among otherwise independent providers and provider groups formed after March 23, 2010 that have otherwise been approved to participate, or seek to participate, as ACOs in the Shared Savings Program.

The Antitrust Policy Statement sets forth an antitrust "Safety Zone" for certain ACOs. Specifically, the Antitrust Policy Statement provides that the Antitrust Agencies, absent extraordinary circumstances, will not challenge an ACO that otherwise meets the CMS criteria to participate in the Shared Savings Program if ACO participants that provide the same service (common service) have a combined share of 30 percent or less of each common service in each ACO participant's Primary Service Area (PSA), wherever two or more ACO participants provide that service to patients from that PSA. Also, under the Rural Exception set forth in the Antitrust Policy Statement, ACOs may qualify for the Safety Zone under certain circumstances even if their combined PSA share for common services would be greater than 30 percent. The Antitrust Policy Statement further provides that an ACO outside the Safety Zone may proceed without scrutiny by the Antitrust Agencies if its combined PSA share for each common service, wherever two or more ACO

participants provide that service to patients from that PSA, is less than or equal to 50 percent. An ACO in this category is also highly unlikely to present competitive concerns if it avoids certain specified conduct. The Antitrust Policy Statement explains, however, that for ACOs that do not meet the Rural Exception, a combined PSA share for common services of more than 50 percent provides a valuable indication of an ACO's potential for competitive harm.

The Antitrust Policy Statement outlines a methodology by which ACOs can calculate their shares of common services (that is, the same services provided by two or more ACO participants) provided to patients from the same PSA. The common services consist of physician specialties, major diagnostic categories ("MDCs") for inpatient settings, and outpatient categories for outpatient settings. We will make public the information necessary to designate common services and to calculate the pertinent PSA shares.

We plan to continue to work with the Antitrust Agencies to determine the extent to which additional action may be appropriate with regard to ACOs in the Shared Savings Program. Nothing in this proposed rule should be construed to modify, impair, or supersede the applicability of any of the Federal antitrust laws. For further guidance, ACOs should review the Antitrust Policy Statement.

4. Prohibition Against Shared Savings Program Participation by ACOs With Market Power

a. Coordinating the Shared Savings Program Application With the Antitrust Agencies

In light of the Antitrust Agency Policy Statement, we propose to require that, except for an ACO that qualifies for the rural exception articulated in the Policy Statement, an ACO with a PSA share above 50 percent for any common service that two or more ACO participants provide to patients from the same PSA must submit to us, as part of its Shared Savings Program application, a letter from the reviewing Antitrust Agency confirming that it has no present intent to challenge or recommend challenging, the proposed ACO. Absent such a letter, the proposed ACO will not be eligible to participate in the Shared Savings Program. In addition, the Antitrust Policy Statement explains that ACOs that are outside the Safety Zone and below the 50 percent mandatory review threshold frequently may be procompetitive. It highlights how ACOs in this category that do not impede the functioning of a competitive market and that engage in procompetitive activities will not raise competitive concerns and may proceed without Agency scrutiny. However, to provide additional antitrust guidance, the Antitrust Policy Statement identifies five types of conduct that an ACO can avoid to significantly reduce the likelihood of an antitrust investigation. An ACO in this category that desires further certainty regarding the application of the antitrust laws to its formation and planned operation also can seek an expedited review from the Antitrust Agencies, similar to the mandatory review described previously. Such an ACO will not be eligible to participate in the Shared Savings Program if the reviewing Antitrust Agency reviews the ACO and determines that it is likely to challenge or recommend challenging the ACO as anticompetitive. Finally, we propose that an ACO that falls within the Safety Zone would not be required to obtain an Antitrust Agency review as a condition of participation. As noted in the Antitrust Policy Statement, the Antitrust Agencies are committed to providing expedited reviews for ACOs that exceed the 50 percent threshold and for those ACOs that fall below the 50 percent threshold and seek greater antitrust certainty. The procedures for obtaining such review are set forth in the Antitrust Policy Statement.

ACO PSA Share	Review Process
≤ 30 percent (with a rural exception)	*Safety Zone* -- No antitrust review necessary by the Antitrust Agencies
>30 percent and ≤50 percent	*Expedited review, compliance with list of conduct restrictions, or proceed without antitrust assurances* – ACOs may: 1. Request an expedited review by the Antitrust Agencies and submit letter from the reviewing Antitrust Agency confirming that it has no present intent to challenge or recommend challenging the ACO, 2. Begin to operate and abide by a list of conduct restrictions, reducing significantly the likelihood of an antitrust investigation, or 3. Begin to operate and remain subject to antitrust investigation if it presents competitive concerns.
>50 percent	*Required expedited review* -- ACO must seek review by the Antitrust Agencies to assess likelihood of procompetitive and anticompetitive effects. ACO eligibility to participate in Shared Savings Program is contingent on the ACO's submission of a letter from the reviewing Antitrust Agency confirming that it has no present intent to challenge or recommend challenging the proposed ACO.

Additionally, we recognize there may be instances during the 3-year agreement period where there is a material change (as discussed in section II. C.) in the participant and/or provider/supplier composition of an ACO. When this occurs, we have proposed that the ACO must notify us of the change within 30 days and that the ACO must recalculate and report at that time their PSA shares for common services that two or more independent ACO participants provide to patients from the same PSA. We propose that if any revised PSA share is calculated to be greater than 50 percent, the ACO will be subject to mandatory review or re-review by the Antitrust Agencies in order to maintain the benefits of competition for Medicare beneficiaries and eligibility to participate in the Shared Savings Program. Finally, we propose that if the ACO fails to obtain a letter from the reviewing Antitrust Agency confirming that it has no present intent to challenge or recommend challenging the ACO, the ACO will be terminated from the Shared Savings Program.

The purpose of requiring Antitrust Agency confirmation that it has no present intent to challenge or recommend challenging the ACO as a condition of participation is two-fold. First, the proposal ensures that ACOs participating in the Shared Savings Program will not present competitive problems that could subject them to antitrust challenge that may prevent them from completing the term of their 3-year agreement with us. Section 1899(b)(2)(B) of the Act provides that ACOs shall enter into an agreement with the Secretary to participate in the program for not less than a 3-year period. We believe the requirement that ACOs be willing and able to commit to a 3-year agreement to participate in the Shared Savings Program is necessary to ensure that the program achieves its long-term goal of redesigning health care processes, and our proposal here furthers that intent.

Second, the proposal maintains competition for the benefit of Medicare beneficiaries by reducing the potential for the creation of ACOs with market power. As discussed in more detail later in the document, we believe that competition in the marketplace benefits Medicare and the Shared Savings Program because it promotes quality of care for Medicare beneficiaries and protects beneficiary access to a variety of providers. Furthermore, competition benefits the Shared Savings Program by allowing the opportunity for the formation of two or more ACOs in an area, which could accelerate advancements in quality and efficiency. All of these benefits to Medicare patients would be reduced or eliminated if we allow ACOs to participate in the Shared Savings Program when their participation would create market power.

b. Competition and Quality of Care

Because Medicare prices are regulated, ACOs participating in the Shared Savings Program will not compete on the basis of price. Nevertheless, economic theory and competition policy suggest that these ACOs will compete to serve Medicare beneficiaries on the basis of nonprice dimensions such as quality of care, innovations that improve care, and choice in treatment options. Empirical studies of the Medicare program confirm this theory and demonstrate that, where prices are fixed, competition among health care providers produces higher quality for consumers.[22] The most prominent study of markets with fixed prices examined the impact of market concentration on mortality for Medicare heart attack patients. The study found that mortality was significantly higher for patients in more concentrated markets.[23] A later study had similar findings in that high-risk Medicare patients' heart attack mortality was higher in highly concentrated markets, while there was no such effect for low-risk patients.[24] Overall, the evidence suggests that competition in the presence of regulated prices fosters improved quality.

The means by which competition fosters improvements in quality, innovation, and choice for Medicare patients can vary. For example, competition among ACOs can:

- Motivate innovation in the use of existing treatment and care protocols and the development of new protocols. ACOs with better quality would be expected to attract more patients, and ACOs with both better quality and lower costs would obtain a greater percentage of shared savings.
- Accelerate the development of evidence-based best practices. In some instances, physicians may differ on the best course of treatment in a given case. In the early stages of developing evidence-based best practices, there may be no way to know which practice or care protocols among several alternatives would be most effective. An ACO with market power may have less incentive to test alternative practices or care protocols.
- Raise the likelihood of preserving alternatives in the market, ultimately leading to the emergency of better procedures and treatments.
- Provide better benchmarks for quality improvements. For example, although a single ACO might claim that environmental or demographic factors limit what it can achieve in the treatment of certain illnesses, a comparison among multiple ACOs in the same service area could better ensure that the best standards possible under prevailing conditions are being met.

c. Competition, Price, and Access To Care

A concern with potential ACO market power in the commercial (as well as the Medicare) market is warranted, because recent commentary suggests that health care providers are more likely to create ACOs under the Shared Savings Program if they can use the same ACOs to serve both Medicare beneficiaries and patients covered by commercial insurance.[25] If we permitted the creation of ACOs with market power to operate in the Shared Savings Program, those ACOs would likely operate in the commercial market as well. In the commercial market, however, prices are not regulated, so newly created ACOs with market power could raise prices to private purchasers and payers of health care insurance above competitive levels.

Higher commercial prices create disparities in payment rates between commercial purchasers and payers compared to Medicare rates. As reported in a study by MedPAC staff, hospitals with high payments from private payers had high levels of overall profitability.[26] Similarly, ACOs may wish to increase the profitable private patients they serve and, as a result, reduce the number of

[22] *See* Daniel P. Kessler & Mark B. McClellan, *Is Hospital Competition Socially Wasteful*? 115 Quarterly Journal of Econ. 577 (2000); Daniel P. Kessler & Jeffrey J. Geppert, *The Effects of Competition on Variation in the Quality and Cost of Medical Care,* 14 Journal of Econ. and Mgmt. Strategy 575 (2005). See also Abigail Tay *Assessing Competition in Hospital Care Markets: The Importance of Accounting for Quality Differentiation* 34 RAND Journal of Econ. 786 (2003).

[23] Daniel P. Kessler & Mark B. McClellan, *Is Hospital Competition Socially Wasteful*? 115 Quarterly Journal of Econ., 577 (2000).

[24] Daniel P. Kessler & Jeffrey J. Geppert, *The Effects of Competition on Variation in the Quality and Cost of Medical Care* 14 Journal of Econ. and Mgmt. Strategy, 575 (2005).

[25] Federal Trade Commision & Department of Health and Human Services, Medicare Program; Workshop Regarding Accountable Care Organizations, and Implications Regarding Antitrust, Physician Self-Referral, Anti-kickback, and Civil Monetary Penalty (CMP) Laws, 75 FR 57039.

[26] *Report to Congress: Medicare Payment Policy,* 111th Cong. (2010), *available at http://www.medpac.gov/documents/Mar10_EntireReport.pdf.*

Medicare beneficiaries they serve. In this way, commercial price increases resulting from newly created ACOs with market power could limit access to care for Medicare beneficiaries. Our proposal to require ACOs that exceed the 50 percent threshold to undergo a mandatory antitrust review seeks to ensure that there are sufficient providers to allow the formation of competing ACOs to serve Medicare beneficiaries.

In summary, we believe that it is reasonable and appropriate to make approval of an ACO's Shared Savings Program application and continuation in the program contingent on the absence of a determination by the reviewing Antitrust Agency that it is likely to challenge or recommend challenging the ACO, or in the case of an ACO that exceeds the 50 percent threshold, on the ACO's submission of written confirmation from the reviewing Antitrust Agency that it has no present intent to challenge or recommend challenging the ACO.

We plan to continue to work with the Antitrust Agencies to determine the extent to which additional actions may be appropriate with regard to ACOs participating in the Shared Savings Program. We will also work closely with the Innovation Center (which is charged with considering whether the models it tests demonstrate effective linkage with other public and private sector payers) and will use the results from the ACO models it tests to inform possible future rulemaking that may be necessary in order to maintain ACO competition for the benefit of Medicare beneficiaries. Nothing in these regulations shall be construed to modify, impair, or supersede the applicability of the antitrust laws.

J. Overlap With Other CMS Shared Savings Initiatives

1. Duplication in Participation in Medicare Shared Savings Programs

The statute includes a provision that precludes duplication in participation in shared savings programs. Section 1899 of the Act states that providers of services or suppliers that participate in certain programs are not eligible to participate in the Shared Savings Program. Section 1899(b)(4)(A) and (B) of the statute, as added by section 3022 of the Affordable Care Act, states these exclusions are "(A) a model tested or expanded under section 1115A [the Innovation Center] that involves shared savings under this title or any other program or demonstration project that involves such shared savings; (B) the independence at home medical practice pilot program under section 1866E."

Other shared savings programs that include the opportunity for Medicare-enrolled TINs to earn payment, in the form of shared savings, for savings to Medicare for Part A and B services rendered to Medicare FFS beneficiaries would be considered duplicative. We have determined that the following existing shared savings programs overlap with the Shared Savings Program and therefore, a Medicare-enrolled TIN may not participate in both the Shared Savings Program and one of the following:

- Independence at Home Medical Practice Demonstration program, as established by section 3024 of the Affordable Care Act.
- Medicare Health Care Quality Demonstration Programs, as established by section 646 of the Medicare Modernization Act.
- Medical home demonstrations with a shared savings element: Currently, the only such Medicare demonstration that includes a shared savings component is the multi-payer advanced primary care demonstration
- Physician Group Practice Transition Demonstration.

Additional programs, demonstrations, or models with a shared savings component may be introduced in the Medicare program in the future. Interested parties should check the CMS Web site for an updated list to ensure that a provider or supplier participating in the Shared Savings Program does not participate in another Medicare program or demonstarion involving shared savings.

The prohibition against duplication in participation in shared savings programs applies only to programs that involve shared savings under Medicare, and the following are examples of such programs established by the Affordable Care Act which are unlikely to generate duplicative shared savings:

- State initiatives to provide health homes for Medicaid enrollees with chronic conditions as authorized under section 2703 of the Affordable Care Act.
- Program to establish community health teams to support patient-centered medical homes under section 3502 of the Affordable Care Act.

We believe a principal reason underlying the prohibition against participation in multiple shared savings programs is to prevent a provider or supplier from being rewarded twice for achieving savings in the cost of care provided to the same beneficiary. As discussed in section II.D. of this proposed rule, we propose that beneficiaries will be assigned to an ACO based upon the TIN of the ACO participant from which they receive the plurality of their primary care services. Therefore, to ensure that a provider or supplier is rewarded only once with shared savings for the care of a beneficiary, an ACO participant may not also participate in another Medicare program or demonstration involving shared savings. However, in order to maintain as much flexibility as possible for ACO providers/suppliers to participate concurrently in multiple CMS shared savings programs, we do not believe it is appropriate to extend this prohibition to individual providers and suppliers. We explore alternative provider incentives, payment arrangements and care delivery mechanisms through its shared savings programs, often specific to subsets of Medicare or Medicaid beneficiaries. To further our understanding of the delivery of cost effective and high quality care, and to ensure beneficiaries receive the most appropriate care possible relative to their needs, individual practitioners should have the opportunity to concurrently participate in multiple shared savings programs. Accordingly, an ACO provider/supplier who submits claims under multiple Medicare-enrolled TINs may participate in both the Shared Savings Program and another shared savings program if the patient population is unique to each program and if none of the relevant Medicare-enrolled TINs participate in both programs. For example, an ACO practitioner participating in the Shared Savings Program under an ACO participant practice TIN could also participate in the Independence at Home Demonstration under a different TIN that is not an ACO participant since there would be no duplication in beneficiary assignment; and therefore, no duplication in shared savings.

We propose a process for ensuring that savings associated with beneficiaries assigned to an ACO participating in the Shared Savings Program are not duplicated by savings earned in another Medicare program or demonstration involving shared savings. If such a program assigns beneficiaries based upon the TINs of health care providers from whom they receive care, we will compare the participating TINs in the program with those in the Shared Savings Program to ensure that TINs used for beneficiary assignment to an ACO participating in the Shared Savings Program are unique and that beneficiaries are assigned to only one shared savings program. If the other program or demonstration involving shared savings does not assign beneficiaries based upon the TINs of the health care providers from whom they

receive care, but uses an alternate beneficiary assignment methodology, we propose working with the developers of the respective demonstrations and initiatives to devise an appropriate method to ensure no duplication in shared savings payment. Applications for participation in the Shared Savings Program that include TINs that are already participating in another Medicare shared savings program will be rejected.

2. Transition of the Physician Group Practice (PGP) Demonstration Sites Into the Shared Savings Program

The PGP demonstration, authorized under section 1866A of the Act, was our first experience with a shared savings program in Medicare. The PGP demonstration serves as a model for many aspects of the Shared Savings Program. Section 1899(k) of the Act speaks directly to the treatment of the PGP demonstration. "During the period beginning on the date of the enactment of this section and ending on the date the program is established, the Secretary may enter into an agreement with an ACO under the demonstration under section 1866A of the Act, subject to rebasing and other modifications deemed appropriate by the Secretary." As the final performance year of the initial five year PGP demonstration concluded in March 2010, this section of the Affordable Care Act authorizes the Secretary to extend the PGP demonstration.

It is likely that the 10 physician groups in the PGP demonstration will be uniquely situated and qualified to be among the organizations which are ready to become early participants in the Shared Savings Program. As noted previously, consistent with section 1899(b)(4) of the Act, to be eligible to participate in the Shared Savings Program, a provider of services or supplier may not also be participating in a demonstration project that involves shared savings, such as the PGP demonstration. Thus, the PGP sites would be permitted to participate in either the PGP demonstration or the Shared Savings Program under section 1899 of the Act, but could not participate in both. Since assignment methodologies are similar between the Shared Savings Program and the PGP demonstration, we will provide for unique assignment of beneficiaries by ensuring there is no overlap in participating Medicare-enrolled TINs as mentioned previously.

We believe it is appropriate to consider what transition process should be available for those PGP demonstration sites that wish to participate in the Shared Savings Program. We do not believe that automatically transferring the PGP demonstration sites into the Shared Savings Program is appropriate because we are concerned that some of the PGP demonstration participants may be incapable of meeting the Shared Savings Program's requirements, thereby jeopardizing the participant's ability to achieve the overall goals associated with the Shared Savings Program, including the ability to achieve shared savings. On the other hand, requiring the PGP sites to undergo the same application process as all other entities would not account for our familiarity with these organizations, and their experience with redesigning care processes and improving quality in a shared savings setting. In addition, requiring the sites to undergo the full application process could potentially deter qualified sites that are currently participating in the PGP demonstration from transitioning from the PGP demonstration to the Shared Savings Program.

We propose that should a PGP site decide to apply for participation to the Shared Savings Program, we will give the site the opportunity to complete a condensed application form. The condensed application form would require the applicant to provide the information that is required for the standard Shared Savings Program application but that was not already obtained through its application for or via its participation in the PGP demonstration and, if necessary, to update any information contained in its application for the PGP demonstration that is also required on the standard Shared Savings Program application. For instance, the condensed application would ensure that the PGP site satisfies the eligibility requirements of the Shared Savings Program, as follows:

- Establishing a shared governance structure and leadership and management structure according to program requirements;
- Providing documentation around processes for quality management and patient engagement, and patient-centeredness criteria as described in section II.B of this proposed rule.

However, it should be noted that some PGP sites applying to the Shared Savings Program may not constitute a newly created ACO and therefore would be exempt from the antitrust review described previously in the Coordination With Other Agencies section of this preamble.

3. Overlap With the Center for Medicare & Medicaid Innovation (Innovation Center) Shared Savings Models

Section 1899(i) of the Act gives the Secretary the authority under the Shared Savings Program to use other payment models determined to be appropriate, including partial capitation and any additional payment model that the Secretary determines will improve the quality and efficiency of items and services furnished under Medicare. The purpose of the Innovation Center, established in section 1115A of the Act, as amended by section 3021 of the Affordable Care Act, is to test innovative payment and service delivery models to reduce expenditures under Medicare, Medicaid, and the CHIP, while preserving or enhancing the quality of care furnished to individuals under these programs. Preparations are currently underway to develop this capability. Within the Innovation Center, it may be possible to test different payment models, provide assistance to groups of providers and suppliers that wish to develop into an ACO, or enhance our understanding of different benchmarking methods. As the Innovation Center gains experience with different ACO payment models, we can use proven methods to enhance and improve the Shared Savings Program over time.

As mentioned previously, section 1899(b)(4) of the Act also restricts providers of services and suppliers from participating in both the Shared Savings Program and other shared savings programs and demonstrations. We intend to coordinate our efforts to ensure that there is no duplication of participation in shared savings programs through provider or supplier participation in both the Shared Savings Program and any shared savings models tested by the Innovation Center. Similarly, we will also take steps to ensure there is a methodology to avoid duplication of payments for beneficiaries aligned with providers and suppliers in both the Shared Savings Program and any current or future models tested by the Innovation Center.

Finally, the Innovation Center is seeking input on how it can best test different payment models that provide financial and technical assistance to groups of providers and suppliers that may wish to develop into an ACO.

III. Collection of Information Requirements

As stated in section 3022 of the Affordable Care Act, Chapter 35 of title 44, United States Code, shall not apply to the Shared Savings Program.

Consequently, the information collection requirements contained in this proposed rule need not be reviewed by the Office of Management and Budget.

IV. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

V. Regulatory Impact Analysis

A. 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 (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, the rule has been reviewed by the Office of Management and Budget.

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 does not include any mandate that would result in spending by State, local or tribal governments, in the aggregate, or by the private sector in the amount of $136 million in any one year. We acknowledge that there will be costs borne by the private sector, as discussed in this regulatory impact section, in order to participate in this program; however, participation is voluntary and is not mandated.

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, pre-empts State law, or otherwise has Federalism implications. We do not believe that there is anything in this proposed rule that either explicitly or implicitly pre-empts any State law, and furthermore we do not believe that this proposed rule will have a substantial direct effect on State or local governments, preempt States law, or otherwise have a Federalism implication.

B. Statement of Need

This proposed rule is necessary to implement section 3022 of the Affordable Care Act which amended Title XVIII of the Act (42 U.S.C. 1395 *et seq.*) by adding a new section 1899 of the Act to establish a Shared Savings Program that promotes accountability for a patient population, coordinates items and services under parts A and B, and encourages investment in infrastructure and redesigned care processes for high quality and efficient service delivery. Section 1889(a)(1) of the Act requires the Secretary to establish this program not later than January 1, 2012. Also, section 1889(a)(1)(A) of the Act states that under this program, "groups of providers of services and suppliers meeting criteria specified by the Secretary may work together to manage and coordinate care for Medicare fee-for-service beneficiaries through an accountable care organization (referred to as an 'ACO');" and section 1889(a)(1)(B) of the Act provides that "ACOs that meet quality performance standards established by the Secretary are eligible to receive payments for shared savings * * *."

The Shared Savings Program is a new approach to the delivery of health care aimed at reducing fragmentation, improving population health, and lowering overall health care costs.

The Shared Savings Program should provide an entry point for all willing organizations who wish to move in a direction of providing value-driven healthcare. Consequently, in accordance with the authority granted to the Secretary under sections 1899(d) and 1899(i) of the Act, we looked at creating both a shared savings model (one-sided) and a shared savings/losses model (two-sided). The sharing parameters under the two options are balanced so as to provide greater reward for organizations accepting risk while maintaining sufficient incentive to encourage providers to participate in the one-sided model, providing an entry point to risk-oriented models.

As detailed in Table 10, we estimate a total aggregate median impact of $510 million in net Federal savings for CYs 2012 through 2014 from the implementation of the Shared Savings Program. (An estimate produced by the Office of the Actuary on April 22, 2010 showed no net impact only because the statute by itself lacked enough detail to allow for scoring.) The 10th and 90th percentiles of the estimate distribution, for the same time period, show net savings of $960 million and $170 million. These estimated impacts represent the effect on Federal transfers. The estimated aggregate cost for start-up investment and first year operating expenditures for ACOs in the Shared Savings Program range from $131,643,825 to $263,287,650, assuming 75 to 150 ACOs participating in the Shared Savings Program. Furthermore, the Shared Savings Program would benefit beneficiaries since the program requires ACOs to be accountable for Medicare beneficiaries, improve the coordination of FFS items and services, encourage investment in infrastructure and redesigned care processes for high quality and efficient service delivery that demonstrate a dedication and focus toward patient-centered care. Accordingly, we have prepared a RIA that to the best of our ability presents the costs and benefits of this proposed rule. We solicit comment on the assumptions and analysis presented throughout this regulatory impact section.

Table 10: Estimated Net Federal Savings, Costs and Benefits, Years 1-3

Federal Savings	Year 1	Year 2	Year 3	Total (Years 1-3)
90th Percentile	$30 Million	$90 Million	$50 Million	$170 Million
Median	$100 Million	$210 Million	$200 Million	$510 Million
10th Percentile	$190 Million	$380 Million	$390 Million	$960 Million
Costs	Total ACO start-up investment and first year operating expenditures average from $131,643,825 to $263,287,650, for the estimated range of 75-150 participating ACOs.			
Benefits	Improved healthcare delivery and quality of care and better communication to beneficiaries through patient centered-care.			

As discussed in the preamble of this proposed rule, the Shared Savings Program establishes a program whereby groups of suppliers and providers can work together through ACOs that would assume responsibility for managing and coordinating the care of groups of traditional FFS Medicare patients. Participating ACOs will have the opportunity to earn shared savings payments by reducing Medicare expenditure growth for their assigned beneficiaries below specified target thresholds or benchmarks while simultaneously meeting quality performance measures. An ACO could initially opt for one of two program tracks. The first option (one-sided model) offers eligibility for shared savings payments in years 1 and 2 without the risk of being responsible for repaying any losses if actual expenditures exceed the benchmark, followed by a third year offering a higher percentage of shared savings but also risk for excess expenditures above the benchmark. The second option (two-sided model) provides an opportunity for receiving a higher percentage of shared savings for all 3 years, but with potential liability in each of the 3 years for annual expenditures that exceed the benchmark.

There is substantial uncertainty as to the number of ACOs that will participate in the program, their characteristics, provider and supplier response to the financial incentives offered by the program, and the ultimate effectiveness of the changes in care delivery that may result as ACOs work to improve the quality and efficiency of patient care. These program design and other uncertainties complicate efforts to assess the financial impacts of the Shared Savings Program and result in a wide range of potential outcomes regarding the net impact on Medicare expenditures.

To best reflect these uncertainties, we designed a stochastic model that incorporates assumed probability distributions for each of the key variables that will affect the overall financial impact of the Shared Savings Program. Using a Monte Carlo simulation approach, the model randomly draws a set of specific values for each variable, reflecting the expected covariance among variables, and calculates the program's financial impact based on the specific set of assumptions. We repeated the process for a total of 5,000 random trials, tabulating the resulting individual cost or savings estimates to produce a distribution of potential outcomes that reflects the assumed probability distributions of the incorporated variables, as shown in Table 10. In this way, we can evaluate the full range of potential outcomes based on all combinations of the many factors that will affect the financial impact, and with an indication of the likelihood of these outcomes. It is important to note that these indications do not represent formal statistical probabilities in the usual sense, since basis for the underlying assumptions for each of the factors in the model are based on reasonable judgments, using independent expert opinion when available.

The median result from the distribution of simulated outcomes represents the "best estimate" of the financial effect of the Shared Savings Program, recognizing the uncertainty inherent in a new program with uncertain responses. The full distribution illustrates the uncertainty surrounding the mean or median financial impact from the simulation.

As detailed in Table 11, the median estimate involves a combination of: (1) Reduced actual Medicare expenditures due to more efficient care; (2) shared savings payments to ACOs; and (3) payments to CMS for shared losses when actual expenditures exceed the benchmark, resulting in a projected total of $510 million in net savings over CYs 2012 through 2014. Approximately 97 percent of the stochastic trials resulted in a net savings to the Medicare program, while the other 3 percent produced a net cost. At the extremes, the greatest simulated savings was approximately $1,960 million, while the greatest simulated cost was $270 million.

A net savings (costs) occurs when the payment of earned and unearned shared-savings bonuses (less penalties collected) resulting from— (1) Reductions in spending; (2) program design; and (3) random group claim fluctuation, in total are less than (greater than) assumed savings from reductions in expenditures.

As we finalize the Shared Savings Program provisions, and as the actual number of participating ACOs and their characteristics become known, the range of financial outcomes will narrow. Similarly, as data become available on the initial differences between actual expenditures and the target expenditures reflected in ACO benchmarks, it will be possible to evaluate the financial effects with greater certainty. The estimate distribution shown provides an objective and reasonable indication of the likely range of financial outcomes, given the chosen variables and their assumed distributions at this time in the program's development.

C. Anticipated Effects

1. Effects on the Medicare Program

As a voluntary program involving an innovative and complex mix of financial incentives for quality of care and efficiency gains within FFS Medicare, the Shared Savings Program could result in a wide range of possible outcomes. While examples exist across the

healthcare marketplace for risk-sharing arrangements leading to efficiency gains, a one-sided model would presumably provide a weaker incentive to ACOs than other possible approaches. The optional two-sided risk model, and the requirement for all other ACOs to accept downside risk in their third program year, both provide stronger incentives than a shared savings only approach. For example, under the one-sided model, a provider's worst-case outcome is the failure to earn shared-savings. A provider would operate under the significant possibility that there would be no impact on their Medicare reimbursement. The two-sided risk model, however, presents liability for excessive expenditures, significantly increasing a provider's perceived likelihood that aggregate Medicare revenue will depend on the level of efficiency with which they operate. In addition, the two-sided model offers a lower minimum savings rate and a greater sharing percentage, both of which enhance the incentive for efficiency. However, participating ACOs may be more likely to choose the one-sided model for the first 2 years and thereby avoid the potential for financial loss if expenditures experience a significant upward fluctuation or if efficiency improvements are less effective than planned.

In the third year of their first agreement period, as noted previously, all ACOs that participate in the one-sided model during the first 2 years of the agreement period will be required to transition to the two-sided risk model. We believe certain participating ACOs may choose to terminate their agreement early after the first 2 years. For example, ACOs in Track 1 that failed to meet the expenditure growth targets in the first 2 years (but were protected from penalties by being in the one-sided model), would likely reconsider their continuing participation. Certain other ACOs, such as those in higher-cost areas of the country, could also terminate their agreement if they anticipate that the national growth formula, relative to their local baseline cost, puts them in jeopardy of experiencing losses in the third year. (Under section 2899(d) of the Act, we update ACO benchmarks by the estimated annual increase in the absolute amount of national average Medicare Part A and Part B expenditures, expressed as a flat dollar amount for each year. As a result, the updates to ACO benchmarks in percentage terms will be higher in low-cost areas of the country and lower in high-cost areas.) This scenario could contribute to selective program participation by ACOs favored by the national flat-dollar growth target.

While shared FFS savings, even with optional liability for a portion of excess expenditures, offers less incentive to reduce costs or improve efficiency than, say, full capitation, it still represents a new incentive for efficiency. Shared-savings (and potential liabilities) will have varying degrees of influence on hospitals, primary physicians, specialty physicians, and other providers. The expectation is for different ACOs to comprise a varying mix of these providers and suppliers. And while certain care improvements might be achieved relatively quickly (for example, prevention of hospital readmissions and emergency-room visits for certain populations with chronic conditions), many potential ACOs might need more than 3 years to achieve comprehensive efficiency gains. Challenges include identification of assigned beneficiaries, managing care furnished by providers and suppliers outside the ACO, lack of similar contracts with other payers, achieving buy-in from ACO providers and suppliers, and the extent to which possible future shared savings or losses will affect the perceived value of immediate FFS revenue for providers and suppliers participating in the ACO.

a. Assumptions and Uncertainties

We sought input from a wide range of external experts, including credentialed actuaries, consultants, and academic researchers, to identify the pertinent variables that could determine the efficacy of the program, and to identify the reasonable ranges for each variable. The assumptions identified and stochastically modeled include the following:

- Number of participating ACO provider groups.
- Size mix of participating ACOs.
- Type of ACO that would consider accepting risk under the two-sided risk option.
- Participating ACOs' current level of integration and preparedness for improving the quality and efficiency of care delivery.
- Baseline per-capita costs for prospective ACOs, relative to national average.
- Number and profile of providers and suppliers unavailable to participate in the Shared Savings Program due to participation in ACO models tested by the Innovation Center.
- Range of savings for participating ACOs within the first three years of the program.
- Local variation in expected claims cost growth relative to the national average.
- Quality reporting scores and resulting attained sharing (or loss) percentages.

Overall we assumed 1.5 to 4 million Medicare beneficiaries would align with a participating ACO during the first three years of the program. We assumed ACOs to be more likely to participate from markets exhibiting baseline per-capita FFS expenditures above the national average. In addition, we assumed the level of savings generated by an ACO to positively correlate to the achieved quality performance score and resulting sharing percentage.

Of particular relevance is the high degree of variability observed for local per-capita cost growth rates relative to the national average "flat dollar" growth (used to update ACO benchmarks). The benchmark or expenditure target effectively serves as the only measure of efficiency for participating ACOs. Factors such as lower-than-average baseline per-capita expenditure and variation in local growth rates relative to the national average can trigger Shared Savings Program shared savings payments even in the absence of any efficiency gains. Similarly, some ACOs could find that in the determination of shared savings by factors such as prevailing per-capita expenditure growth in their service area that is higher than the national average overshadows their hard-fought efficiency gains.

b. Detailed Stochastic Modeling Results

Table 11 shows the distribution of the estimated net financial impact for the 5,000 stochastically generated trials. (The amounts shown are in millions, with negative net impacts representing Medicare savings). The net impact is defined as the total cost of shared savings less—(1) any amount of savings generated by reductions in actual expenditures; and (2) any losses collected for ACOs that accepted risk and have actual expenditures exceeding their benchmark.

The median estimate of the Shared Savings Program financial impact for calendar years 2012 through 2014 is a net savings of $510 million. This amount represents the "best estimate" of the 3-year financial impact of the Shared Savings Program initiative. It is important to note, however, the relatively wide range of possible outcomes. Overall, 97 percent of the stochastic trials resulted in net program savings, and the other 3 percent represented cost increases. The 10th and 90th percentiles of the estimated

distribution show net savings of $960 million and $170 million, respectively, suggesting a 10 percent likelihood that the actual impact would fall outside respective percentile amounts. In the extreme scenarios, the results were as large as $2 billion in savings or $270 million in costs.

Our Office of the Actuary (OACT) prepared the stochastic model and resulting financial estimates. OACT believes that the median result of $510 million in savings is a reasonable "point estimate" of the impact of the Shared Savings Program provision in current law, as it would be implemented through this proposed rule. However, OACT emphasizes the possibility of outcomes that differ substantially from the median estimate, as illustrated by the estimate distribution. With the adoption of final program provisions and with additional data on the actual number and characteristics of participating ACOs, we can estimate the financial impact with greater precision.

The projections assume the assignment of roughly 1.5 to 4 million beneficiaries to participating ACOs over the first 3 years. To the extent that the Shared Savings Program will result in net savings or costs to Part B of Medicare, revenues from Part B beneficiary premiums would also be correspondingly lower or higher. In addition, because MA payment rates depend on the level of spending within traditional FFS Medicare, Shared Savings Program savings or costs would result in corresponding adjustments to MA payment rates. Neither of these secondary impacts has been included in the analysis shown.

Table 11—Stochastic Distribution for Estimated Total 3-Year Net Savings (–) or Costs (+)

(Dollar amounts in millions)

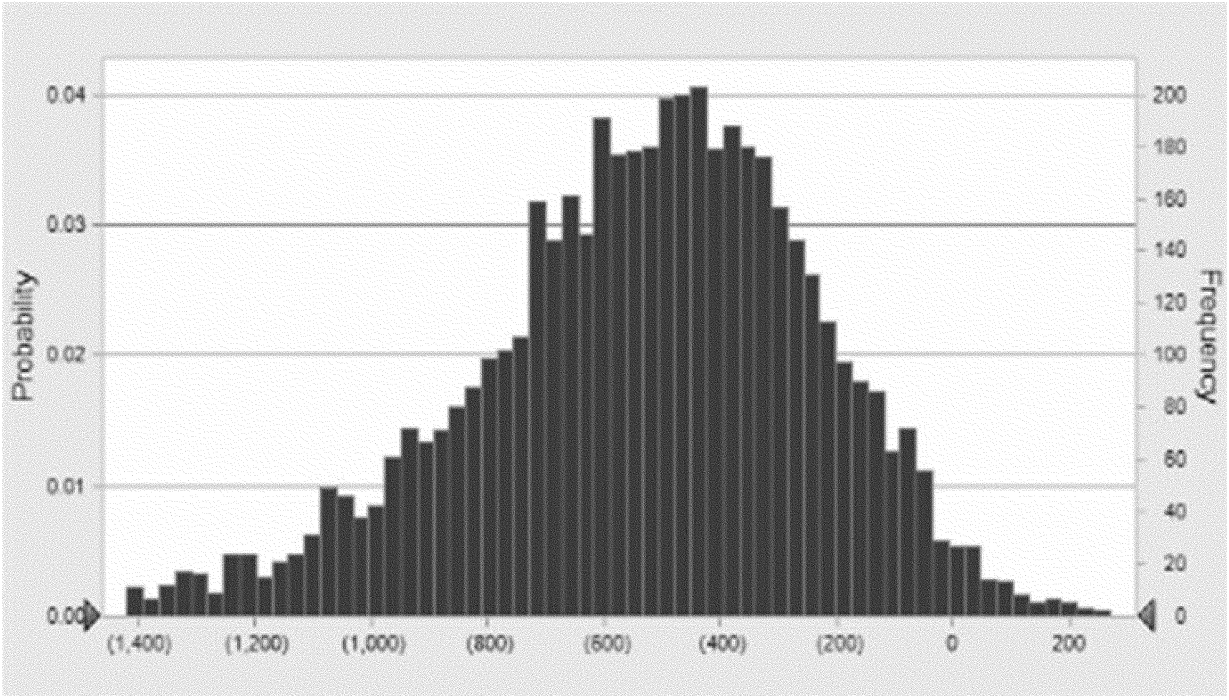
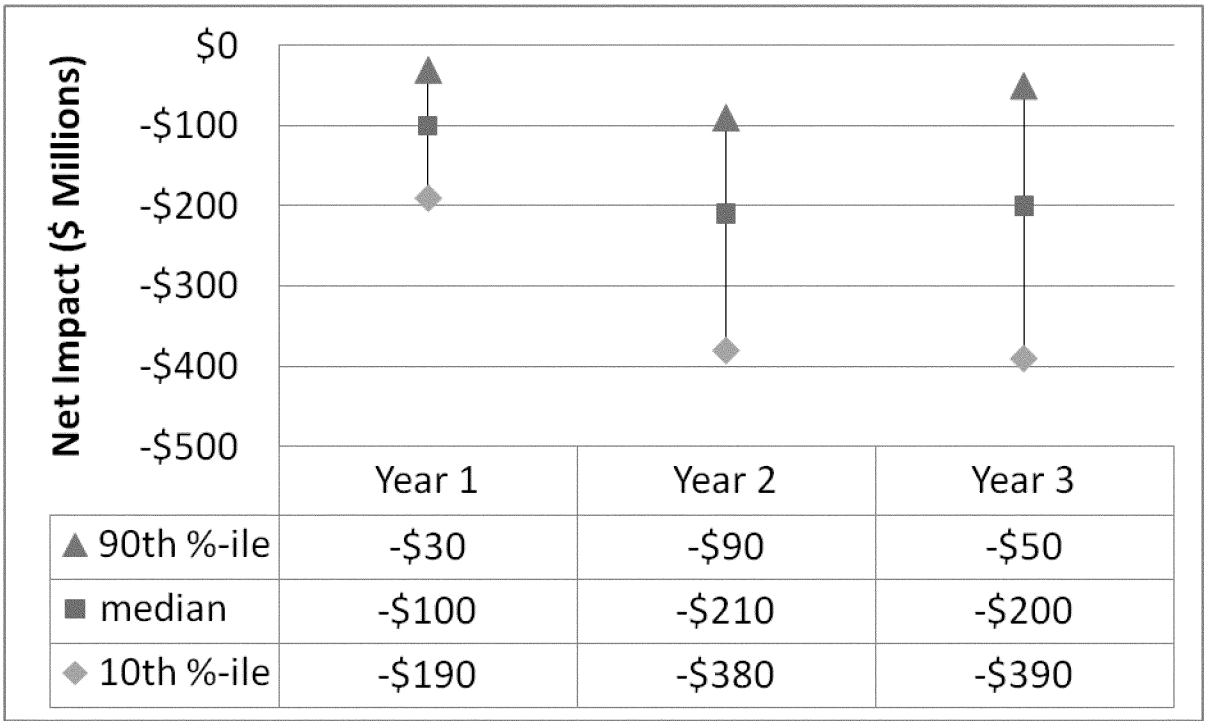


Table 12 shows the median estimated financial effects for the Shared Savings Program initiative, and the associated 10th and 90th percentile ranges, broken out for each of the first 3 years. For the first year, 2012, the median projection indicates a $100 million savings, primarily because the ACO cost-efficiency initiatives are generally not assumed to have matured, but a number of provider groups that benefit from favorable random claim fluctuations or from low baseline expenditure relative to the national average would receive shared saving payments. By the second and third years, 2013 and 2014, of the projection, the median estimates indicate net savings of $210 million and $200 million, respectively, from increased cost-saving effectiveness offset in part by shared savings paid due to random variation and the (increasing) variation in the accuracy of updated national targets compared to actual local growth as well as participation and sharing percentage changes resulting from mandatory transition to two-sided risk in the third year. As a result, the projections for years 2 and 3 cover a wider range of possible outcomes, reflecting a growing dependence on uncertain assumptions for savings and expenditure growth variation relative to the national average.

Table 12—Stochastic Distribution for Estimated Net Savings (–) or Costs (+), Years 1-3

(Dollar amounts in millions)



	Year 1	Year 2	Year 3
▲ 90th %-ile	-$30	-$90	-$50
■ median	-$100	-$210	-$200
◆ 10th %-ile	-$190	-$380	-$390

c. Further Consideration

The impact analysis shown is only for the first 3-year agreement period. Beyond this initial period, there is additional uncertainty, in significant part because the rules governing subsequent Shared Savings Program agreement periods have not yet been developed. A risk exists that by ACOs in low-cost areas could dominate the Shared Savings Program, where participation could be a relatively risk-free opportunity to achieve shared savings simply due to the generous benchmark presented by national average "flat-dollar" growth. On the other hand, the first 3-year agreement period ACOs could foster significant improvements in the quality and cost-efficiency of health care delivery, leading to broader use of these techniques nationwide and accelerated adoption of risk-sharing arrangements (such as partial capitation, bundled payments, etc.). These changes could result in significant efficiency gains in FFS Medicare. The stochastic model for the first 3 years of the program, does not incorporate either of these longer-run scenarios, but both remain possibilities—subject to the final program design and implementation. At this time, an impact estimate expanded to include performance beyond the initial 3-year period would likely entail a significantly wider range of possible outcomes. The results of the first performance cycle, however, will help inform estimates of the ongoing financial effects of the Shared Savings Program.

2. Impact on Beneficiaries

We anticipate the Shared Savings Program will benefit beneficiaries because the intent of the program is to require ACOs to be accountable for Medicare beneficiaries, improve the coordination of FFS items and services, encourage investment in infrastructure and redesigned care processes for high quality and efficient service delivery that demonstrates a dedication and focus toward patient-centered care. Patient-centered care is a concept that focuses healthcare delivery and communication on the patient and those who are close to the patient and bases the care and communication delivered around the needs of the beneficiary, thus benefitting the beneficiary community. This program does not affect the beneficiary's freedom of choice regarding providers or care. Also, a requirement of ACO participation in the Shared Savings Program is reporting of, and successful performance related to, quality measures and patient-experience surveys. These aspects of the Shared Savings Program will encourage the provider and supplier community to focus on and deliver improved quality care. In addition to existing Medicare monitoring programs that are in place to protect beneficiaries, the Shared Savings Program will include monitoring and auditing processes to protect beneficiary choice as well as ensure that beneficiaries are receiving the appropriate care. As is discussed in more detail in the preamble, these processes include monitoring ACO avoidance of at-risk beneficiaries, assessing and providing follow up on beneficiary complaints, audits (including, for example, analysis of claims, chart review, beneficiary surveys, coding audits) and analysis of quality performance.

More specifically, we believe that beneficiary impacts would be maximized as the ACO meets the mission of the Shared Savings Program, as established by the Affordable Care Act and embraces the following goals of better health and experience of care for individuals, better health for populations and lower expenditure growth. The ACO's impact will be demonstrated by how effectively it delivers care as measured under the financial methodology outlined in

section II. F, Shared Savings Determination, of this proposed rule, how well it improves and delivers high quality care outlined in the quality measurement and reporting methodology in section II.E. of this proposed rule, and in meeting program requirements for patient centered care outlined in the eligibility section II.B. of this proposed rule.

Therefore, because of the accountability of ACOs for both the quality and overall cost of care provided to their assigned beneficiary population and must meet the quality performance standards prior to sharing any savings; they have new incentives to improve the health and well being of the beneficiaries they treat. ACOs will report on conditions and areas that are high prevalence and high cost in the Medicare population, such as chronic disease, ambulatory care sensitive conditions, care transitions and readmissions, and patient experience. We have observed that measuring quality and providing incentives can result in redesigned care processes that provide clinicians with actionable information on their patients at the point of care which can lead to improved patient care processes and outcomes. For example, the Medicare Physician Group Practice Demonstration Fact Sheet (CMS, August 2009) showed that over the first three years of the PGP Demonstration, physician groups increased their quality scores an average of 10 percentage points on the 10 diabetes measures, 11 percentage points on the ten congestive heart failure measures, 6 percentage points on the coronary artery disease measures, 10 percentage points on the cancer screening measures, and 1 percentage point on the hypertension measures. Further analysis is provided in the Physician Group Practice Demonstration Evaluation Report (Report to Congress, 2009; *http://www.cms.gov/DemoProjectsEvalRpts/downloads/PGP_RTC_Sept.pdf*).

In addition to the overall increases in quality scores, we can examine the impact of the PGP Demonstration on quality can be examined by comparing the values of the seven claimsbased quality measures for each PGP site and its comparison group. Our analysis found that, on the claims-based measures, PGP performance exceeded that of the comparison groups (CGs) on all measures between the base year (BY) and performance year 2 (PY2). It also found that the PGP sites exhibited more improvement than their CGs on all but one measure between the BY and PY2. Even after adjusting for pre-demonstration trends in the claims-based quality indicators, the PGP sites improved their claims-based quality process indicators more than their comparison groups.

3. Impact on Providers and Suppliers

In order to participate in the program, we realize that there will be costs borne in building the organizational, financial and legal infrastructure that is required of an ACO as well as performing the tasks required (as discussed throughout the Preamble) of an eligible ACO, such as: quality reporting, conducting patient surveys and investment in infrastructure for effective care coordination. While provider and supplier participation in the Shared Savings Program will be voluntary, we have examined the potential costs that program participation will create.

The proposed rule allows for flexibility regarding the specific structure of an ACO and, as such, we expect the costs to vary greatly. Furthermore, beyond the statutorily required assignment of at least 5,000 Medicare beneficiaries to an ACO, the size of ACOs will also vary in relation to beneficiary participation and associated cost. Due to the limited precedence for this program and uncertainty regarding the structure and strategies that the provider community will pursue in order to participate as an ACO, estimates of expected provider costs are difficult to create. An analysis produced by the Government Accountability Office (GAO) of first year total operating expenditures for participants of the Medicare PGP Demonstration varied greatly, from $436,386 to $2,922,820, with the average for a physician group at $1,265,897 (Medicare Physician Payment: Care Coordination Programs Used in Demonstration Show Promise, but Wider Use of Payment Approach May Be Limited. GAO, February 2008). These costs (for groups which all had 200 or more physicians) include investments in infrastructure and information technology enhancements, management, quality reporting, and focused care coordination programs. The GAO also discovered that start-up investment expenditures in the PGP Demonstration varied between $82,573 and $917,398, with the average for a physician group at $489,354.

It is worth noting that the 10 participating physician groups in the demonstration were large compared with other physician practices in terms of annual medical revenues and nonphysician staff. GAO claims that their larger relative size gave the 10 participating physician groups in the PGP Demonstration three size-related advantages over smaller physician practices. First, participants typically had institutional affiliations with an integrated delivery system, a general hospital, or a health insurance entity. Specifically 9 of the 10 participating physician groups were part of an integrated delivery system, 8 affiliated with a general hospital, and 5 affiliated with an entity that marketed a health insurance product. As a result of these affiliations, GAO claims that participating physician groups generally had greater access to relatively large amounts of financial capital needed to initiate or expand programs. The second advantage, GAO claims, the 10 large participating physician groups had over smaller physician practices is the increased probability of having or acquiring EHR systems, which was essential in participants' ability to gather data and track progress in meeting quality-of-care targets. For example, 8 of the 10 participating physician groups had an EHR in place before the demonstration began, and the 2 other participants, out of necessity, developed alternative methods for gathering patient data electronically. Lastly, GAO claims that the third size-related advantage that most of the 10 participating physician groups had over smaller physician practices was the larger groups' experience with other pay-for-performance systems prior to participating in the PGP Demonstration. That is, 8 of the 10 participants had previous experience with pay-for-performance programs initiated by private or public sector organizations. This experience, GAO concludes, may have eased their adjustment to the PGP Demonstration and allowed them greater initial and overall success.

We use this analysis not to predict cost investment and operating expenditures, but to demonstrate that we expect the range of investment to vary greatly across ACOs and to provide potential scope for aspiring participants. We expect that due to the difference in program requirements between the Shared Savings Program and the PGP Demonstration Project, and the potential variation in ACO size and structure, the PGP related costs may be a subset of the investment required by entities seeking participation in this program. However, we recognize that potential advantageous key drivers for participating physician groups would include institutional affiliations that allow greater access to financial capital, access to and experience using EHR and other IT systems and experience with pay-for-performance programs. As a result, we present a rough estimate of

$1,755,251, based on the GAO findings to reflect the total average start-up investment and first year operating expenditures for a participant in the Shared Savings Program. Lastly, assuming a range of expected ACOs participating in the Shared Savings Program at 75 to 150 yields an estimated aggregate cost, for ACO start-up investment and first year operating expenditures in the Shared Savings Program, in the range of $131,643,825 to $263,287,650.

Participating in the Shared Savings Program will require groups of providers and suppliers to (among other things): invest in or improve upon information technology systems, focus on evidence-based medicine, improve care coordination and quality and generally refine all processes of caring for their patients and community. While, as we discussed previously, there will be a financial cost placed on ACOs in order to do so, there will be benefits to the respective organizations in the form of increased operational and healthcare delivery efficiency. Furthermore, as discussed previously, and explained in more detail in the preamble of this proposed rule, there will be an opportunity for financial reward for success in the program in the form of shared savings. The estimated bonuses paid are a median of $800 million over 3 years, with $560 million and $1,130 million reflecting the 10th and 90th percentiles. Also, participating ACO's will be assuming a risk of a financial penalty for failing to achieve savings (that is, if actual expenditures exceed the benchmark). The estimated penalties paid are a median of $40 million over 3 years, with $10 million and $80 million reflecting the 10th and 90th percentiles. (It is important to note that the given percentiles for bonuses, penalties, and net impacts are independently tabulated and therefore are not additive across the three parameters.) The actuality of the risk is dependent on which of the two options an ACO selects for their first agreement period. Due to the voluntary nature of this program, we expect the formation of ACOs by entities that aspire to receive benefits that outweigh their costs. We anticipate that not all ACOs will achieve shared savings and some will incur a financial loss, due to requirement to repay a share of actual expenditures in excess of their benchmark.

As is previously stated, we expect the costs and benefits of establishing and maintaining an ACO to vary and solicit comment on this issue, including total ACO expenditures for start-up investment and annual operating costs for the 3 years of the Shared Savings Program.

D. Alternatives Considered

The proposed rule contains a range of policies. Many tenets of the program are statutorily mandated and thus allow for little, if any, flexibility in the rulemaking process. Where there was flexibility, we made our policy decisions regarding alternatives based on a balance between creating the least possible negative impact on the stakeholders affected by the program on and satisfactorily fitting the vision of the program within given operational constraints.

For example, while the Affordable Care Act mandates that an ACO be large enough to care for minimum of 5,000 assigned beneficiaries, as is described in the preamble, we are proposing a sliding minimum percentage and confidence interval for the savings threshold based on the size of an ACO. This proposal is a balance of protecting the program from paying out savings based on random variation, while allowing attainable thresholds for smaller sized potential ACOs and thus encouraging participation from various sized entities.

The preceding preamble provides descriptions of the various statutory provisions that are addressed, identifies those policies when discretion has been allowed and exercised, presents the rationales for our proposals and, where relevant, alternatives that were considered. An important example involves adjustments to an ACO's benchmark for changes in FFS price adjustments (such as the geographic practice cost index (GPCI) under the PFS and hospital wage index). Such price changes regularly occur and often impact counties or other localities in magnitudes that can significantly differ from the national average. If, for example, operating cost payments are reduced for section 508 hospitals (as will occur under current law at the end of FY 2011) then ACO-attributed claims incurred in a 508 hospital would exhibit significant price decreases which could lead to shared savings payments unrelated to real improvements in ACO efficiency. Absent such adjustments, these statutory changes will impact the comparison of actual expenditures and the benchmark. However, as we have previously noted, the statute provides authority for adjustment to the benchmark for "such other factors as the Secretary determines appropriate."

Another design element involves the method for constructing a participating ACO's benchmark. One proposed method employs a similar approach to that used in the CMS PGP Demonstration and is based on risk-adjusting to take into account changes in the health status of the population between the benchmark period and performance year. If HCC risk adjustments are specified in the final program then it must be applied in a manner that does not reward ACOs for more complete and accurate coding of their assigned patient population to protect the program from costs due to paying shared savings as a result of greater diagnosis coding intensity in ACOs than would occur for a comparable group of beneficiaries receiving care outside an ACO.

Finally, a key design element involves the method for establishing quality standards. We propose aggregating the quality domain scores into a single overall ACO score used to calculate the ACOs final sharing rate for purposes of determining shared savings or shared losses as described in section II.E of this proposed rule. We would average all domain scores for an ACO together equally to calculate the overall quality score used to calculate the ACO's final sharing rate as previously described. We also considered a variety of scoring methodology that would have differing incentives for improving clinical outcomes such as: Scoring measures individually under a method that would weight all measures equally as well as weighting quality measures by their clinical importance. In addition to the performance score approach that rewards ACOs for better quality with larger percentages of shared savings as modeled in this analysis, we could use a threshold approach that allows any ACO that meets minimum standards for the quality to realize the full shared savings. By design this approach could ensure higher net savings to the Medicare program, depending on the quality threshold and sharing percentage chosen.

The provisions adopted in the final Shared Savings Program rule may differ from the current proposals, possibly resulting in material changes in the projected financial impact of the program. We solicit comment on other potentially effective and reasonably feasible alternatives especially those that reduce burdens and maintain flexibility and freedom of choice for the public.

E. Accounting Statement and Table

As required by OMB Circular A–4 (available at *http://www.whitehouse.gov/sites/default/files/omb/assets/regulatory_matters_pdf/a-4.pdf*), in Table 13, we have prepared an accounting statement showing the classification of transfers, benefits and

costs associated with the provisions of this proposed rule. Because of the uncertainties identified in establishing the economic impact estimates, we intend to update the estimates in the final rule.

TABLE 13: Accounting Statement: Estimated Transfers, Benefits and Costs (CY 2012 to CY 2014

Category	TRANSFERS			
Annualized Monetized Transfers	Year Dollar	Units Discount Rate		Notes
	2011	7%	3%	These estimates represent the range of annualized impact on the Medicare Program for CYs 2012 - 2014.
	Primary Estimate	-$167.72 million	-$169.01 million	
	90th Percentile Estimate	-$56.19 million	-$56.46 million	
	10th Percentile Estimate	-$315.45 million	-$318.02 million	
From/To	Federal Government to ACO Providers			
Category	**BENEFITS**			
Qualitative Benefits	Improved healthcare delivery and communication to beneficiaries through patient centered-care.			
Category	**COSTS**			
Costs	Total ACO start-up investment and first year operating expenditures average from $131,643,825 to $263,287,650, for the estimated range of 75-150 participating ACOs.			

F. Conclusion

As a result of this proposed rule, the median estimate of the financial impact from implementation of the Shared Savings Program, for CYs 2012 through 2014, is a net savings of $510 million. Although this is the "best estimate" for the 3-year financial impact of the Shared Savings Program initiative, a relatively wide range of possible outcomes exists. Overall, 80 percent of the stochastic trials resulted in net program savings, and the other 30 percent represented cost increases. The 10th and 90th percentiles of the estimate distribution show net savings of $960 million and $170 million, respectively, suggesting a 10-percent likelihood that the actual impact would exceed the respective percentile amounts. In the extreme scenarios, the results were as large as $1,960 million in savings or $270 million in costs. Lastly, the estimated aggregate cost for ACO start-up investment and first year operating expenditures in the Shared Savings Program range from $131,643,825 to $263,287,650, based on an assumed 75 to 150 ACOs participating in the Shared Savings Program.

In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

List of Subjects in Part 425

Administrative practice and procedure, Health facilities, Health professions, Medicare, 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 by adding part 425 to read as follows:

SUBCHAPTER B—MEDICARE PROGRAM

PART 425—MEDICARE SHARED SAVINGS PROGRAM

Sec.

Subpart A—General Provisions

Subpart B—Shared Savings Program Requirements

Subpart A—General Provisions

§ 425.2 Basis and scope.

(a) *Basis.* This part implements section 1899 of the Act by establishing a shared savings program that promotes accountability for a patient population, coordinates items and services under parts A and B, and encourages investment in infrastructure and redesigned care processes for high quality and efficient services. Under this program, groups of providers of services and suppliers meeting criteria specified by the Secretary may work together to manage and coordinate care for Medicare fee-for-service beneficiaries through an accountable care organization (ACO). ACOs that meet quality performance standards established by the Secretary are eligible to receive payments for shared savings. During years in which the ACO is participating in a two-sided model, the ACO may be required to share losses.

(b) *Scope.* This part sets forth the following:

(1) The eligibility requirements for an ACO to participate in the Medicare Shared Savings Program (Shared Savings Program).

(2) Program requirements, including quality and other reporting requirements.

(3) The method for assigning Medicare fee-for-service beneficiaries to ACOs.

(4) Payment criteria and methodologies (one-sided model and two-sided model).

(5) Compliance monitoring and sanctions for noncompliance.

(6) Reconsideration of adverse determinations.

§ 425.4 Definitions.

As used in this part, unless otherwise indicated—

Accountable care organization (ACO) means a legal entity that is recognized and authorized under applicable State law, as identified by a Taxpayer Identification Number (TIN), and comprised of an eligible group (as defined at § 425.5(b)) of ACO participants that work together to manage and coordinate care for Medicare fee-for-service beneficiaries and have established a mechanism for shared governance that provides all ACO participants with an appropriate proportionate control over the ACO's decision-making process.

ACO participant means a provider (as defined in § 400.202) or a supplier (as defined at § 400.202), as identified by a TIN.

ACO provider/supplier means—

(1) A provider (as defined in § 400.202); or

(2) A supplier (as defined at § 400.202) that bills for items and services it furnishes to Medicare beneficiaries under a Medicare billing number assigned to the TIN of an ACO participant in accordance with applicable Medicare rules and regulations.

ACO professional means an ACO provider/supplier who is either of the following:

(1) A doctor of medicine or osteopathy legally authorized to practice medicine and surgery by the State in which he performs such function or action, including an osteopathic practitioner within the scope of his or her practice as defined by State law.

(2) A practitioner who is one of the following:

(i) A physician assistant (as defined at § 410.74(a)(2)).

(ii) A nurse practitioner (as defined at § 410.75(b)).

(iii) A clinical nurse specialist (as defined at § 410.76(b)).

Antitrust Agency means the Department of Justice or Federal Trade Commission.

Antitrust Policy Statement means the Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations Participating in the Medicare Shared Savings Program issued by the antitrust agencies.

Assignment means the operational process by which CMS determines whether a beneficiary has chosen to receive a sufficient level of the requisite primary care services from primary care physician(s) who is an ACO provider/supplier so that the ACO may be appropriately designated as exercising basic responsibility for that beneficiary's care.

At-risk beneficiary means a beneficiary who—

(1) Has a high risk score on the CMS–HCC risk adjustment model;

(2) Is considered high cost due to having two or more hospitalizations each year;

(3) Is dually eligible for Medicare and Medicaid;

(4) Has a high utilization pattern; or

(5) Has had a recent diagnosis that is expected to result in increased cost.

CAP means a corrective action plan.

Covered professional services has the same meaning give these terms under section 1848(k)(3) of the Act.

Eligible professional has the meanings given this term under section 1848(k)(3) of the Act.

Hospital means a hospital subject to the prospective payment system specified in § 412.1(a)(1) of this chapter.

Marketing materials and activities include, but are not limited to, general audience materials such as brochures, advertisements, outreach events, letters to beneficiaries, web pages, data sharing opt out letters, mailings, or other activities conducted by or on behalf of the ACO, or by ACO participants, or ACO providers/suppliers participating in the ACO, or by other individuals on behalf of the ACO or its participating providers and suppliers when used to educate, solicit, notify, or contact Medicare beneficiaries or providers and suppliers regarding the Shared Savings Program. The following beneficiary communications are not marketing materials and activities: Informational materials customized or limited to a subset of beneficiaries; materials that do not include information about the ACO or providers in the ACO; materials that cover beneficiary-specific billing and claims issues or other specific health-related issues; or educational information on specific medical conditions (for example, flu shot reminders), or referrals for Medicare covered items and services.

Medicare fee-for-service beneficiary means an individual who is—

(1) Enrolled in the original Medicare fee-for-service program under parts A and B; and

(2) Not enrolled in any of the following:

(i) A MA plan under part C.

(ii) An eligible organization under section 1876 of the Act.

(iii) A PACE program under section 1894 of the Act.

Medicare Shared Savings Program (Shared Savings Program) means the program, established under section 1899 of the Act and implemented in this part.

One-sided model means a model under which the ACO may share savings with the Medicare program, if it meets the requirements for doing so, but is not liable for sharing any losses incurred under the provisions of § 425.7(c).

Physician Quality Reporting System means the system established under section 1848(k) of the Act.

Primary care physician means a physician (as defined at § 410.20(b)(1)) who has a primary specialty designation of internal medicine, general practice, family practice, or geriatric medicine.

Primary care services mean the set of services identified by the following HCPCS codes: 99201 through 99215, 99304 through 99340, and 99341 through 99350, G0402 (the code for the Welcome to Medicare visit); and G0438 and G0439 (codes for the annual wellness visits).

Reporting period means January 1 through December 31.

TIN means Federal taxpayer identification number.

Two-sided model means a model under which the ACO may share savings with the Medicare program, if it meets the requirements for doing so, and is also liable for sharing any losses incurred under the provisions of § 425.7(d).

Subpart B—Shared Savings Program Requirements

§ 425.5 Eligibility and governance requirements.

(a) *General requirements.* (1) Under the Shared Savings Program, ACO participants may work together to manage and coordinate care for Medicare fee-for-service beneficiaries through an ACO that participates in the Shared Savings Program and meets the criteria specified in this part.

(2) ACOs that exceed a minimum savings rate established under § 425.7(c)(2) and (d)(2), meet the minimum quality performance standards established under § 425.10, and otherwise maintain their eligibility to participate in the Shared Savings Program under this section are eligible to receive payments for shared savings under § 425.7 of this subpart.

(3) ACOs that operate under the two-sided model established in this section must share losses with the Medicare program under § 425.7 of this subpart.

(b) *Eligible providers and suppliers.* The following ACO participants, which must have established a mechanism for

shared governance, are eligible, separately or in combination, to form ACOs that may participate in the Shared Savings Program:

(1) ACO professionals in group practice arrangements.

(2) Networks of individual practices of ACO professionals.

(3) Partnerships or joint venture arrangements between hospitals and ACO professionals.

(4) Hospitals employing ACO professionals.

(5) Providers or suppliers otherwise recognized under the Act that are not ACO professionals or hospitals, as defined in § 425.4.

(6) CAHs that bill under Method II (as described in § 413.70(b)(3))

(c) *Reporting of TINs.* (1) Each ACO must report to CMS the TINs of the ACO participants comprising the ACO along with a list of associated National Provider Identifiers (NPIs), at the beginning of each performance year and at other such times as specified by CMS.

(2) For purposes of the Shared Savings Program, each ACO participant TIN upon which beneficiary assignment is dependent is required to commit to a 3-year agreement with CMS and will be exclusive to one ACO.

(3) ACO participant TINs upon which beneficiary assignment is not dependent are required to commit to a 3-year agreement to the ACO, and the ACO participant must not be required to be exclusive to a single ACO.

(d) *Other requirements.* (1) *Accountability for beneficiaries.* As part of its application and 3-year agreement, the ACO must certify that the providers and suppliers forming the ACO have agreed to become accountable for and report to CMS on the quality, cost, and overall care of the Medicare fee-for-service beneficiaries assigned to the ACO. Each ACO must make information on its accountability for quality, cost, and the overall care of its assigned population available to the public in a standardized format, as determined by CMS.

(2) *Coordination of Antitrust Agency review.* (i) Except for an ACO that qualifies for the Rural Exception articulated in the Antitrust Policy Statement or other controlling guidance from the antitrust agencies, an ACO with a Primary Service Area (PSA) share, as described in the Antitrust Policy Statement, greater than 50 percent for any common service that two or more ACO participants provide to patients from the same PSA must do both of the following:

(A) Request an expedited antitrust review from the Antitrust Agencies.

(B) Submit, as part of its application, a letter from the reviewing Antitrust Agency confirming that it has no present intent to challenge or to recommend challenging the proposed ACO.

(ii) Except for an ACO that qualifies for the Rural Exception articulated in the Antitrust Policy Statement, or other controlling guidance from the antitrust agencies, an ACO with a PSA share, as described in the Antitrust Policy Statement, greater than 30 percent and less than or equal to 50 percent may do one of the following:

(A) Request an expedited antitrust review from the Antitrust Agencies.

(B) Submit a letter from the reviewing Antitrust Agency confirming that it has no present intent to challenge or to recommend challenging the proposed ACO.

(C) Begin to operate and abide by a list of conduct restrictions, reducing significantly the likelihood of antitrust concern.

(D) Begin to operate and remain subject to antitrust investigation if it presents competitive concerns.

(iii) An ACO must notify CMS at least 30 days before any material change within the 3-year agreement period of its ACO participants or ACO providers/suppliers and must submit recalculated PSA shares for common services that two or more independent ACO participants provide to patients from the same PSA. If any revised PSA share is calculated to be greater than 50 percent, the ACO will be subject to review or re-review by an Antitrust Agency in order to remain eligible to participate in the Shared Savings Program.

(iv)(A) If an ACO receives a letter from a reviewing Antitrust Agency stating that the Antitrust Agency will likely challenge or recommend challenging the ACO, then the ACO will be ineligible to participate in the Shared Savings Program.

(B) The ACO must promptly inform CMS if it receives such a letter at any time from an Antitrust Agency.

(3) Agreement requirements. (i) Upon being notified by CMS of its approval to participate in the Shared Savings Program, an executive of that ACO who has the ability to legally bind the ACO must sign and submit to CMS a 3-year agreement.

(ii) The 3-year agreement must require the ACO to comply with the provisions in this part in order to participate in the Shared Savings Program.

(iii) All contracts or arrangements between or among the ACO, ACO participants, ACO providers/suppliers, and other entities furnishing services related to ACO activities must require compliance with the requirements and conditions of this part, including those specified in the 3-year agreement. The ACO must provide a copy of the 3-year agreement to these individuals and entities.

(iv)(A) The ACO must certify the accuracy, completeness, and truthfulness of its information contained in the following:

(*1*) Shared Savings Program application.

(*2*) 3-year agreement.

(*3*) Submissions of quality data and other information.

(B) Certification must be made at the time the ACO submits the following:

(*1*) Application to participate in the Shared Savings Program.

(*2*) Executes the 3-year agreement.

(*3*) Submits any information, including quality data, on which shared savings payments or shared losses are calculated.

(C) Certification must be signed by an individual with the authority to legally bind the ACO (for example the ACO's chief executive officer (CEO) or chief financial officer (CFO)).

(v) The ACO must establish partnerships with community stakeholders in order to advance the three-part aim of better care for individuals, better health for populations, and lower growth in expenditures.

(vi) The ACO must agree, and must require its ACO participants, ACO providers/suppliers, and contracted entities performing functions or services on behalf of the ACO to agree, or to comply with applicable provisions of the following:

(A) Federal criminal law.

(B) The False Claims Act (31 U.S.C. 3729 et seq.).

(C) The anti-kickback statute (42 U.S.C. 1320a–7b(b)).

(D) The civil monetary penalties law (42 U.S.C. 1320a–7a).

(E) The physician self-referral law (42 U.S.C. 1395nn).

(vii)(A) The ACO must agree, as a condition of receiving any shared saving payment and participating in the program, that an individual with the authority to legally bind the ACO must certify that any data or information requested by or submitted to CMS is accurate, complete, and truthful.

(B) If data or information is generated by an entity other than the ACO, such entity must similarly certify the accuracy, completeness, and truthfulness of the information or data.

(4) *Marketing materials.* (i) Any ACO marketing materials or activities, as defined in § 425.4, must be approved by CMS before use.

(ii) Any changes to CMS-approved marketing materials or activities must be approved by CMS before use.

(5) *Notice of ACO participation.* (i) ACO participants must notify beneficiaries that their ACO providers/suppliers are participating in an ACO.

(ii) Except as specified in paragraph § 412.1(a)(1) of this section, all beneficiary communications any materials or activities used by ACO participants or ACO providers/suppliers on behalf of the ACO to communicate about the ACO in any manner to Medicare beneficiaries, must be approved by CMS before use.

(6) *Tracks during agreement periods.* (i) For its initial agreement period, an ACO may elect to operate under one of the following tracks:

(A) *Track 1.* Under Track 1, the ACO operates under the one-sided model (as described under § 425.7(c) of this part) for 2 years, and under the two-sided model (as described under § 425.7(d) of this part) for the third year. In the third year of the ACO's agreement under Track 1, the methodology used to reconcile ACOs under the first year of the two-sided model would apply except ACOs must meet the quality performance standard that applies in the third year.

(B) *Track 2.* Under Track 2, the ACO operates under the two-sided model (as described under § 425.7(d) of this part), sharing both savings and losses with the Medicare program for 3 years.

(ii) For subsequent agreement periods, an ACO may operate only under the two-sided model, sharing both savings and losses with the Medicare program (as described in § 425.7(d) of this part).

(iii) In both models an ACO's share in savings will be subject to 25 percent withholding in order to help ensure repayment of any losses to the Medicare program. The withheld amount will be applied towards repayment of an ACO's losses.

(iv) ACOs must obtain reinsurance, place funds in escrow, obtain surety bonds, establish a line of credit as evidenced by a letter of credit that the Medicare program can draw upon, or establish another appropriate repayment mechanism in order to ensure repayment of any losses to the Medicare program in advance of entering a period of participation in the Shared Savings Program under the two-sided model.

(v) An ACO that is applying for participation in the Shared Savings Program must, as part of its application, submit documentation of such a repayment mechanism for approval by CMS. This documentation must include details supporting the adequacy of the mechanism for repaying losses equal to at least 1 percent of the ACO's per capita expenditures for its assigned beneficiaries from the most recent year available.

(iv) CMS will determine the adequacy of an ACO's repayment mechanism.

(v) An ACO must demonstrate the adequacy of this repayment mechanism annually, prior to the start of each performance year in which it takes risk.

(vi) To the extent that such an ACO's repayment mechanism does not enable CMS to fully recoup the losses for a given performance year, any unpaid losses will be carried forward into subsequent performance years and agreement periods (to be recouped either against additional financial reserves, or offset by shared savings earned by the ACO).

(7) *Legal structure.* (i) An ACO must be constituted as a legal entity for purposes of all of the following:

(A) Receiving and distributing shared savings.

(B) Repaying shared losses.

(C) Establishing, reporting, and ensuring provider compliance with health care quality criteria, including quality performance standards.

(D) Other ACO functions identified in this part.

(ii) An ACO must certify that it is recognized as a legal entity in the State in which it was established and that it is authorized to conduct business in each State in which it operates.

(8) *Shared governance.* (i) An ACO must establish and maintain a governing body with adequate authority to execute the functions of an ACO as defined under this part, including but not limited to, the definition of processes to promote evidence-based medicine and patient engagement, report on quality and cost measures, and coordinate care.

(ii) The governing body must be comprised of the following:

(A) ACO participants or their designated representatives.

(B) Medicare beneficiary representative(s) served by the ACO who do not have a conflict of interest with the ACO, and who have no immediate family member with conflict of interest with the ACO.

(iii) The governing body must have and possess broad responsibility for the ACO's administrative, fiduciary, and clinical operations.

(iv) At least 75 percent control of the ACO's governing body must be held by ACO participants. Each ACO participant must choose an appropriate representative from within its organization to represent them on the governing body and each ACO participant must have appropriate proportionate control over governing body decision making.

(v)(A) The members of the governing body may serve in a similar or complementary manner for an existing participant in the ACO.

(B) The governing body of the ACO must be separate and unique to the ACO in cases where the ACO comprises multiple, otherwise independent entities (for example, several independent physician group practices).

(C) The ACO must provide evidence within its application that the governing body is a separate legal entity.

(vi)(A) Except as specified in paragraph (d)(8)(vi)(b) of this section, a separate governing body must be established.

(B) If the ACO is comprised of a single entity that is financially and clinically integrated, and if at least 75 percent control of the entity's governing body is comprised of representatives of the entity, the ACO governing body may be the same as the governing body of that entity, provided it satisfies the other requirements of this section.

(9) *Leadership and management structure.* (i) As part of its application process, an ACO must submit supporting materials to CMS that demonstrate the ACO's leadership and management structure, including clinical and administrative systems that align with and support the goals of the Shared Savings Program and the aims of better care for individuals, better health for populations, and lower growth in expenditures.

(ii) The ACO's operations must be managed by an executive, officer, manager, or general partner whose appointment and removal are under the control of the organization's governing body and whose leadership team has demonstrated the ability to influence or direct clinical practice to improve efficiency processes and outcomes.

(iii) Clinical management and oversight must be managed by a full-time senior-level medical director who is physically present on a regular basis in an established ACO location, and who is a board-certified physician and licensed in the State in which the ACO operates.

(iv) ACO participants and ACO providers/suppliers must have a meaningful commitment to the ACO's clinical integration program to ensure its likely success. Meaningful commitment may include, for example, a meaningful financial investment in the ACO or a meaningful human investment (for example, time and effort) in the ongoing operations of the ACO such that the potential loss or recoupment of the investment is likely to motivate the

participant and provider/supplier to make the clinical integration program succeed.

(v) A physician-directed quality assurance and process improvement committee must oversee an ongoing action-oriented quality assurance and improvement program. The quality assurance program must establish internal performance standards for quality of care and services, cost effectiveness, and process and outcome improvements, and hold ACO's providers/suppliers accountable for meeting the performance standards. The program must have processes and procedures in place to identify and correct poor compliance with such standards and to promote continuous quality improvements.

(vi) The ACO must implement evidence-based medical practice or clinical guidelines and processes for delivering care consistent with the aims of better care for individuals, better health for populations, and lower growth in health care expenditures. The guidelines and care delivery processes must cover diagnoses with significant potential for the ACO to achieve quality and cost improvements, taking into account the circumstances of individual beneficiaries.

(vii) ACO participants and providers/suppliers must agree to comply with these guidelines and processes and to be subject to performance evaluations and potential remedial actions, including their expulsion from the ACO. The ACO must have policies and procedures for expulsion of ACO participants and ACO provider/suppliers from the ACO.

(viii) The ACO must have an infrastructure, such as information technology (which may include EHR technology certified to the standards and implementation specifications adopted by the Secretary for the purposes of the meaningful use EHR incentive programs), that enables the ACO to collect and evaluate data and provide feedback to ACO participants and ACO providers/suppliers across the entire ACO, including providing information to influence care at the point of care.

(ix) The supporting materials that are submitted in the application must include all of the following:

(A) ACO documents (for example, participation agreements, employment contracts, and operating policies) that describe the ACO participants' rights and obligations in the ACO, including distribution of shared savings to encourage ACO participants and ACO providers/suppliers to adhere to the quality assurance and improvement program and the evidenced-based clinical guidelines.

(B) Documents that describe the scope and scale of the quality assurance and clinical integration program, including documents that describe all relevant clinical integration program systems and processes, such as the internal performance standards and the processes for monitoring and evaluating performance.

(C) Supporting materials documenting the ACO's organization and management structure, including an organizational chart, a list of committees (including names of committee members) and their structures, and job descriptions for senior administrative and clinical leaders.

(D) Evidence that the ACO has a board-certified physician as its medical director who is licensed in the State in which the ACO resides and that a principal CMS liaison is identified in its leadership structure.

(E) Evidence that the governing body is comprised of representatives the ACO participants who form the ACO, and that these ACO participants comprise at least 75 percent of the governing body.

(F) Upon request, the ACO must provide copies of all documents effectuating the ACO's formation and operation, including, without limitation the following:

(*1*) Charters.

(*2*) By-laws.

(*3*) Articles of incorporation.

(*4*) Partnership agreement.

(*5*) Joint venture agreement.

(*6*) Management or asset purchase agreements.

(*7*) Financial statements and records.

(*8*) Descriptions of the remedial processes that will apply if an ACO participant or an ACO provider/supplier fails to comply with the ACO's internal procedures and performance standards, including a CAP and the circumstances under which expulsion from the ACO could occur.

(G) A copy of the ACO's compliance plan or documentation describing the plan that will be put in place at the time the ACO's agreement with CMS becomes effective.

(H) A description of how the ACO will partner with community stakeholders.

(I) Written standards for beneficiary access and communication. These standards must include the ACO's process for beneficiaries to access their medical record.

(x) CMS retains the right to give consideration to an innovative ACO with a management structure not meeting these requirements.

(10) *Compliance plan.* (i) The ACO must have a compliance plan that includes at least the following elements:

(A) A designated compliance official or individual who is not legal counsel and who has the ability to report directly to the ACO's governing body.

(B) Mechanisms for identifying and addressing compliance problems related to the ACO's operations and performance.

(C) A method for employees or contractors of the ACO, ACO participants, and ACO providers/suppliers to report suspected problems related to the ACO.

(D) Compliance training for the ACO, the ACO participants, and the ACO providers/suppliers.

(E) A requirement to report suspected violations of law to an appropriate law enforcement agency.

(ii) To achieve an effective compliance program, an ACO may consider coordinating its compliance efforts with existing compliance efforts of its ACO providers/suppliers.

(11) *Distribution of savings.* As part of its application to participate in the Shared Savings Program, an ACO must describe how:

(i) It plans to use shared savings payments, including the criteria it plans to employ for distributing shared savings among its participants.

(ii) The proposed plan will achieve the specific goals of the Shared Savings Program.

(iii) The proposed plan will achieve the general aims of better care for individuals, better health for populations, and lower growth in expenditures.

(12) *Written request for shared savings payment.* (i) After receipt of notification from CMS of the anticipated shared savings payment or amount of shared losses, an individual with the authority to legally bind the ACO (such as the ACO's CEO or CFO), must make a written request to CMS for payment of the shared savings (or acknowledge the amount of shared losses) in a document that certifies the ACO's compliance with program requirements as well as the accuracy, completeness, and truthfulness of any information submitted directly or indirectly by the ACO, its ACO participants, the ACO providers/suppliers, or any other entity to CMS, including any quality data or other information or data relied upon by CMS in determining the ACO's eligibility for, and the amount of a shared savings payment or the amount owed by the ACO to CMS.

(ii) If such data are generated or submitted by ACO participants, ACO providers/suppliers, or another entity,

such ACO participant, ACO provider/supplier, must similarly certify the accuracy, completeness, and truthfulness of the data and provide the government with access to such data for audit, evaluation, investigation, and inspection.

(13) *Sufficient number of primary care providers and beneficiaries.* (i) CMS will deem an ACO to have a sufficient number of primary care physicians and beneficiaries if the number of beneficiaries historically assigned to the ACO participants using the assignment methodology in § 425.6 is 5,000 or more.

(ii) If at the end of a performance year, an ACO's assigned population falls below 5,000, then that ACO will be issued a warning and placed on a CAP.

(A) While under the CAP, an ACO remains eligible for shared savings and losses during that performance year.

(B) If the ACO's assigned population has not returned to at least 5,000 by the end of the next performance year, then that ACO's agreement will be terminated and the ACO will not be eligible to share in savings for that year.

(14) *Required reporting on participating ACO professionals.* A participating ACO must maintain, update, and annually report to CMS a list of the following:

(i) Each ACO participant's TIN.

(ii) Each ACO providers/supplier's NPI and/or TIN.

(15) *Required processes and patient-centeredness criteria.* (i) *Required processes.* In its application to participate in the Shared Savings Program, an ACO must provide CMS with documentation of its plans to do all of the following:

(A) Promote evidence-based medicine.

(B) Promote beneficiary engagement.

(C) Internally report quality and cost metrics.

(D) Coordinate care.

(ii) *Patient-centeredness criteria.* (A) An ACO should adopt a focus on patient-centeredness that is promoted by the governing body and integrated into practice by leadership and management working with the organization's health care teams.

(B) An ACO must demonstrate patient-centeredness by addressing all of the following areas:

(*1*) Have a beneficiary experience of care survey in place (using the Clinician and Group CAHPS survey, including an appropriate functional status survey module) and describe how the ACO will use the results to improve care over time.

(*2*) Patient involvement in ACO governance.

(*3*) A process for evaluating the health needs of the ACO's assigned population, including consideration of diversity in its patient populations, and a plan to address the needs of its population.

(*4*) Systems in place to identify and update high-risk individuals and processes to develop individualized care plans for targeted patient populations including integration of community resources to address individual needs.

(*i*) Such plans must promote improved outcomes for, at a minimum, high-risk and multiple chronic condition patients, and as appropriate, other patients with chronic conditions.

(*ii*) The plan must be tailored to the beneficiary's health and psychosocial needs, account for beneficiary preferences and values, and identify community and other resources to support the beneficiary in following the plan.

(*5*) A mechanism in place for the coordination of care (for example, via use of enabling technologies or care coordinators).

(*i*) The ACO is required to describe its mechanism for coordinating care for Medicare beneficiaries.

(*ii*) The ACO should have a process in place (or clear path to develop such a process) to exchange summary of care information when patients transition to another provider or setting of care, both within and outside the ACO.

(*iii)* For providers enrolled in the electronic exchange of information, this process must be consistent with meaningful use requirements under the Medicare EHR Incentive Program (as described in part 495 of this chapter).

(*6)* A process in place for communicating clinical knowledge/evidence-based medicine to beneficiaries in a way that is understandable to them.

(*7*) A process in place for beneficiary engagement and shared decision-making that takes into account the beneficiaries' unique needs, preferences, values, and priorities.

(*8*) Written standards in place for beneficiary access and communication, and a process in place for beneficiaries to access their medical record.

(*9*) Internal processes in place for measuring clinical or service performance by physicians across the practices, and using these results to improve care and service over time.

§ 425.6 Assignment of Medicare fee-for-service beneficiaries to ACOs.

(a) *General rule.* (1) Medicare fee-for-service beneficiaries are assigned to an ACO based on their utilization of primary care services provided under this title by a primary care physician who is an ACO provider/supplier during the performance year for which shared savings are to be determined.

(2) Beneficiary assignment to an ACO is for purposes of determining the population of Medicare fee-for-service beneficiaries for whose care the ACO is accountable, and for determining whether an ACO has achieved savings under § 425.7 of this part, and in no way diminishes or restricts the rights of beneficiaries assigned to an ACO to exercise free choice in determining where to receive health care services.

(b) *Assignment methodology.* CMS employs the following methodology to assign Medicare beneficiaries to an ACO:

(1) For each ACO, identify all primary care physicians as defined in § 425.4 of this part who were an ACO participant during the performance year.

(2) At the end of each performance year, determine all beneficiaries who received services from primary care physicians in the ACO, as determined under paragraph (b)(1) of this section.

(3) Determine the total allowed charges for the primary care services (as identified by HCPCS code in the definition of primary care services under § 425.4 of this section) that each of the beneficiaries identified in paragraph (b)(2) received from any provider or supplier during the performance year.

(4) For each beneficiary, add together the allowed charges for the primary care services provided by the primary care physicians (identified in paragraph (b)(1) of this section) in each ACO (identified in paragraph (b)(1) of this section).

(5) Assign a beneficiary to an ACO if the beneficiary has received a plurality of his or her primary care services, as determined by the sum of allowed charges for those services under paragraph (b)(4) of this section, from primary care physicians identified under paragraph (b)(1) of this section, who are an ACO participant.

(c) *Beneficiary information and notification.* ACO participants will post signs in each of their facilities and provide written notification for beneficiaries about their participation in the Shared Savings Program.

§ 425.7 Payment and treatment of savings.

(a) *Establishing a benchmark.* (1) Using a 6-months claims run-out, CMS will retrospectively estimate and update an ACO's benchmark for an agreement period starting with ACO participants identified at the start of the agreement period.

(2) Using the claim records of ACO participants and applying the methodology for assigning beneficiaries

in § 425.6 of this part, CMS will compute per capita expenditures for beneficiaries who would have been assigned to the ACO in any of the prior three most recent available years.

(b) *Computing per capita Medicare Part A and Part B expenditures and updating the benchmark.* In computing these per capita expenditures, CMS uses the per capita Parts A and B fee-for-service expenditures for beneficiaries that would have been assigned to the ACO in each of these 3 prior years, we will estimate a fixed benchmark that is adjusted for overall growth and beneficiary characteristics, including health status using prospective HCC adjustments. This benchmark will then be updated annually during the agreement period, according to statute, based on the absolute amount of growth in national per capita expenditures for Parts A and B services under the original Medicare fee-for-service program. CMS will do all of the following:

(1) Calculate annual Parts A and B fee-for-service per capita expenditures for the beneficiaries who would have been assigned for each of the benchmark years. To minimize variation from catastrophically large claims, CMS truncates an assigned beneficiary's total—

(i) Parts A and B fee-for-service per capita expenditures at the 99th percentile as determined for each benchmark year.

(2) Using CMS Office of the Actuary national Medicare expenditure data for each of the years making up the benchmark, CMS determines national growth trend indices and trend them to the third benchmark year (BY3) dollars.

(3) Using health status measures for the beneficiary population in each of the years making up the benchmark, CMS establishes health status indices for each year and adjust these indices so they are restated in BY3 risk.

(4) CMS computes a 3-year risk-and growth-trend adjusted per capita expenditure amount for the patient populations in each of the 3 benchmark years by combining the initial per capita expenditures for each year with the respective growth and health status indices. The result is risk adjusted per capita expenditures for beneficiaries historically assigned to the ACO in each of the 3 years used to establish the benchmark stated in BY3 risk and expenditure amounts, and assigned patient populations.

(5) CMS weights the most recent year of the benchmark, BY3 at 60 percent, BY2 at 30 percent and BY1 at 10 percent to ensure that the benchmark reflects more accurately the latest expenditure and health status of the ACO's assigned beneficiary population.

(6) CMS updates this fixed benchmark by the projected absolute amount of growth in national per capita expenditures for Parts A and B services under the original Medicare fee-for-service program using data from CMS's Office of the Actuary.

(7) In performing these steps, CMS does not take into consideration expenditure increases or decreases under Section 1848 related to value-based purchasing programs or the HITECH Act; specifically, any of the following:

(i) Physician Quality Reporting Initiative as provided in § 414.90.

(ii) Electronic prescribing program as provided in § 414.92.

(iii) HITECH Act incentives for eligible professionals as provided in § 495.102.

(c) *Determination of savings and shared savings rate for ACOs under the one-sided model.* (1) *Savings determination.* For each performance year, CMS determines whether the estimated average per capita Medicare expenditures under the ACO for Medicare fee-for-service beneficiaries for Parts A and B services, adjusted for beneficiary characteristics, is below the applicable benchmark determined under paragraph (b) of this section. To minimize variation from catastrophically large claims, CMS truncates that assigned beneficiary's total annual Parts A and B fee-for-service per capita expenditures at the 99th percentile as determined for each performance year. In order to qualify for a shared savings payment, the ACO's average per capita Medicare expenditures for the performance year must be below the applicable benchmark by more than a minimum savings rate established for the ACO under paragraph (c)(2) of this section.

(2) *Minimum savings rate (MSR).* CMS computes a minimum savings rate for each ACO based on the number of beneficiaries assigned to the ACO under § 425.6 of this part. The minimum savings rates for ACOs based on the numbers of assigned beneficiaries will be as follows:

Number beneficiaries	MSR (low end of assigned beneficiaries) %	MSR (high end of assigned beneficiaries) %
5,000–5,999	3.9	3.6
6,000–6,999	3.6	3.4
7,000–7,999	3.4	3.2
8,000–8,999	3.2	3.1
9,000–9,999	3.1	3.0
10,000–14,999	3.0	2.7
15,000–19,999	2.7	2.5
20,000–49,999	2.5	2.2
50,000–59,999	2.2	2.0
60,000 +	2.0	

(3) *Qualification for shared savings payment.* In order to qualify for shared savings, an ACO must exceed its minimum savings rate determined under paragraph (c)(2) of this section, meet the minimum quality performance standards established under § 425.10 of this part, and otherwise maintain its eligibility to participate in the Shared Savings Program under this part.

(4) *Net savings threshold.* An ACO under the one-sided model that exceeds its minimum savings rate is eligible to share savings net 2 percent of its benchmark as determined under § 425.7(b). An ACO with fewer than 10,000 assigned beneficiaries in the most recent year for which CMS has complete claims data, and that meets any one of the following criteria, is exempt from the 2 percent net savings threshold adjustment under the one-sided model:

(i) All ACO participants are physicians or physician groups.

(ii) 75 percent or more of the ACO's assigned beneficiaries reside in counties outside an MSA in the most recent year for which CMS has complete claims data.

(iii) 50 percent or more of an ACO's assigned beneficiaries in the most recent year for which CMS has complete claims data were assigned on the basis of services received from Method II CAHs.

(iv) At least 50 percent of the assigned beneficiaries had at least one encounter with a participating FQHC or RHC in the most recent year for which CMS has complete claims data such that the ACO has achieved maximum sharing for this activity.

(5) *Final sharing rate.* The final sharing rate for an ACO in the one-sided model will be calculated by adding the ACO's earned quality performance sharing rate and any additional increase described in § 425.7(c)(6)) (up to the performance payment limit described in § 425.7(c)(7)).

(6) *Quality performance sharing rate.* An ACO that meets all the requirements for shared savings payments under the one-sided model will receive a shared savings payment based on quality performance of up to 50 percent, as determined on the basis of its quality performance under § 425.10 of this part.

(7) *Additional increase to the shared savings rate.* Under the one-sided model, an ACO's shared savings rate may be increased by up to 2.5 percentage points if the ACO includes a rural health clinic (RHC) or Federally qualified health center (FQHC) (as defined under § 405.2401(b) of this chapter) within its structure, determined on a sliding scale based on the number of assigned Medicare beneficiaries with one or more visit to an RHC or FQHC during the performance year. The sliding scale will operate according to the following table:

Percentage of ACO assigned beneficiaries with 1 or more visits to an FQHC/RHC during the performance year	Percentage point increase in shared savings rate (one-sided model)
1–10	0.5
11–20	1
21–30	1.5
31–40	2
41–50	2.5

(8) *Performance payment limit.* The amount of shared savings an eligible ACO receives under the one-sided model may not exceed 7.5 percent of its benchmark.

(d) *Determination of savings or losses, and shared savings or loss rates for ACOs under the two-sided model.* (1) For each performance year, CMS determines whether the estimated average per capita Medicare expenditures under the ACO for Medicare fee-for-service beneficiaries for parts A and B services, adjusted for beneficiary characteristics, is above or below the benchmark determined under paragraph (b) of this section. In order to qualify for a shared savings payment under the two-sided model, or to be responsible for sharing losses with CMS, an ACO's average per capita Medicare expenditures for the performance year must be below or above the benchmark, respectively, by more than the minimum savings or loss rate under paragraph (d)(2) of this section.

(2) *Minimum savings or loss rate.* (i) To qualify for shared savings under the two-sided model, an ACO's average per capita Medicare expenditures for the performance year must be below its benchmark costs for the year by at least 2 percent.

(ii) To be responsible for sharing losses with the Medicare program, an ACO's average per capita Medicare expenditures for the performance year must be at least 2 percent above its benchmark costs for the year.

(3) *Qualification for shared savings payment.* To qualify for shared savings, an ACO must meet the minimum savings rate requirement established under paragraph (d)(2) of this section, meet the minimum quality performance standards established under § 425.10 of this part, and otherwise maintain its eligibility to participate in the Shared Savings Program under this part.

(4) *Final sharing rate.* The final sharing rate for an ACO in the two-sided model will be calculated by adding the ACO's earned quality performance sharing rate under paragraph (d)(5) and any additional increase described in § 425.7(c)(6)) up to the performance payment limit described in § 425.7(d)(7).

(5) *Quality performance sharing rate.* An ACO that meets all the requirements for receiving shared savings payments under the two-sided model will receive a payment of up to 60 percent of all the savings under the benchmark as determined on the basis of its quality performance under § 425.10 of this part.

(6) *Additional increase to the shared savings rate.* Under the two-sided model, an ACO's shared savings rate may be increased by the following up to 5.0 percentage points if the ACO includes a RHC or FQHC (as these terms are defined under § 405.2401(b) of these regulations) within its structure, determined on a sliding scale based on the number of assigned Medicare beneficiaries with one or more visit to an RHC or FQHC during the performance year. The sliding scale will operate according to the following table:

Percentage of ACO assigned beneficiaries with 1 or more visits to an FQHC/RHC during the performance year	Percentage point increase in shared savings rate (one-sided model)
1–10	1.0
11–20	2.0
21–30	3.0
31–40	4.0
41–50	5.0

(7) *Performance payment limit.* The amount of shared savings an eligible ACO receives under the two-sided model may not exceed 10 percent of its benchmark.

(8) *Shared loss rate.* The shared loss rate for an ACO that is required to share losses with the Medicare program for expenditures over the benchmark with the Medicare program is determined based on the inverse of its final sharing rate described in paragraphs (d)(2) through (6) of this section (that is, 1 minus the shared savings rate determined under paragraphs (d)(2) through (6) of this section).

(9) *Loss recoupment limit.* The amount of shared losses for which an eligible ACO is liable may not exceed the following percentages of its benchmark as determined under paragraphs (a) and (b) of this section: 5 percent in the first year of participation in a two-sided model under the Shared Savings Program, 7.5 percent in the second year, and 10 percent in the third year. An ACO in Track 1 who has entered the third year of its agreement period would be liable for an amount not to exceed the percentage of the first year of the two-sided model, that is, it would not exceed 5 percent.

(e) *Notification of savings and losses.* CMS notifies an ACO in writing regarding whether the ACO qualifies for a shared savings payment, and if so, the amount of the payment due. Similarly, CMS will provide written notification to an ACO of the amount of shared losses, if any, that it must pay to the program. If an ACO has shared losses, the ACO must make payment in full to CMS within 30 days of receipt of notification.

§ 425.8 ACO quality and continuous improvement goals.

(a) CMS defines quality and continuous improvement goals for ACOs.

(b) An ACO must meet the quality and continuous improvement goals defined

by CMS under paragraph (a) of this section in order to qualify for shared savings.

§ 425.9 Measures to assess the quality of care furnished by an ACO.

(a) *Selecting measures.* CMS selects the measures designated to determine an ACO's success in promoting the aims of better care for individuals, better health for populations, and lower growth in expenditures.

(b) *Quality measures for quality performance standards.* (1) CMS designates the measures for use in the calculation of the quality performance standard.

(2) ACOs must submit data on the measures determined under this paragraph (b) according to the method of submission established by CMS.

§ 425.10 Calculating the ACO quality performance score and determining shared savings eligibility.

(a) *Measure domains.* CMS groups individual quality performance standard measures into five domains:

(1) Patient/care giver experience.

(2) Care coordination.

(3) Patient safety.

(4) Preventative health.

(5) At-risk population/frail elderly health.

(b) *Methodology for calculating a performance score for each measure.* (1) CMS designates quality performance standards for each measure, including a performance benchmark and minimum attainment level and establishes a point scale for certain measures. Contingent upon data availability, quality measure performance benchmarks are defined by CMS based on Medicare fee-for-service, MA, or ACO performance data.

(i) For the first performance period under the Shared Savings Program, CMS defines the quality performance standard at the level of complete and accurate reporting.

(ii) For all subsequent years, CMS defines the quality performance based on measure scores.

(2) Performance below the minimum attainment level will receive zero points for that measure, for those measures in which the points scale applies.

(3) Performance equal to or greater than the minimum attainment level but less than the performance benchmark must receive points on a sliding scale based on the level of performance, for those measures in which the points scale applies.

(4) Those measures designated as all or nothing measures receive the maximum available points if all criteria are met and zero points if at least one of the criteria are not met.

(c) *Methodology for calculating a performance score for each domain.* CMS designates quality performance standards for each domain's contribution to an overall ACO performance score.

(d) *Shared savings eligibility.* If the ACO demonstrates to CMS that it has satisfied the quality performance requirements for each domain, the requirements of § 425.7 are satisfied, and the ACO meets all other applicable requirements, the ACO is eligible for shared savings. To satisfy the quality performance requirements for a domain:

(1) The ACO must report all measures within a domain, via the mechanisms determined by CMS, in order to be considered for shared savings for that domain.

(2) CMS scores individual measures based on data received.

(3) CMS adds the individual scores for each of the measures within the domain to determine the domain scores.

(i) Each of the 5 domains is equally weighted in determining an ACO's overall quality performance score, regardless of whether the ACO is in Track 1 or Track 2. All measures within a domain must have a score above the minimum attainment level determined by CMS in order for the domain to be eligible for shared savings.

(ii) If the ACO satisfies the quality performance standards for one or more domains, and also satisfies the requirements for realizing shared savings under § 425.7, the ACO may receive the proportion of those shared savings for which it qualifies.

(iii) CMS retains the right to audit and validate quality data reported by an ACO. In an audit, the ACO would be required to provide beneficiary medical record data as requested by CMS. The audit would consist of three phases of medical record review. If, at the conclusion of the third audit process there is a discrepancy greater than 10 percent between the quality data reported and the medical records provided, the ACO will not be given credit for meeting the quality target for any measures for which this mismatch rate exists.

(iv) Failure to report quality measure data accurately, completely, and timely (or to timely correct such data) may subject the ACO to termination or other sanctions, as described in § 425.12.

(4) In the third year of the ACO's agreement under Track 1, the methodology used to reconcile ACOs under the first year of the two-sided model would apply except that ACOs must meet the quality performance standard that applies in the third year, as opposed to the first year standard of full and accurate reporting.

§ 425.11 Incorporating other reporting requirements related to the Physician Quality Reporting System and electronic health records technology.

(a) *Physician quality reporting system.* (1) ACOs, on behalf of their eligible professionals, must submit the measures determined under § 425.10(b) according to the method of submission established by CMS, to qualify for a Physician Quality Reporting System incentive under the Shared Savings Program.

(2) To qualify as a group practice for a Physician Quality Reporting System incentive under the Shared Savings Program, eligible professionals within an ACO must report the measures determined under § 425.10(b) during the reporting period according to the method of submission established by CMS under the Shared Savings Program.

(3) The Physician Quality Reporting System incentive under the Medicare Shared Savings Program is equal to 0.5 percent of the ACO's eligible professional's total estimated Medicare Part B Physician Fee Schedule allowed charges for covered professional services furnished during the calendar year reporting period from January 1 through December 31.

(b) *Electronic health records technology.* (1) At least 50 percent of an ACO's primary care physicians must be meaningful EHR users, using certified EHR technology as defined in § 495.4, in the HITECH Act and subsequent Medicare regulations by the start of the second performance year in order to continue participating in the Shared Savings Program.

(2) CMS may terminate an ACO agreement under § 425.14 of this part if fewer than 50 percent of an ACO's primary care physicians are not meaningfully EHR users, using certified EHR technology as defined in § 495.4, the HITECH Act and subsequent Medicare regulations by the start of the ACO's second performance year.

§ 425.12 Monitoring.

(a) *Monitoring of ACOs: General rule.* (1) CMS monitors and assesses the performance of ACOs and their participating providers/suppliers.

(2) CMS employs a range of methods to monitor and assess the performance of ACOs, including but not limited to any of the following, as appropriate:

(i) Analysis of specific financial and quality measurement data reported by the ACO as well as aggregated annual and quarterly reports.

(ii) Site visits.

(iii) Analysis of beneficiary and provider complaints.

(iv) Audits (including, for example, analysis of claims, chart review (medical record), beneficiary survey reviews, coding audits).

(b) *Monitoring ACO avoidance of at-risk beneficiaries.* To identify ACOs that could be avoiding at-risk beneficiaries, CMS uses a combination of the methods described in paragraph (a)(2) of this section (as appropriate) to identify trends and patterns suggestive of avoidance of at-risk beneficiaries. The results of these analyses may subsequently require further investigation and follow-up with the beneficiary or the ACO and its ACO providers/suppliers in order to substantiate cases of beneficiary avoidance. CMS may take the following actions as set forth in § 425.13(a)(4) of this part, if it determines that an ACO, its ACO participants, any ACO providers/suppliers, or contracted entities performing functions or services on behalf of the ACO avoids at-risk beneficiaries.

(1) The ACO is required to submit a CAP and implement the plan as approved by CMS as set forth in § 425.13(a)(2) of this part.

(i) The ACO will not receive any shared savings payments during the probation period, regardless of the period of performance for which savings were attributable to while under the CAP.

(ii) The ACO will not be eligible to receive shared savings for the performance period attributable to the time the ACO was under the CAP.

(iii) The ACO will not be eligible to earn shared savings attributable to the time the ACO is under the CAP.

(iv) The ACO will be re-evaluated during and after the CAP implementation period to determine if the ACO has continued to avoid at-risk beneficiaries.

(2) ACO may be terminated if CMS determines that the ACO has continued to avoid at-risk beneficiaries during or after the CAP as set forth in § 425.14 of this part.

(c) *Monitoring ACO compliance with quality performance standards.* To identify ACOs that are not meeting the quality performance standards, CMS will review the ACO's submission of quality measurement data under § 425.9(b)(2). CMS may request additional documentation from an ACO, ACO participants, or ACO providers/suppliers, as appropriate. CMS may take the following actions, in addition to actions set forth at § 425.13, if an ACO does not meet quality performance standards or fails to report on one or more quality measures.

(1) The ACO will be given a warning for the first time it fails to meet the minimum attainment level for one or more domain.

(2) The ACO's compliance with the quality performance standards will be re-evaluated the following year. If the ACO continues to fail to meet quality performance standards in the following year, the agreement may be terminated immediately or CMS may take an alternative action as set forth in § 425.13 of this part.

(3) If an ACO fails to report one or more quality measures or fails to report completely and accurately on all measures in a domain, CMS will request the ACO either to submit the required measure data, correct the data, and/or provide a written explanation as to why it did not report completely and accurately. If ACO still fails to report, fails to report by the requested deadline and/or does not provide reasonable explanation for not reporting, the ACO will be terminated immediately as set forth in § 425.14 of this part.

(4) An ACO that exhibits a pattern of inaccurate or incomplete reporting, or fails to make timely corrections following notice to resubmit, may be terminated from the program.

(d) *Monitoring changes to ACO eligibility requirements.* In order to ensure that the ACO continues to meet the eligibility requirements under § 425.5 of this part, CMS uses a combination of the methods described in paragraph (a) of this section (as appropriate).

(e) *Monitoring beneficiary notification of the provider and supplier's role in the ACO and the ability for the beneficiary to op-out of sharing claims data.* In order to ensure that the ACO is notifying beneficiaries concerning sharing of claims data as provided under § 425.15 of these regulations, and providing the opportunity for a beneficiary to opt-out of those data sharing arrangements, as required by that section, CMS uses a combination of the methods described in paragraph (a) of this section (as appropriate).

(f) *Monitoring ACO marketing materials and activities.* (1) CMS may monitor compliance with the requirement for approval of ACO marketing materials and activities set forth in § 425(d)(4).

(2) An ACO that fails to adhere to this requirement may be placed under a CAP or terminated as set forth in § 425.14 of this part, at the discretion of CMS.

§ 425.13 Actions prior to termination.

(a) If based upon the monitoring activities described in § 425.12, CMS concludes that an ACO's performance may subject the ACO to termination from the Shared Savings Program, CMS, in its sole discretion, may take one or more or all of the following actions prior to termination of the ACO from the Shared Savings Program.

(1) Provide a warning notice to the ACO of the specific performance at issue.

(2) Request a CAP from the ACO.

(i) The ACO must submit a CAP for CMS approval by CMS deadline indicated on the notice of violation.

(ii) The CAP must address what actions the ACO will take to ensure that the ACO, ACO participants, and ACO providers/suppliers and/or contracted entities performing services or functions on behalf of the ACO will correct any deficiencies and remain in compliance with Shared Savings Program requirements.

(iii) The ACO's performance will be monitored during the CAP process.

(iv) Failure to submit, obtain approval for, or implement a CAP may result in termination of the agreement.

(v) ACO failure to demonstrate improved performance upon completion of the CAP may result in termination.

(vi) This CAP process does not apply to determinations made by the Antitrust Agencies and must not be construed to negate, diminish, or otherwise alter the applicability of existing laws, rules, and regulations, or determinations made by other government agencies.

(3) Place the ACO on a special monitoring plan.

(4) These procedures do not apply to either of the following:

(i) Determinations that an ACO has violated the Sherman antitrust act (15 U.S.C. 1), Clayton Act (15 U.S.C. 12), or the Federal Trade Commission Act (15 U.S.C. 45).

(ii) Determinations made by other government agencies.

(5) The procedures established under this section do not negate, diminish, or otherwise alter the applicability of existing laws, rules, and regulations.

§ 425.14 Termination, suspension, and repayment of Shared Savings.

(a) *Grounds for terminating an ACO agreement.* CMS may terminate an agreement with an ACO if the ACO, the ACO participants, the ACO providers/suppliers or contracted entities performing services or functions on behalf of the ACO:

(1) Avoid at-risk beneficiaries.

(2) Fail to meet quality performance standards.

(3) Fail to completely and accurately report information or fail to make timely corrections to reported information.

(4) Are not in compliance with eligibility requirements or have fallen

out of compliance with the requirements of the part because the ACO has undergone material changes that affect the ACO's eligibility to participate in the Shared Savings Program, including, but not limited to changes in governing body composition, a significant change (as defined in § 425.21(b)), and the imposition of sanctions or other actions taken against the ACO by an accrediting organization, State, Federal or local government agencies.

(5) Are unable to effectuate any required regulatory changes during the agreement period after given the opportunity for a CAP as set forth in § 425.20.

(6) Are not in compliance with requirements to notify beneficiaries of ACO provider/supplier participation in an ACO.

(7) Engage in material noncompliance, or demonstrates a pattern of noncompliance, with public reporting and other CMS reporting requirements.

(8) Fail to submit an approvable CAP, fail to implement an approved CAP, or fail to demonstrate improved performance after the implementation of a CAP.

(9) Violate the physician self-referral prohibition, civil monetary penalties (CMP) law, Anti-kickback statute, other antifraud and antitrust laws (or enter into a final judgement or other final resolution of antitrust charges by an Antitrust Agency), or any other applicable Medicare laws, rules, or regulations that are relevant to ACO operations.

(10) Submit to CMS false, inaccurate, or incomplete data and or information, including but not limited to, information provided in the Shared Savings Program application, quality data, financial data, and information regarding the distribution of shared savings.

(11) Use marketing materials or participate in activities or other beneficiary communications, that are subject to review and approval, that have not been approved by CMS.

(12) Fail to maintain an assigned beneficiary population of at least 5,000 beneficiaries.

(13) Fail to offer beneficiaries the option to opt-out of sharing claims information.

(14) Limit or restrict internally compiled beneficiary summary of care or medical records from other providers/suppliers both within and outside of the Shared Savings Program to the extent permitted by law.

(15) Improperly use or disclose claims information received from CMS in violation of the HIPAA Privacy Rule, Medicare Part D Data Rule, Privacy Act, or the data use agreement.

(16) Fail to demonstrate that the ACO has adequate resources in place to repay losses and to maintain those resources for the agreement period.

(b) *Reapplication after termination.* An ACO that has been terminated from the Shared Savings Program may apply to participate in the Shared Savings Program again only after the end of the original 3-year agreement period.

(i) To be eligible to participate in the Shared Savings Program, the ACO must demonstrate in its application that it has corrected the deficiencies that caused it to be terminated from the Shared Savings Program and has processes in place to ensure that it will remain in compliance with the terms of the new participation agreement.

(ii) ACOs with corrected deficiencies that wish to reenter the program have the option to do so only under the two-sided model.

(c) *Forfeiture of mandatory withholding after termination.* If an agreement is terminated for any reason before the 3-year agreement period is completed, the ACO the ACO would forfeit its mandatory 25 percent withhold of shared savings.

(d) *Termination of an agreement by an ACO.* (1) ACO must notify CMS, its ACO participants, and other organizations of its decision to terminate 60 days before the date of termination.

(2) The ACO participants must notify beneficiaries of the ACO's decision to terminate in a timely manner.

(3) All termination notification materials must meet marketing guidelines as set forth at § 425.12(f).

(e) *Grounds for shared saving payment suspension.* If an ACO has been placed under a CAP because the ACO, ACO participants, ACO providers/suppliers, or contracted entities performing services or functions on behalf of the ACO were found to have avoided at-risk beneficiaries—

(1) The ACO must not receive shared savings payments while it is under the CAP, regardless of the period of performance it is attributable to; and

(2) The ACO is not eligible to earn any shared savings for the performance period attributable for the time the ACO was under the CAP.

§ 425.15 Reconsideration review process.

(a) There is no reconsideration, appeals, or other administrative or judicial review of the following determinations under this section:

(1) The specification of quality and performance standards under § 425.9 of this part.

(2) The assessment of the quality of care furnished by an ACO under the performance standards established in § 425.10.

(3) The assignment of Medicare fee-for-service beneficiaries under § 425.6 of this part.

(4) The determination of whether an ACO is eligible for shared savings under § 425.7(c) of this part, and the amount of such shared savings, including the determination of the estimated average per capita Medicare expenditures under the ACO for Medicare fee-for-service beneficiaries assigned to the ACO and the average benchmark for the ACO under § 425.7(a) and (b) of this part.

(5) The percent of shared savings specified by the Secretary and the limit on the total amount of shared savings established under § 425.7(c) of this part.

(6) The termination of an ACO for failure to meet the quality performance standards established under § 425.14 of this part.

(7) A determination made by the reviewing antitrust agency that it is likely to challenge or recommend challenging the ACO.

(b) An ACO may appeal an initial determination that is not prohibited from administrative or judicial review under paragraph (a) of this section by requesting a reconsideration review by a CMS reconsideration official.

(1) An ACO that wants to request reconsideration review by a CMS reconsideration official must submit a written request by an authorized official for receipt by CMS within 15 days of the notice of the initial determination.

(i) If the 15th day is a weekend or a Federal holiday, then the timeframe is extended until the end of the next business day.

(ii) Failure to submit a request for reconsideration within 15 days will result in denial of the request for reconsideration.

(2) The reconsideration review may be held orally (that is, in person, by telephone or other electronic means) or on the record (review submitted documentation) at the discretion of the reconsideration official.

(3) The reconsideration official will send an acknowledgement of the reconsideration review request to the ACO and CMS that includes the following:

(A) Review procedures.

(B) Procedures for submission of evidence including format and timelines.

(C) Date, time and location of the review. The reconsideration official may, on his or her own motion, or at the request of CMS or the ACO, change the time and place for the reconsideration

review, but must give the parties to the reconsideration review notice of the change.

(4) The burden of proof is on the ACO to demonstrate to the reconsideration official with convincing evidence that the initial determination is not consistent with CMS' regulations or statutory authority.

(i) The reconsideration official's review will be based only on evidence submitted by the reconsideration official's requested deadline, unless requested by the reconsideration official.

(ii) Documentation submitted for the record as evidence cannot be documentation that was not previously submitted to CMS by its required applicable timelines and in the requested format.

(iii) All evidence submitted both from the applicant and CMS, in preparation for the reconsideration review will be shared with participating parties prior to the scheduled date of the hearing, as indicated in the acknowledgement notice.

(iv) All parties will be notified of the reconsideration official's recommendation.

(c) If any of the parties disagree with the recommendation of the reconsideration official, they may request an on the record review of the initial determination and recommendation by an independent CMS official who was not involved in the initial determination or the reconsideration review process.

(1) Any party that wishes to request an on the record review of the reconsideration official's recommendation must submit an explanation of why they disagree with the recommendation by the timeframe and in the format indicated on the recommendation letter.

(2) The on the record review process will be based only on evidence presented for the reconsideration review.

(3) The CMS official will consider the recommendation of the reconsideration official and make a final agency determination.

(d) CMS's decision after review of the reconsideration official's recommendation is final and binding.

(e) The review process under this section shall not be construed to negate, diminish, or otherwise alter the applicability of existing laws, rules, and regulations or determinations made by other government agencies.

(f) If CMS' initial decision to deny an ACO's application to participate in the Shared Savings Program is upheld, the application will remain denied based on the effective date of the original notice of denial.

(g) An ACO that requests a reconsideration review for termination will remain operational throughout the review process. If CMS initial determination to terminate the agreement with the ACO is upheld, termination of the agreement is effective as indicated in the initial notice of termination.

(1) If CMS' initial determination to terminate an agreement with an ACO is upheld, the decision to terminate the agreement is effective as of the date indicated in the initial notice of termination.

(2) If CMS' initial determination to terminate an ACO is reversed, the ACO is reinstated into the Shared Savings Program, retroactively back to the original date of termination.

§ 425.16 Audits and record retention.

(a) *Right to audit.* The ACO must agree, and must require its ACO participants, ACO providers/suppliers, and contracted entities performing services or functions on behalf of the ACO to agree, that the DHHS the Comptroller General, the OIG or their designees have the right to audit, inspect, and evaluate any books, contracts, records, documents and other evidence of the ACO, ACO participants, and ACO providers/suppliers, and other contracted entities that pertain to—

(1) The ACO's compliance with program requirements;

(2) The quality of services performed and determination of amount due to or from CMS under the contract; and

(3) The ability of the ACO to bear the risk of potential losses and to repay any losses to CMS.

(b) *Maintenance of records.* An ACO must agree, and must require its ACO participants, ACO providers/suppliers, and contracted entities performing functions or services on behalf of the ACO to agree to the following:

(1) To maintain and give DHHS, OIG, the Comptroller General, or their designees access to all books, contracts, records, documents, and other evidence (including data related to Medicare utilization and costs, quality performance measures, shared savings distributions, and other financial arrangements related to ACO activities) sufficient to enable the audit, evaluation, and inspection of the ACO's compliance with program requirements, quality of services performed, right to any shared savings payment, or obligation to repay losses, ability to bear the risk of potential losses, and ability to repay any losses to CMS.

(2) To maintain such books, contracts, records, documents, and other evidence for a period of 10 years from the final date of the agreement period or from the date of completion of any audit, evaluation, or inspection, whichever is later, unless—

(i) CMS determines there is a special need to retain a particular record or group of records for a longer period and notifies the ACO at least 30 days before the normal disposition date;

(ii) There has been a termination, dispute, or allegation of fraud or similar fault by the ACO, its ACO participants, its ACO providers/suppliers, or contracted entities that perform functions or services on behalf of the ACO, in which case ACOs must retain records for an additional 6 years from the date of any resulting final resolution of the termination, dispute, or allegation of fraud or similar fault.

(iii) There is a reasonable possibility of fraud or similar fault by the ACO or its participating providers/suppliers, or contracted entities performing services or functions on behalf of the ACO, in which case CMS may inspect, evaluate, and audit the ACO at any time.

(c) Notwithstanding any arrangements between or among an ACO, ACO participants, ACO providers/suppliers, and contracted entities performing functions or services on behalf of the ACO, the ACO must have ultimate responsibility for adhering to and otherwise fully complying with all terms and conditions of its agreement with CMS, including the requirements set forth in this section.

§ 425.17 Requirements for data submission by ACOs.

(a) ACOs must submit data in a form and manner specified by CMS on the measures designated by CMS under § 425.9 of this part.

(b) ACOs that successfully must, on behalf of their eligible professionals, submit the measures designated by CMS under § 425.9 according to the method of submission established under the Shared Savings Program for purposes of the quality data requirements will be considered satisfactory reporters for purposes of the Physician Quality Reporting System incentive under § 425.11(a).

§ 425.18 The 3-year agreement with CMS

(a) *General rule.* In order to participate in the Shared Savings Program, an ACO must enter into an agreement with CMS. ACO applications must be submitted by the deadline established by CMS. CMS will determine whether to approve or deny applications from eligible organizations

prior to the end of the calendar year in which the applications are submitted.

(b) *An ACO's duration of agreement.* The participation agreement must be for a term of 3 years, starting on the January 1 following approval of an application or such other date specified in the agreement.

(c) *Performance period.* Unless otherwise specified, the ACO's annual performance period under the agreement must be the 12-month period beginning on January 1 of each year during the term of the agreement.

§ 425.19 Data sharing with ACOs.

(a) *General rules.* CMS shares both aggregate and beneficiary identifiable data with ACOs under the following general conditions:

(1) The ACO does not unnecessary limitations or restrictions on the use or disclosure of individually identifiable health information that it internally compiles from providers and suppliers both within and outside of the ACO.

(2) The ACO observes all relevant statutory and regulatory provisions regarding the appropriate use of data and the confidentiality and privacy of individually identifiable health information and complies with the terms of the data use agreement described in paragraph (f) of this section.

(b) *Sharing aggregate data.* (1) CMS shares aggregate data (data that omits the 18 identifiers listed at 45 CFR 164.514(b) with ACOs as follows:

(i) Aggregate data reports at the start of the agreement period based on the historical beneficiaries used to calculate the benchmark, and each quarter thereafter during the agreement period.

(ii) Quarterly reports will be based upon the most recent 12 months of data for beneficiaries that could potentially be assigned to the ACO under the assignment methodology in § 425.6. These data will not include beneficiary identifying information, but will include de-identified claims history of the services rendered for the ACO's assigned FFS beneficiaries, as determined under § 425.6 of this part.

(2) These aggregate data reports will include, when available, the following information:

(i) Financial performance.

(ii) Quality performance scores.

(iii) Aggregated metrics on the assigned beneficiary population.

(iv) Utilization data at the start of the agreement period based on historical beneficiaries used to calculate the benchmark.

(c) Identification of historically assigned beneficiaries used to calculate the benchmark established under § 425.7.

(1) At the beginning of the agreement period, and at the end of each performance period, CMS will, upon the ACO's request for the data for purposes of population-based activities relating to improving health or reducing health care costs, protocol development, case management, and care coordination, provide the ACO the following data about each beneficiary that was included in the records used under § 425.7(a) and (b) of this part to generate the ACO's benchmark:

(i) Beneficiary names.

(ii) Date of birth.

(iii) HICN.

(2) In its request for these data, the ACO must certify that it is seeking the following information:

(i) As a HIPAA covered entity, and the request reflects the minimum data necessary for the ACO to conduct its own health care operations work that falls within the first or second paragraph of the definition of health care operations at 45 CFR 164.501.

(ii) As the business associate of its ACO participants, who are HIPAA covered entities, and the request reflects the minimum data necessary for the ACO to conduct health care operations work that falls within the first or second paragraph of the definition of health care operations at 45 CFR 164.501 on behalf of those participants.

(d) *Sharing beneficiary identifiable data.* Subject to the opt-out described in this paragraph (g) of this section, CMS will, upon the ACO's request for the data for purposes of evaluating ACO provider/supplier performance, conducting quality assessment and improvement activities, and conducting population-based activities relating to improved health, provide the ACO with monthly claims data for potentially assigned beneficiaries.

(1) If an ACO wishes to receive beneficiary identifiable claims data, it must either request these data as part of the application process or later submit a formal request for data.

(2) The ACO must certify that it is requesting claims data about either of the following:

(i) Its own patients, as a HIPAA covered entity, and the request reflects the minimum data necessary for the ACO to conduct its own health care operations work that falls within the first or second paragraph of the definition of health care operations at 45 CFR 164.501.

(ii) The patients of its HIPAA covered entity ACO participants as the business associate of these HIPAA covered entities, and the request reflects the minimum data necessary for the ACO to conduct health care operations work that falls within the first or second paragraph of the definition of health care operations at 45 CFR 164.501 on behalf of those participants.

(3) The use of identifiers and claims data will be limited to developing processes and engaging in appropriate activities related to coordinating care and improving the quality and efficiency of care that are applied uniformly to all Medicare beneficiaries assigned to the ACO, and that these data will not be used to reduce, limit or restrict care for specific beneficiaries.

(4) To ensure that beneficiaries have a meaningful opportunity to opt-out of having their claims data shared with the ACO, the ACO may only request such claims data about a beneficiary if—

(i) The beneficiary has been seen in the office of a participating primary care physician (as defined in § 425.4 of this part), during the performance year,

(ii) The beneficiary was informed about how the ACO intends to use beneficiary identifiable claims data in order to improve the quality of care that is furnished to the beneficiary and, where applicable, coordinate care offered to the beneficiary; and

(iii) The beneficiary did not exercise the opportunity to opt-out of having his/her claims data shared with the ACO as provided in paragraph (g) of the section.

(5) CMS will continue to provide ACOs with certain beneficiary identifiable claims data on a monthly basis, subject to beneficiary's opportunity to opt-out of the data sharing under paragraph (g) of this section.

(6) If an ACO requests beneficiary identifiable information, compliance with the terms of the data use agreement described in paragraph (f) of this section is a condition of an ACO's participation in the Shared Savings Program.

(e) *Minimum necessary data set.* (1) The minimum necessary Parts A and B data elements may include the following data elements:

(i) Beneficiary ID.

(ii) Date of birth.

(iii) Gender.

(iv) Date of death.

(v) Claim ID.

(vi) The from and through dates of service.

(vii) The provider or supplier ID.

(viii) The claim payment type.

(2) The minimum necessary Part D data elements may include the following data elements:

(i) Beneficiary ID.

(ii) Prescriber ID.

(iii) Drug service date.

(iv) Drug product service ID.

(v) Quantity dispensed.

(vi) Days supplied.

(vii) Gross drug cost.
(viii) Brand name.
(ix) Generic name.
(x) Drug strength.
(xi) Indication if the drug is on the formulary, as designated by CMS.

(f) *Data Use Agreement.* Prior to receiving any beneficiary identifiable data, ACOs must enter into a DUA with CMS. The DUA must—

(1) Specify that the ACO will comply with the limitations on the use and disclosure of individually identifiable health information that the HIPAA Privacy Rule places on HIPAA covered entities, as well as all other applicable privacy and confidentiality requirements;

(2) Prohibit the ACO from using the data received under the Shared Savings Program for any prohibited use of individually identifiable health information.

(3) Specify that if an ACO misuses or discloses data in a manner that violates any applicable statutory or regulatory requirements or that is otherwise non-compliant with the provisions of the DUA, it will no longer be eligible to receive data, could potentially be terminated from the shared savings program as well as subject to additional sanctions and penalties available under the law.

(g) *Beneficiary opportunity to opt-out of claims data sharing.* (1) Prior to requesting claims data about a particular beneficiary, the ACO must inform the beneficiary that it may request personal health information about the beneficiary for purposes of its care coordination and quality improvement work, and give the beneficiary meaningful opportunity to opt-out of having his/her claims information shared with the ACO.

(2) The ACO must supply beneficiaries with a form allowing them to opt-out of data sharing. The form must be provided to each beneficiary as part of an office visit with a primary care physician as defined under § 425.4, whose services are used to assign beneficiaries to the ACO.

(3) This requirement will not apply to the initial four data points that CMS will provide to ACOs for individuals in the 3-year base data set (Beneficiary Name, Beneficiary DOB, Beneficiary Sex, and Beneficiary HICN) under paragraph (c) of this section.

§ 425.20 New program standards established during the 3 year agreement period.

(a)(1) ACOs will be subject to all statutory changes.

(2) ACOs will be subject to all regulatory changes with the exception of the following program areas:

(i) Eligibility requirements concerning the structure and governance of ACOs.
(ii) Calculation of sharing rate.
(iii) Beneficiary assignment.

(b) In those instances where changes in law or regulations require, or otherwise cause an ACO to change its processes in a manner that affects the design of its care processes and delivery of care, changes to the quality of care, or changes in planned distribution of shared savings, the ACO will be required to submit to CMS for review and approval a supplement to its original application detailing how it will address key changes in processes resulting from these modifications.

(c) If an ACO cannot effectuate the changes needed to adhere to the regulatory modifications after being given an opportunity to act upon a CAP, the ACO would be terminated from the program.

(d) Nothing in the regulations under this part shall be construed to affect the payment, coverage, program integrity, and other requirements that apply to providers and suppliers under FFS Medicare.

§ 425.21 Managing significant changes to the ACO during the agreement period.

(a)(1) During the 3-year agreement, an ACO may remove, but not add, ACO participants (identified by TINs), and it may remove or add ACO providers/suppliers (identified by NPI and/or TIN).

(2) ACOs must notify CMS at least 30 days prior to any significant change, as defined in paragraph (b).

(3) CMS will review the ACO's notification and make one of the following determinations:

(i) The ACO may continue to operate under the new structure with savings calculations for the performance year based upon the updated list of ACO participant TINs.

(ii) The ACO structure is so different from the initially approved ACO that it must submit a new application, and, if applicable, undergo an antitrust review.

(iii) The ACO is materially different from the initially approved ACO because of the inclusion of additional ACO providers/suppliers such that, in order to continue in the program, the ACO must obtain an antitrust review and a letter from the reviewing Antitrust Agency stating that it has no present intent to challenge, or to recommend challenging, the ACO. An ACO's failure to timely request antitrust review shall be deemed to constitute voluntary termination of its 3-year agreement.

(iv) The ACO no longer meets the eligibility criteria for the program and its 3-year agreement must be terminated.

(v) CMS and the ACO may mutually decide to terminate the agreement.

(b) A "significant change" occurs when an ACO is unable to fulfill its 3-year agreement due to:

(i) Deviation from its approved application such as a reorganization of the ACO's legal structure or other changes in eligibility.

(ii) A material change as defined in § 425.14.

(iii) Government-required reorganization as a result of fraud or antitrust concerns.

(c) The ACO must notify CMS within 30 days of the event for reevaluation of its eligibility to continue to participate in the Shared Savings Program.

(d) ACO participants continue to be subject to all requirements applicable to fee-for-service Medicare, including routine CMS business operation updates, and changes in fee-for-service coverage decisions.

§ 425.22 Future participation of previous Shared Savings Program participants.

(a) The ACO must disclose to CMS whether the ACO, its ACO participants, or its ACO providers/suppliers have participated in the Medicare program under the same or a different name, or is related to or has an affiliation with another Shared Savings Program ACO. The ACO must specify whether the related ACO was terminated or withdrew voluntarily from the program.

(b) If the ACO was previously terminated from the program, the applicant must identify the cause of termination and what safeguards are now in place to enable the applicant ACO to participate in the program for the full of the three-year agreement period. For new ACOs, this should be disclosed on a prospective ACO's application. For ACOs that are already participating in the Shared Savings Program, this information should be included in the annual updates that the ACOs will provide to CMS on their ACO participants and ACO providers/suppliers.

§ 425.23 Public reporting and transparency.

For purposes of the shared savings program, each ACO will publicly report the following information regarding the ACO a standardized format specified by CMS:

(a) Name and location.
(b) Primary contact.
(c) Organizational information including all of the following:

(1) Participating providers of services and suppliers.

(2) Identification of participants in joint ventures between ACO professionals and hospitals.

(3) Identification of the representatives on its governing body.

(4) Associated committees and committee leadership.

(5) Quality performance standard scores.

(d) Shared savings or losses information, including the amount of any shared savings performance payment received by the ACOs or shared losses owed to CMS.

(e) Total proportion of shared savings that was distributed among ACO participants and total proportion that was used to support quality performance and the aims of better care for individuals, better health for populations, and lower growth in expenditures.

§ 425.24 Overlap with other CMS Shared Savings initiatives.

(a) Medicare providers and suppliers may not participate in the Shared Savings Program as ACO participants if they participate in the independence at home medical practice pilot program under section 1866E of the Act, a model tested or expanded under section 1115A of the Act that involves shared savings, or any other Medicare initiative that involves shared savings. CMS will review and reject an ACO's application if ACO participants are participating in another Medicare initiative that involves shared savings payments so that beneficiaries are assigned to only one such initiative and in order to avoid duplicate shared savings payments.

(b) PGP demonstration sites applying for participation to the Shared Savings Program will be required to complete a condensed application form.

(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: *March 29, 2011.*

Kathleen Sebelius,

Secretary.

[FR Doc. 2011–7880 Filed 3–31–11; 11:15 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–1345–NC2]

Office of the Inspector General

RIN 0938–ZB05

Medicare Program; Waiver Designs in Connection With the Medicare Shared Savings Program and the Innovation Center

AGENCY: Centers for Medicare & Medicaid Services (CMS) and Office of the Inspector General (OIG), HHS.

ACTION: Notice with comment period.

SUMMARY: Section 1899(f) of the Social Security Act (of the Act), as added by the Affordable Care Act (ACA) authorizes the Secretary to waive certain fraud and abuse laws as necessary to carry out the provisions of section 1899 of the Act (the Medicare Shared Savings Program). This notice with comment period describes and solicits public input regarding possible waivers of the application of the Physician Self-Referral Law, the Federal anti-kickback statute, and certain civil monetary penalties (CMP) law provisions to specified financial arrangements involving accountable care organizations (ACOs) under the Medicare Shared Savings Program. In addition, section 1115A(d)(1) of the Act, as added by section 3021 of the ACA, authorizes the Secretary to waive the same fraud and abuse laws, among others, as necessary solely for the purposes of carrying out the provisions of section 1115A of the Act with respect to the testing of certain innovative payment and service delivery models by the Center for Medicare and Medicaid Innovation. This notice with comment period also solicits public input regarding that separate waiver authority.

DATES: To assure consideration, public comments must be delivered to the address provided below by no later than 5 p.m. on June 6, 2011.

ADDRESSES: In commenting, please refer to file code CMS–1345–NC2. 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):

- *Electronically.* You may submit electronic comments on this regulation to *http://www.regulations.gov.* Follow the "Submit a comment" instructions.
- *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–1345–NC2, P.O. Box 8013, Baltimore, MD 21244–8013.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

- *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–1345–NC2, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.
- *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.

Comments received by CMS will be shared with OIG.

For information on viewing public comments, *see* the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: Neal Shah (410) 786–1167 or Troy Barsky (410) 786–8873, for general issues and issues related to the Physician Self-Referral Law. James A. Cannatti III (202) 619–0335, for general issues and issues related to the anti-kickback statute or civil monetary penalties.

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. Medicare Shared Savings Program: Background

A. Introduction

This notice with comment period seeks public comment on proposed waivers of sections 1128A(b)(1) and (2), 1128B(b)(1) and (2), and 1877(a) of the Social Security Act (of the Act) in the specific circumstances described below, as necessary to carry out the provisions of section 1899 of the Act (as added by section 3022 of the Patient Protection and Affordable Care Act (Pub. L. 111–148), as amended by the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152) (collectively, the "Affordable Care Act")). We seek to address application of these fraud and abuse laws to accountable care organizations (ACOs [1]) formed in connection with the Medicare Shared Savings Program [2] so that the laws do not unduly impede development of beneficial ACOs, while also ensuring that ACO arrangements are not misused for fraudulent or abusive purposes that harm patients or Federal health care programs. Elsewhere in this issue of the **Federal Register**, the Centers for Medicare & Medicaid Services (CMS) published a proposed rulemaking

[1] For purposes of this notice with comment period, the terms "ACO," "ACO participants," and "ACO providers/suppliers" have the meanings ascribed to them in the Medicare Shared Savings Program proposed rule.

[2] We note that some ACOs may also operate under arrangements with private payers. We address waivers as they might relate to how ACOs distribute payments from private payers in section III. of this notice with comment period.

setting forth proposed requirements for ACOs under the Medicare Shared Savings (hereinafter referred to as the Medicare Shared Savings Program proposed rule). Section 3022 of the Affordable Care Act describes the Medicare Shared Savings Program as a program to promote accountability for a patient population, coordinate items and services under Parts A and B, and encourage investment in infrastructure and redesigned care processes for high quality and efficient service delivery. As described in the Medicare Shared Savings Program proposed rule, the Medicare Shared Savings Program is designed to achieve three goals: better health, better care, and lower cost. CMS's expectation is that ACOs will help foster a new approach to delivering care that reduces fragmented or unnecessary care and excessive costs for Medicare fee-for-service beneficiaries and other patients.

The Physician Self-Referral Law, the anti-kickback statute, and the civil monetary penalty (CMP) provision addressing hospital payments to physicians to reduce or limit services, discussed elsewhere in this notice with comment period, are important tools to protect patients and the Federal health care programs from fraud, improper referral payments, unnecessary utilization, underutilization, and other harms. However, stakeholders have expressed concern that the restrictions these laws place on certain financial arrangements between physicians, hospitals, and other individuals and entities may impede development of some of the innovative integrated-care models envisioned by the Medicare Shared Savings Program. Section 1899(f) of the Act authorizes the Secretary to waive these and certain other laws as necessary to carry out the Medicare Shared Savings Program.

In section II. of this notice with comment period, we set forth proposals for waivers of these fraud and abuse laws that we believe, based on public input and our own analysis, may be necessary to carry out the Medicare Shared Savings Program. We seek public comment on these proposed waivers. In section III. of this notice with comment period, we solicit public input on the possibility of additional or different waivers, as well as input on other related considerations.

We expect to issue waivers applicable to ACOs participating in the Medicare Shared Savings Program concurrently with CMS's publication of final regulations for the Medicare Shared Savings Program. The requirements of the final regulations will bear on the scope of any waivers granted for the Medicare Shared Savings Program. Because of the close nexus between the final regulations governing the structure and operation of ACOs under the Medicare Shared Savings Program and the development of waivers necessary to carry out the provisions of the Medicare Shared Savings Program, we may consider comments submitted in response to the Medicare Shared Savings Program proposed rule and the provisions of the Medicare Shared Savings Program final rule when crafting waivers applicable to the Medicare Shared Savings Program. CMS may also consider comments received in response to this notice with comment period when finalizing its regulations for the Medicare Shared Savings Program.

B. Section 1899 of the Social Security Act

Section 1899 of the Act establishes the Medicare Shared Savings Program to encourage the development of ACOs in Medicare. The Medicare Shared Savings Program is one of the first initiatives that will be implemented under the Affordable Care Act aimed specifically at improving "value" in the Medicare program—that is, both higher quality and lower total expenditures for individual Medicare beneficiaries and the Medicare program. Section 1899 of the Act encourages ACOs to promote accountability for individual Medicare beneficiaries and population health management, improve the coordination of patient care under Parts A and B, and encourage investment in infrastructure and redesigned care processes for high quality and efficient service delivery. The redesigned care processes developed by ACOs should also improve care and lower costs for all patients served by the ACO.

As proposed in the Medicare Shared Savings Program proposed rule, ACOs will enter into an agreement with the Secretary to participate in the Medicare Shared Savings Program for not less than a 3-year period under one of two tracks. Under the first track, an ACO would have the opportunity to share in actual savings during the first 2 years of the agreement. During the third year, the ACOs would be in a "two-sided risk" model in which they would be eligible to receive a higher potential shared savings, but also would be required to repay the Medicare program if costs for the ACO's aligned beneficiaries exceed certain thresholds. Under the second track, ACOs would operate under the two-sided risk model from the beginning of their agreement period. Under either model, in order to share a percentage of achieved savings with the Medicare program, ACOs must successfully meet quality and savings requirements and certain other conditions under the Medicare Shared Savings Program. ACO participants and ACO providers/suppliers will continue to receive fee-for-service payments, and the ACO legal entity may choose how it distributes shared savings or allocates risk among its ACO participants and its ACO providers/suppliers.

C. Waiver Authority Under Section 1899(f) of the Act

Section 1899(f) of the Act provides that "[t]he Secretary may waive such requirements of sections 1128A and 1128B and title XVIII of [the] Act as may be necessary to carry out the provisions of [section 1899 of the Act]." This waiver authority is specific to the Medicare Shared Savings Program, and does not address other similar integrated-care delivery models. We may consider waivers (where authorized under the Affordable Care Act), exceptions, or safe harbors, as applicable, for other types of ACOs, integrated-care delivery models, or financial arrangements at a later date.

We note that a waiver of a specific fraud and abuse law is not needed for an arrangement to the extent that the arrangement: (1) Does not implicate the specific fraud and abuse law; or (2) implicates the law, but either fits within an existing exception or safe harbor, as applicable, or does not otherwise violate the law. We note further that many exceptions and safe harbors already exist that might apply to ACO arrangements, depending on the circumstances.

D. Fraud and Abuse Laws—Background

1. Physician Self-Referral Law (Section 1877 of the Act)

Section 1877 of the Act (42 U.S.C. 1395nn, the "Physician Self-Referral Law") is a civil statute that prohibits physicians from making referrals for Medicare "designated health services," including hospital services, to entities with which they or their immediate family members have a financial relationship, unless an exception applies. These entities may not bill Medicare for services rendered as a result of a prohibited referral and section 1877(g)(1) of the Act states that no payment may be made for prohibited designated health service referrals. Civil monetary penalties also apply to any person who presents (or causes to be presented) a bill for services for which he or she knows or should know payment may not be made under section 1877(g)(1) of the Act. For additional

details, *see* section 1877(g)(3) of the Act. Violations of the statute may also result in liability under the False Claims Act (31 U.S.C. 3729–33).

2. The Anti-Kickback Statute (Section 1128B(b) of the Act)

Section 1128B(b) of the Act (42 U.S.C. 1320a-7b(b), the "anti-kickback statute") provides criminal penalties for individuals or entities that knowingly and willfully offer, pay, solicit, or receive remuneration to induce or reward the referral of business reimbursable under any of the Federal health care programs, as defined in section 1128B(f) of the Act. The offense is classified as a felony and is punishable by fines of up to $25,000 and imprisonment for up to 5 years. Violations of the anti-kickback statute may also result in the imposition of CMPs under section 1128A(a)(7) of the Act (42 U.S.C. 1320a-7a(a)(7)), program exclusion under section 1128(b)(7) of the Act (42 U.S.C. 1320a-7(b)(7)), and liability under the False Claims Act (31 U.S.C. 3729–33). Certain practices that meet all of the conditions of a statutory exception at section 1128B(b)(3) of the Act or regulatory safe harbor at 42 CFR 1001.952 are not subject to prosecution or sanctions under the anti-kickback statute.

3. Prohibition on Hospital Payments to Physicians To Induce Reduction or Limitation of Services (Sections 1128A(b)(1) and (2) of the Act)

Sections 1128A(b)(1) and (2) of the Act (the "Gainsharing CMP") apply to certain payment arrangements between hospitals and physicians, including arrangements commonly referred to as "gainsharing" arrangements. Under section 1128A(b)(1) of the Act, a hospital is prohibited from making a payment, directly or indirectly, to induce a physician to reduce or limit services to Medicare or Medicaid beneficiaries under the physician's direct care. Hospitals that make (and physicians who receive) such payments are liable for CMPs of up to $2,000 per patient covered by the payments (sections 1128A(b)(1) and (2) of the Act).

E. Summary of Public Input Opportunities

Since the passage of the Affordable Care Act, the U.S. Department of Health and Human Services (DHHS) has offered numerous opportunities for the public to provide input into the design and operation of ACOs and waivers necessary to carry out the provisions of the Medicare Shared Savings Program. For example, CMS issued a Request for Information Regarding Accountable Care Organizations and the Medicare Shared Saving Program on November 10, 2010,[3] and held multiple listening sessions with stakeholders. CMS, OIG, and the Federal Trade Commission held a joint workshop on October 5, 2010, entitled "Workshop Regarding Accountable Care Organizations, and Implications Regarding Antitrust, Physician Self-Referral, Anti-Kickback, and Civil Monetary Penalty (CMP) Laws."[4] We also received and reviewed written public comments in connection with the workshop.[5] Through these means, the DHHS has received public input representing a wide spectrum of views.

There appears to be a general consensus among public stakeholders that ACOs have the potential to change health care delivery in a manner that improves patient care, and that some waivers of the fraud and abuse laws may be necessary to facilitate their operations. However, in general, no clear consensus has emerged on the scope of the waivers necessary to carry out the Medicare Shared Savings Program, perhaps because the relevant regulations have not yet been published. Moreover, it is possible that the Medicare Shared Savings Program final regulations will include additional modifications in response to public comments to the proposed regulations. Therefore, our approach is to propose and solicit comments on possible waivers in section II. of this notice with comment period, and to solicit comments on different, potentially broader waivers, as well as additional waiver design considerations, in section III. of this notice with comment period. This approach will facilitate full and informed stakeholder input on, and government consideration of, these important, inter-connected issues.

II. Medicare Shared Savings Program: Proposed Waivers

We currently contemplate that, pursuant to the authority granted under section 1899(f) of the Act, the Secretary would waive sections 1128A(b)(1) and (2), 1128B(b)(1) and (2), and 1877(a) of the Act in the specific circumstances described below. The waivers would not apply to any other provisions of Federal or State law. All financial arrangements not covered by a waiver would be required to comply with existing laws. We invite the public to comment on the proposed waivers described in this section.

To promote efficiency and ease of use, it is our intent to promulgate waivers that will be consistent across the fraud and abuse laws to the extent possible given the different scope and structure of the laws. We also intend to apply these waivers uniformly to all qualified ACOs, ACO participants, and ACO providers/suppliers participating in the Medicare Shared Savings Program.

A. Threshold Qualification for Proposed Waivers

In order to qualify for any of the proposed waivers described in section II.B. of this notice with comment period—

- ACOs would be required to enter into an agreement with CMS to participate in the Medicare Shared Savings Program; and
- ACOs, ACO participants, and ACO providers/suppliers would be required to comply with the agreement, section 1899 of the Act, and its implementing regulations (including, without limitation, all transparency, reporting, and monitoring requirements).

B. Scope of the Proposed Waivers

1. Physician Self-Referral Law (Section 1877(a) of the Act)

Under this proposal, the Secretary would waive application of the provisions of section 1877(a) of the Act (42 U.S.C. 1395nn(a)) to distributions of shared savings received by an ACO from CMS under the Medicare Shared Savings Program: (1) To or among ACO participants, ACO providers/suppliers, and individuals and entities that were ACO participants or ACO providers/suppliers during the year in which the shared savings were earned by the ACO; or (2) for activities necessary for and directly related to the ACO's participation in and operations under the Medicare Shared Savings Program. Our intent with this proposal would be to protect financial relationships created by the distribution of shared savings within the ACO, as well as financial relationships created by a distribution of shared savings outside the ACO, but only if the distribution outside the ACO relates closely to the requirements for an ACO under section 1899 of the Act, including achieving the quality and savings goals of the Medicare Shared Savings Program. We do not intend to protect distributions of shared savings dollars to referring physicians outside the ACO, unless those referring physicians are being compensated (using shared savings) for activities necessary for and directly related to the

[3] 75 FR 70165 (2010).

[4] Information about the workshop is available on CMS's Web site at *http://www.cms.gov/center/physician.asp.*

[5] The public comments are available on the FTC's Web site at *http://www.ftc.gov/os/comments/aco/index.shtm.*

ACO's participation in and operations under the Medicare Shared Savings Program. Other financial relationships with referring physicians outside the ACO would need to meet an existing exception under the Physician Self-Referral Law (for example, the fair market value, personal services, or indirect compensation exceptions).

This proposed waiver would be limited to distributions of shared savings; all other financial relationships involving physicians (or their immediate family members) or entities participating in the Medicare Shared Savings Program that implicate the Physician Self-Referral Law would still need to satisfy an existing exception.

2. The Anti-Kickback Statute (Sections 1128B(b)(1) and (2) of the Act)

Under this proposal, the Secretary would waive application of the provisions of sections 1128B(b)(1) and (2) of the Act (42 U.S.C. 1320a–7b(b)(1)–(2)) with respect to the following two scenarios:

- Distributions of shared savings received by an ACO from CMS under the Medicare Shared Savings Program: (1) To or among ACO participants, ACO providers/suppliers, and individuals and entities that were ACO participants or ACO providers/suppliers during the year in which the shared savings were earned by the ACO; or (2) for activities necessary for and directly related to the ACO's participation in and operations under the Medicare Shared Savings Program.
- Any financial relationship between or among the ACO, ACO participants, and ACO providers/suppliers necessary for and directly related to the ACO's participation in and operations under the Medicare Shared Savings Program that implicates the Physician Self-Referral Law and fully complies with an exception at 42 CFR 411.355 through 411.357.

As with the proposed waiver of the Physician Self-Referral Law described previously, our intent with the proposal under the first bulleted paragraph would be to protect financial arrangements created by the distribution of shared savings within the ACO, as well as financial arrangements created by a distribution of shared savings outside the ACO, but only if the distribution outside the ACO is for activities necessary for and directly related to the ACO's participation in and operations under the Medicare Shared Savings Program. We do not intend to protect distributions of shared savings dollars to referral sources outside the ACO, unless those referral sources are being compensated (using shared savings) for activities necessary for and directly related to the ACO's participation in and operations under the Medicare Shared Savings Program. Other financial arrangements outside the ACO would need to fit in a safe harbor or otherwise comply with the anti-kickback statute.

Our intent with the proposal under the second bulleted paragraph would be to protect under the anti-kickback statute those financial relationships between and among the ACO, its ACO participants, and its ACO providers/suppliers that relate closely to the ACO's operations under section 1899 of the Act, but only if the relationship implicates the Physician Self-Referral Law and fits squarely in an exception. Ordinarily, compliance with an exception to the Physician Self-Referral Law does not operate to immunize conduct under the anti-kickback statute, and arrangements that comply with the Physician Self-Referral Law are still subject to scrutiny under the anti-kickback statute. Here, however, in light of the specific safeguards proposed to be incorporated in the Medicare Shared Savings Program, the authority under section 1899(f) of the Act for the Secretary to waive the anti-kickback statute as necessary to carry out section 1899 of the Act, and our desire to minimize burdens on entities establishing ACOs under section 1899 of the Act, we are proposing a limited exception to the general rule.

Failure to qualify for one of the proposed waivers under the anti-kickback statute would not mean that an arrangement is automatically illegal under the anti-kickback statute. To the extent that the anti-kickback statute is implicated by a financial arrangement that is not subject to a waiver, the financial arrangement would need to comply with the law. We note that the same financial arrangement might violate the Physician Self-Referral Law and would need to be analyzed for compliance with that law.

3. Prohibition on Hospital Payments to Physicians To Induce Reduction or Limitation of Services (Sections 1128A(b)(1) and (2) of the Act)

Under this proposal, the Secretary would waive application of the provisions of sections 1128A(b)(1) and (2) of the Act (42 U.S.C. 1320a–7a(b)(1) and (2)) with respect to the following two scenarios:

- Distributions of shared savings received by an ACO from CMS under the Medicare Shared Savings Program in circumstances where the distributions are made from a hospital to a physician, provided that—

++ The payments are not made knowingly to induce the physician to reduce or limit *medically necessary* items or services; and

++ The hospital and physician are ACO participants or ACO providers/suppliers, or were ACO participants or ACO providers/suppliers during the year in which the shared savings were earned by the ACO.

- Any financial relationship between or among the ACO, its ACO participants, and its ACO providers/suppliers necessary for and directly related to the ACO's participation in and operations under the Medicare Shared Savings Program that implicates the Physician Self-Referral Law and fully complies with an exception at 42 CFR 411.355 through 411.357.

C. Duration of Waivers

1. Shared Savings Waivers

The waivers related to the distribution of shared savings would apply to the distributions of shared savings earned by the ACO during the term of agreement with CMS to participate in the Medicare Shared Savings Program, even if the actual distributions occur after the expiration of the agreement.

2. Anti-Kickback Statute and Gainsharing CMP Waivers for Arrangements in Compliance With a Physician Self-Referral Law Exception

The anti-kickback statute and Gainsharing CMP waivers described above in sections II.B.2. of this notice with comment period (related to the anti-kickback statute) and II.B.3. of this notice with comment period (relating to the Gainsharing CMP) for arrangements that comply with an existing Physician Self-Referral Law exception would apply during the term of the ACO's agreement with CMS to participate in the Medicare Shared Savings Program.

III. Medicare Shared Savings Program: Solicitation of Public Comments on Additional Waiver Design Considerations

We have proposed waivers in this notice with comment period that address stakeholder input with respect to shared savings distributions and treatment under the anti-kickback statute and Gainsharing CMP for certain arrangements that comply with a Physician Self-Referral Law exception. We recognize that the proposed waivers described in section II. of this notice with comment period do not cover all of the possible financial arrangements involved with setting up and operating an ACO. Some of those arrangements may not need additional protection

under the fraud and abuse laws (for example, they might fit in existing exceptions and safe harbors or might not implicate the laws), while others may need additional protection. Accordingly, we are soliciting comments regarding waivers for financial arrangements that would be necessary to carry out the provisions of the Medicare Shared Savings Program. When commenting in response to this notice with comment period, please explain how any favored waivers, modifications, or additions would be necessary to carry out the provisions of the Medicare Shared Savings Program and why the financial arrangements at issue would not qualify for existing safe harbors or exceptions.

We have received significant public input suggesting that we consider promulgating waivers for ACOs in the Medicare Shared Savings Program that would apply more broadly than our proposals in section II. of this notice with comment period. Accordingly, we are soliciting comments on the topics that follow. Our current view is that we would grant waivers that would apply uniformly to all ACOs, ACO participants, and ACO providers/suppliers participating in the Medicare Shared Savings Program.

Our goal is ultimately to use our waiver authority to support beneficial ACO development under the Medicare Shared Savings Program, while still protecting patients and programs from harms caused by fraud and abuse. Striking this balance is both critically important and particularly challenging in the context of the Medicare Shared Savings Program. This is because providers and suppliers will continue to be paid on a fee-for-service basis, even under the two-sided risk model. We welcome comments on how best to balance these interests.

The topics on which we seek comment are described in the paragraphs that follow. We note that certain comments will be relevant to multiple topics; we will consider comments even when they combine several of the following topics:

- *Arrangements related to establishing the ACO.* We are interested in comments addressing whether it is necessary to waive the Physician Self-Referral Law, anti-kickback statute, or Gainsharing CMP for remuneration, directly related to: (1) Forming the ACO; (2) implementing the governance and administrative requirements applicable to the ACO under the final regulations for the Medicare Shared Savings Program; or (3) building technological or administrative capacity (including providing training) needed to achieve the Medicare Shared Savings Program cost and quality goals. For purposes of this paragraph, we are interested in comments addressing remuneration in the form of payments used to finance actual investment or startup expenses, as well as nonmonetary benefits transferred for the purpose of establishing the ACO. We also seek public comment on the exact type of expenses and corresponding financial arrangements that might be covered by a waiver for arrangements involving initial investments or startup expenses, and the period of time during which an investment or payment would be considered an "initial" investment or "startup" expenditure. We also seek comments on any safeguards that could be incorporated to protect patients or Federal health care programs from fraud and abuse. For example, we seek comments on whether protected remuneration should be required to be commercially reasonable.
- *Arrangements between or among ACO participants and/or ACO providers/suppliers related to ongoing operations of the ACO and achieving ACO goals.* We are interested in comments addressing whether the Physician Self-Referral Law, anti-kickback statute, or Gainsharing CMP should be waived for financial arrangements (other than those created by distributions of shared savings, as described in section II. of this notice with comment period) between or among ACO participants and/or ACO providers/suppliers that are: (1) Necessary for and directly related to operating the ACO; or (2) necessary for and directly related to achieving the integrated care, cost savings, and quality goals of the Medicare Shared Savings Program. If such a waiver is favored, we request public comments on the types of financial arrangements that should be covered by a waiver and whether these financial arrangements should be required to be commercially reasonable and reflect fair market value.
- *Arrangements between the ACO, its ACO participants, and/or its ACO providers/suppliers and outside individuals or entities.* We are interested in comments addressing whether the Physician Self-Referral Law, anti-kickback statute, or Gainsharing CMP should be waived for financial arrangements (other than those created by distributions of shared savings, as described in section II. of this notice with comment period) between the ACO, its ACO participants, and/or its ACO providers/suppliers and entities or individuals outside the ACO, where the financial arrangements are: (1) Necessary for and directly related to establishing the ACO; or (2) necessary for and directly related to achieving the integrated care, cost savings, and quality goals of the Medicare Shared Savings Program. We seek particular input on how this could be done while minimizing the potential for fraud and abuse (including whether these financial arrangements should be required to be commercially reasonable and reflect fair market value).
- *Distributions of shared savings or similar payments received from private payers.* We are interested in comments addressing whether a waiver is necessary to address distributions of shared savings payments received by the ACO from a private payer. We are seeking comments on this topic because ACOs under the Medicare Shared Savings Program may also operate under private payer contracts. Some stakeholders have expressed concern that payments under private payer contracts might implicate the fraud and abuse laws where the payments flow between parties that also have referral relationships with respect to Federal health care program patients. We solicit comments on the advisability of a waiver in this context, the scope and design of such a waiver, and whether any specific conditions are needed or should be imposed to prevent fraud and abuse.
- *Other financial arrangements for which a waiver would be necessary.* We are interested in comments addressing whether there are financial arrangements not addressed in the above topics for which waivers of the Physician Self-Referral Law, anti-kickback statute, or Gainsharing CMP should apply. Specifically, we seek comments describing specific financial arrangements (or combinations of arrangements), why they would be necessary for and directly related to the operations of ACOs under the Medicare Shared Savings Program, why no current exception or safe harbor would apply, and any applicable conditions or safeguards that should apply if a waiver were to be granted.
- *Duration of waivers.* We are interested in views on the duration of any waivers. Except as noted in section II. of this notice with comment period with respect to shared savings distributions, we currently expect that waivers would apply during the term of an ACO's agreement with CMS under the Medicare Shared Savings Program, and that waivers would cease to apply if the agreement is terminated before the end of the term. We solicit comments on this or other approaches.
- *Additional safeguards.* We seek comments addressing any additional

safeguards that might be necessary for and effective to protect patients and the Federal health care programs. We have premised our proposed waivers on the fact that ACOs, ACO participants, and ACO providers/suppliers under the Medicare Shared Savings Program will be required to comply with all applicable rules and regulations governing the program, including, for example, all monitoring, transparency, marketing, and quality requirements. We are interested in public comments addressing the sufficiency of these protections for purposes of fraud and abuse law waivers.

• *Scope of proposed waivers in section II. of this notice with comment period.* We seek comments addressing the scope of the waivers described in section II. of this notice with comment period. In particular, we are interested in comments as to whether the proposed waivers are too broad or too narrow, and, if so, how such over- or under-breadth might best be addressed. In addition, in section II.B. of this notice with comment period, we propose that the Physician Self-Referral Law, anti-kickback statute, and Gainsharing CMP be waived in circumstances where certain activities are "necessary for and directly related to" the ACO's participation in and operations under the Medicare Shared Savings Program. We seek comments on this standard, as well as comments recommending other standards that might be used to ensure that a waiver of the fraud and abuse laws is limited to ACO purposes. We are interested in examples of how this standard might apply to specific arrangements contemplated by ACOs, either to include or exclude the arrangements from the protection of a waiver. For example, we do not intend to extend waiver protections to ACO participants or ACO providers/suppliers that have independent financial arrangements with potential referral sources that are unrelated to the ACO, its operations, or the Medicare Shared Savings Program.

• *Two-sided risk model.* The Medicare Shared Savings Program proposed rule contemplates that all ACOs will eventually participate in a two-sided risk model pursuant to which the ACO would assume financial risk if costs for its aligned beneficiaries exceed certain thresholds. As currently proposed, CMS would not require the ACO to put its ACO participants or ACO providers/suppliers at risk for cost overages. However, CMS would permit ACOs to place some or all ACO participants and/or ACO providers/suppliers at risk. We are interested in comments addressing whether additional or different fraud and abuse waivers might be appropriate for ACOs participating in the two-sided risk model. We are particularly interested in comments on the relative risk of overutilization or increased program costs (and, conversely, the risk of underutilization or stinting) arising from the downside risk feature of the two tracks being proposed for the Medicare Shared Savings Program and whether the relative risk should impact the scope of the waiver. In addition, we seek comments on whether different waivers would be necessary for and appropriate in circumstances where ACO participants and/or ACO providers/suppliers may individually bear risk for the cost of items and services furnished to ACO beneficiaries. For example, we are interested in whether such waivers should extend only to compensation that places referring parties at risk for achieving the quality and performance metrics under the Medicare Shared Savings Program. Similarly, we are interested in comments addressing whether any additional financial arrangements arising in connection with the downside risk (for example, escrow accounts, surety bonds, and letters of credit) necessitate waiver protection and, if so, under what circumstances.

• *Use of existing exception and safe harbor for electronic health records arrangements.* We are interested in comments addressing whether we should waive the Physician Self-Referral Law and anti-kickback statute for ACO arrangements that satisfy the existing exception and safe harbor for electronic health records arrangements (42 CFR 411.357(w) and 42 CFR 1001.952(y)), but that are expected to occur after the sunset date of 2013 currently applicable to that exception and safe harbor.

• *Beneficiary inducements.* We seek comments addressing whether and under what circumstances it would be necessary for the Secretary to waive, in whole or in part, the provisions of section 1128A(a)(5) of the Act (the prohibition on inducements offered to Medicare and Medicaid beneficiaries) in connection with the Medicare Shared Savings Program. Specifically, we seek comments describing arrangements (or combinations of arrangements) that would require protection, why those arrangements would be necessary to carry out the provisions of the Medicare Shared Savings Program, and any applicable conditions or safeguards that should apply if a waiver were to be granted to ensure that beneficiaries are not inappropriately induced to obtain services from ACO participants or ACO providers/suppliers.

• *Timing of waivers.* We seek comments addressing whether final waivers should be published contemporaneously with, in advance of, or soon after final rule regarding the Medicare Shared Savings Program.

IV. Center for Medicare and Medicaid Innovation: Solicitation of Public Comments on Waiver Design Considerations

Section 1115A of the Act establishes within CMS the Center for Medicare and Medicaid Innovation (Innovation Center) "to test innovative payment and service delivery models to reduce program expenditures under the applicable titles while preserving or enhancing the quality of care furnished to individuals under such titles." In selecting models, the Secretary is directed to prefer models that also improve coordination, quality, and efficiency of health care services furnished to Medicare, Medicaid, and dually eligible individuals. In relevant part for purposes of this notice, section 1115A(d)(1) of the Act provides that the Secretary "may waive such requirements of Title XI and XVIII . . . as may be necessary solely for purposes of carrying out this section with respect to testing models described in subsection (b)." This waiver authority is specific to activities carried out under section 1115A of the Act and, like the waiver authority under section 1899(f) of the Act, does not address other arrangements. At this time, we are interested in public comments on the separate waiver authority at section 1115A(d)(1) of the Act and how we might best exercise it to address demonstrations and pilot programs under section 1115A of the Act.

V. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this document.

Authority: Sections 1899 and 1115A of the Act.

Dated: March 24, 2011.

Donald M. Berwick,

Administrator, Centers for Medicare & Medicaid Services.

Dated: March 28, 2011.

Daniel R. Levinson,

Inspector General.

[FR Doc. 2011–7884 Filed 3–31–11; 11:15 am]

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Part III

Environmental Protection Agency

40 CFR Part 52
Response to Petition From New Jersey Regarding SO_2 Emissions From the Portland Generating Station; Proposed Rule

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–HQ–OAR–2011–0081; FRL–9291–2]

RIN 2060–AQ69

Response to Petition From New Jersey Regarding SO_2 Emissions From the Portland Generating Station

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: In this action, EPA proposes to make a finding that the coal-fired Portland Generating Station (Portland Plant) in Upper Mount Bethel Township, Northampton County, Pennsylvania, is emitting air pollutants in violation of the interstate transport provisions of the Clean Air Act (CAA or Act). Specifically, EPA is proposing to find that emissions of sulfur dioxide (SO_2) from the Portland Plant significantly contribute to nonattainment and interfere with maintenance of the 1-hour SO_2 national ambient air quality standard (NAAQS) in New Jersey. This finding is proposed in response to a petition submitted by the State of New Jersey Department of Environmental Protection (NJDEP) on September 17, 2010. In this action, EPA is also proposing emission limitations and compliance schedules to ensure that the Portland Plant will no longer significantly contribute to nonattainment, and no longer interfere with maintenance of the 1-hour SO_2 NAAQS, thereby permitting continued operation of the Portland Plant beyond the 3-month limit established by the CAA for sources subject to such a finding.

DATES: *Comments.* Comments must be received on or before May 27, 2011.

Public Hearing: A public hearing will be held on April 27, 2011, in the Pequest Trout Hatchery and Natural Resources Education Center located in Oxford, Warren County, New Jersey 07863. Please refer to **SUPPLEMENTARY INFORMATION** for additional information on the comment period and the public hearing.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–HQ–OAR–2011–0081 by one of the following methods:

- *http://www.regulations.gov.* Follow the online instructions for submitting comments. Attention Docket ID No. EPA–HQ–OAR–2011–0081.
- *E-mail: a-and-r-docket@epa.gov.* Attention Docket ID No. EPA–HQ–OAR–2011–0081.
- *Fax:* (202) 566–9744. Attention Docket ID No. EPA–HQ–OAR–2011–0081.
- *Mail:* EPA Docket Center, EPA West (Air Docket), Attention Docket ID No. EPA–HQ–OAR–2011–0081, U.S. Environmental Protection Agency, Mailcode: 2822T, 1200 Pennsylvania Avenue, NW., Washington, DC 20460. Please include a total of 2 copies. *Hand Delivery:* U.S. Environmental Protection Agency, EPA West (Air Docket), 1301 Constitution Avenue, Northwest, Room 3334, Washington, DC 20004, Attention Docket ID No. EPA–HQ–OAR–2011–0081. 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–OAR–2011–0081. 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, avoid 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 Air and Radiation Docket and Information Center, EPA/DC, EPA West Building, 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 Air Docket is (202) 566–1742.

FOR FURTHER INFORMATION CONTACT: Mr. Todd Hawes (919–541–5591), *hawes.todd@epa.gov,* or Ms. Gobeail McKinley (919–541–5246), *mckinley.gobeail@epa.gov,* Air Quality Policy Division, Office of Air Quality Planning and Standards (C539–04), Environmental Protection Agency, Research Triangle Park, NC 27711.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Where can I get a copy of this document and other related information?

In addition to being available in the docket, an electronic copy of this proposal will also be available on the World Wide Web. Following signature by the EPA Administrator, a copy of this action will be posted on EPA's Web site *http://www.epa.gov/ttn/oarpg/new.html.*

B. What should I consider as I prepare my comments for EPA?

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. Send or deliver information identified as CBI only to the following address: Roberto Morales, OAQPS Document Control Officer (C404–02), U.S. EPA, Research Triangle

Park, NC 27711, Attention Docket ID No. EPA–HQ–OAR–2011–0081.

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.

C. How can I find information about the public hearing?

The EPA will hold a public hearing on this proposal on April 27, 2011. The hearing will be held at the following location: Pequest Trout Hatchery and Natural Resources Education Center located on 605 Pequest Road in Oxford, New Jersey 07863. The public hearing will begin at 12 noon and continue until 8 p.m., or later if necessary depending on the number of speakers. The EPA will make every effort to accommodate all speakers that arrive and register before 8 p.m. A dinner break is scheduled from 4 p.m. until 5 p.m. during the hearing. Oral testimony will be limited to 5 minutes per commenter. The EPA encourages commenters to provide written versions of their oral testimonies either electronically or in paper copy. Verbatim transcripts and written statements will be included in the rulemaking docket. If you would like to present oral testimony at the hearing, please notify Ms. Pam S. Long, Air Quality Policy Division (C504–03), U.S. EPA, Research Triangle Park, NC 27711, telephone number (919) 541–0641, *long.pam@epa.gov.* Persons interested in presenting oral testimony should notify Ms. Long at least 2 days in advance of the public hearing. Commenters should notify Ms. Long if they will need specific equipment, or if there are other special needs related to providing comments at the public hearing. The EPA will provide equipment for commenters to show overhead slides or make computerized slide presentations if we receive special requests in advance. The EPA encourages commenters to provide EPA with a copy of their oral testimony electronically (via e-mail or CD) or in hard copy form. For updates and additional information on the public hearing, please check EPA's Web site for this rulemaking, *http://www.epa.gov/ttn/oarpg/new.html.* The public hearing will provide interested parties the opportunity to present data, views, or arguments concerning the proposed rule. The EPA may ask clarifying questions during the oral presentations, but will not respond to the presentations or comments at that time. Written statements and supporting information submitted during the comment period will be considered with the same weight as any oral comments and supporting information presented at a public hearing.

D. How is the preamble organized?

SUPPLEMENTARY INFORMATION:

II. EPA's Proposed Decision on NJDEP's September 17, 2010 Section 126 Petition

EPA is proposing to grant the request in NJDEP's September 17, 2010, section 126 petition for a finding that emissions from the Portland Plant significantly contribute to nonattainment or interfere with maintenance of the 1-hour SO_2 NAAQS in New Jersey. EPA's proposed finding is based on EPA's review of NJDEP's air quality modeling, EPA's independent assessment of the AERMOD [1] dispersion modeling, and

[1] AERMOD stands for the American Meteorological Society/Environmental Protection Agency Regulatory Model.

other technical analysis conducted by EPA.

In granting this request, EPA is also proposing to allow the continued operation of the plant and to establish specific emission limitations and compliance schedules (including increments of progress) to bring the plant into compliance as expeditiously as practicable with the CAA prohibition of emissions that significantly contribute to nonattainment or interfere with maintenance. EPA is proposing to require that the Portland Plant reduce its SO_2 emissions to a limit no greater than 1,105 lbs/hour for unit 1 and 1,691 lbs/hour for unit 2. EPA proposes that the Portland Plant achieve and maintain these emission limitations by no later than 3 years after the effective date of the final rulemaking. EPA is taking comment on possible interim emission reductions such as proposing that the Portland Plant reduce its SO_2 emissions to a level no greater than 2,910 lbs/hr for unit 1, and 4,450 lbs/hr for unit 2, one year after the effective date of the final rulemaking, and other compliance activities to demonstrate appropriate increments of progress toward compliance. EPA has identified a number of existing, proven control technologies, as well as operational changes that can be employed to reduce emissions from these units. Nevertheless, EPA is also taking comment on an alternative compliance option should the Portland Plant decide to cease operation at the units subject to the emission limits, and is requesting comment on appropriate timeframes and measures for increments of progress to include for that alternative compliance option. EPA proposes that the emission limits and other measures established along with this finding are sufficient to remedy the Portland Plant's significant contribution to nonattainment and interference with maintenance in the impacted area in New Jersey.

III. Background

A. Section 126 of the Clean Air Act

The statutory authority for this action is provided by the CAA, including but not necessarily limited to, sections 126 and 110(a)(2)(D)(i).

Section 126(b) of the CAA provides, among other things, that any State or political subdivision may petition the Administrator of EPA to find that any major source or group of stationary sources in upwind States emits or would emit any air pollutant in violation of the prohibition of section 110(a)(2)(D)(i),[2] which we describe later in detail. 42 U.S.C. 7426(b). Findings by the Administrator, pursuant to this section, that a source or group of sources emit air pollutants in violation of the section 110(a)(2)(D)(i) prohibition are commonly referred to as section 126 findings. Similarly, petitions submitted pursuant to this section are commonly referred to as section 126 petitions.

Section 126(c) explains the impact of a section 126 finding and establishes the conditions under which continued operation of a source subject to such a finding may be permitted. Specifically, section 126(c) provides that it would be a violation of section 126 of the Act and of the applicable State implementation plan: (1) For any major proposed new or modified source subject to a section 126 finding to be constructed or operate in violation of the prohibition of section 110(a)(2)(D)(i); or (2) for any major existing source for which such a finding has been made to operate more than three months after the date of the finding. 42 U.S.C. 7426(c). The statute, however, also gives the Administrator discretion to permit the continued operation of a source beyond three months if the source complies with emission limitations and compliance schedules provided by EPA to bring about compliance with the requirements contained in sections 110(a)(2)(D)(i) and 126 as expeditiously as practicable but no later than 3 years from the date of the finding. *Id.*

Section 110(a)(2)(D) of the CAA, often referred to as the "good neighbor" or "interstate transport" provision of the Act, requires States to prohibit certain emissions from in-State sources if such emissions impact the air quality in downwind States. Specifically, section 110(a)(2)(D) requires all States, within 3 years of promulgation of a new or revised NAAQS, to submit State implementation plans (SIPs) that: contain adequate provisions prohibiting any source or other type of emissions activity within the State from emitting any air pollutant in amounts which will contribute significantly to nonattainment in, or interfere with maintenance by, any other State with respect to any such national primary or secondary ambient air quality standard, or interfere with measures required to be included in the applicable implementation plan for any other State under part C to prevent significant deterioration of air quality or to protect visibility. (42 U.S.C. 7410(a)(2)(D)).

EPA has previously promulgated rules to quantify the specific SO_2 and nitrogen oxide (NO_X) emission reductions required in certain eastern States by section 110(a)(2)(D)(i)(I) with respect to the NAAQS for ozone and fine particulate matter ($PM_{2.5}$). *See* 62 FR 57356 (NO_X SIP Call); 70 FR 25162 (CAIR).[3] EPA has also promulgated Federal rules to directly require such reductions. *See* 71 FR 25318 [finalizing Federal Implementation Plans for Clean Air Interstate Rule (CAIR)]; 65 FR 2674 (making section 126 findings for numerous large EGUs and finalizing a remedy for the affected sources). Most recently, EPA proposed the Transport Rule to address significant contribution to nonattainment and interference with maintenance with respect to the 1997 ozone and the 1997 and 2006 $PM_{2.5}$ NAAQS (75 FR 45210). Among other things, this proposed rule identifies SO_2 and NO_X reductions that will be needed in certain States to address $PM_{2.5}$ nonattainment and maintenance problems in other States. *See* 75 FR 45129–21 (discussing the air quality problems and the specific NAAQS addressed by the proposal). SO_2 and NO_X are identified as the pollutants of concern because of their impact on downwind States' ability to attain and maintain the $PM_{2.5}$ and ozone NAAQS. *See* 75 FR 45237, 45299. SO_2 and NO_X are $PM_{2.5}$ precursors and NO_X is also an ozone precursor.

The problems associated with high levels of SO_2 in the air, however, are separate and distinct from the problems associated with high levels of $PM_{2.5}$ and are addressed by a separate NAAQS, namely the 1-hour SO_2 NAAQS. 75 FR 35520 (Primary National Ambient Air Quality Standard for Sulfur Dioxide). The Transport Rule will not seek to identify or quantify reductions necessary to address significant contribution or interference with maintenance with respect to the 1-hour SO_2 NAAQS. In other words, the proposed Transport Rule does not address transport with respect to the 1-hour SO_2 NAAQS and thus does not address the concern raised in NJDEP's section 126 petition. Similarly, State 110(a)(2)(D)(i) SIP submissions relating to the ozone or $PM_{2.5}$ NAAQS would address only significant contribution to nonattainment and interference with maintenance of those NAAQS and thus would not address the concerns raised

[2] The text of section 126 codified in the United States Code cross references section 110(a)(2)(D)(ii) instead of section 110(a)(2)(D)(i). The courts have confirmed that this is a scrivener's error and the correct cross reference is to section 110(a)(2)(D)(i), *See Appalachian Power Co.* v. *EPA, 249 F.3d 1032, 1040–44 (DC Cir. 2001).*

[3] CAIR was subsequently found unlawful and remanded to EPA without vacatur, and thus remains in place while EPA responds to the remand. *See North Carolina* v. *EPA,* 531 F.3d 896, modified on reh'g, 550 F.3d 1176 (DC Cir. 2006).

regarding significant contribution to nonattainment and interference with maintenance of the 1-hour SO_2 NAAQS.

In addition, it is worth noting that the plain language of the statute confirms that section 126 remedies can, and in some cases must, be promulgated prior to the due date for good neighbor SIPs. Not only does section 126 provide a very stringent deadline for EPA to respond to section 126 petitions, but section 110(a)(2)(D)(ii) also calls for remedies promulgated pursuant to section 126 to be included in the SIP submissions that are due 3 years after a NAAQS is promulgated or revised. Section 110(a)(2)(D)(ii) requires State SIPs to contain adequate provisions "insuring compliance with the applicable requirements of [CAA section 126]". 42 U.S.C. 7410(a)(2)(D). Consistent with the requirement in CAA section 110(a)(1), the Commonwealth of Pennsylvania will be required to adopt and submit to the Administrator, by June 2013 (3 years after the promulgation of the 1-hour SO_2 NAAQS), a SIP that satisfies the requirements of 110(a)(2) including the interstate transport requirements of 110(a)(2)(D)(ii). In other words, the statute requires the State SIP submittal to include any emission limits promulgated by EPA pursuant to section 126. The fact that Congress required the SIP submittals due 3 years after promulgation or revision of a NAAQS to include any emission limits promulgated pursuant to section 126 is meaningful. If Congress had intended to limit EPA's authority to act on section 126 petitions until after the deadline for States to submit 110(a)(2)(D)(i) SIPs, it could have done so. Instead, it provided a mechanism for section 126 remedies promulgated prior to the SIP submission deadline to be incorporated into the State SIPs. EPA is bound by the language of the CAA. Since the statute establishes firm deadlines for action on section 126 petitions, does not provide an exception for petitions submitted prior to the good neighbor SIP submission deadline, and provides a mechanism for incorporating reductions required in response to section 126 petitions into the State SIPs, EPA believes it does not have discretion to delay action on a section 126 petition just because the State SIP submission deadline has not yet passed. EPA requests comment on this interpretation and all interpretations of section 126 in this section.

EPA has received one prior petition, in 1979, asking for a section 126 finding with respect to a single source. In this petition, the Air Pollution Control District of Jefferson County, Kentucky, requested that EPA find, pursuant to the version of section 110(a)(2)(E)(I) of the CAA in effect at that time, that emissions from the Gallagher Power Station in southern Indiana were preventing attainment and maintenance with respect to the 1971 3-hour, 24-hour, and annual SO_2 NAAQS.[4] 47 FR 6624 (1982). The petition also sought a reduction of SO_2 emissions from the plant. EPA denied that petition basing its decision, in part, on a modeling analysis concluding that the Gallagher Power Station's modeled allowable emissions were substantially below amounts that would prevent attainment or maintenance of the NAAQS. In this proposal, EPA is also using modeling analyses to decide whether to make a section 126 finding or deny the petition. EPA's decision on the 1979 petition was upheld by the U.S. Court of Appeals for the Sixth Circuit.[5]

B. Summary of Section 126 Petitions Submitted by NJDEP

1. NJDEP's May 13, 2010 Petition

On May 13, 2010, EPA received from the NJDEP a section 126 petition requesting that EPA make a finding that the Portland Plant is emitting air pollutants in violation of the interstate transport provisions of the CAA. The petition alleges that emissions from the Portland Plant significantly contribute to nonattainment and/or interfere with maintenance of the 2006 24-hour $PM_{2.5}$ NAAQS and the 1971 3-hour and 24-hour SO_2 NAAQS in New Jersey. That petition is still under consideration and this action does not address the petition submitted on May 13, 2010.

2. NJDEP's September 17, 2010 Petition

On September 17, 2010, EPA received another section 126 petition from NJDEP requesting that EPA make a finding under section 126(b) of the CAA that the Portland Plant is emitting air pollutants in violation of the interstate transport provisions of the CAA with respect to the 1-hour SO_2 NAAQS promulgated on June 2, 2010 (75 FR 35520). NJDEP stated that this petition provided additional documentation to supplement the section 126 petition from May 13, 2010.

NJDEP also submitted a modeling and trajectory analysis to support the assertions in the September 17, 2010, petition. This analysis, it asserts, demonstrates that the Portland Plant causes violations of the 1-hour SO_2 NAAQS in Warren, Sussex, Morris, and Hunterdon Counties in New Jersey. NJDEP's petition asks EPA to directly regulate the Portland Plant and requests the installation of appropriate air pollution controls, such as a scrubber, which it asserts would provide the necessary abatement. As an alternative to address the alleged violations, NJDEP's petition suggests that the EPA could impose emission limits no less stringent than New Jersey's Reasonably Available Control Technology (RACT) rules set forth at N.J.A.C. 7:27–1.1 *et seq.*

C. EPA Extensions for Acting on the Section 126 Petition

Any action taken by EPA under section 126 to make a finding or deny a petition is subject to the procedural requirements of CAA section 307(d). *See* 42 U.S.C. 7607(d)(1)(N). One of these requirements is notice-and-comment rulemaking. *See* 42 U.S.C. 7607(d)(3). In light of the time required for notice-and-comment rulemaking, CAA section 307(d)(10) provides for a time extension, under certain circumstances, for rulemaking subject to section 307(d).

In accordance with section 307(d)(10), EPA determined that the 60-day period afforded by section 126(b) for responding to the petition from the NJDEP was not sufficient to allow the public and EPA adequate opportunity to carry out the purposes of section 307(d). Specifically, EPA determined that the 60-day period was insufficient for EPA to develop an adequate proposal and allow time for notice-and-comment on whether the Portland Plant contributes significantly to nonattainment and/or maintenance problems in New Jersey. Based on these determinations, on November 16, 2010, EPA published a notice extending the deadline for action on the September 17, 2010, petition until May 16, 2011 (75 FR 69889). In this notice, EPA also explained its conclusion that the September 17, 2010, petition submitted by NJDEP is a new petition and not a supplement to the May 13, 2010, petition.

D. Background on the Portland Plant and Its Surrounding Area

The Portland Plant is a 427 megawatt (MW) coal-fired plant located in Upper Mount Bethel Township in Northampton County, Pennsylvania. It is within 500 feet of Knowlton Township in Warren County, New

[4] Section 110(a)(2)(E)(i)(I) of the CAA was superseded by 110(a)(2)(D)(i)(I) in the 1990 CAA amendments, in part to strengthen the prohibitions of interstate transport of emissions (64 FR 28262). The relevant wording under 110(a)(2)(E)(i)(I) was changed from "prevent attainment or maintenance by any other State" to "contribute significantly to nonattainment in, or interfere with maintenance by, any other State" under 110(a)(2)(D)(i)(I).

[5] *See* Air Pollution Control District of Jefferson County, *Kentucky* v. *EPA,* 739 F.2d 1071, (U.S. Court of Appeals, Sixth Circuit).

Jersey, directly across the Delaware River. There are two main units, unit 1 with a capacity of 160 MW and unit 2 with a capacity of 240 MW. There is an auxiliary boiler which burns oil and 3 small turbines (units 3, 4, and 5) which all burn oil and natural gas, and have very small emissions.

Units 1, 2, and 5 utilize continuous emissions monitoring system (CEMS). In 2009, SO_2 emissions combined from units 1 and 2 at the plant were 30,465 tons and emissions from unit 5 were 0.3 tons which are reported from CEMS data. Between 2007 and 2010, units 1 and 2 operated, on average, approximately 7,000 hours per year. Also, between 2007 and 2010, unit 5 operated for less than 100 hours per year.[6]

The auxiliary boiler, unit 3, and unit 4 do not have CEMS, but emissions data are available from the 2008 National Emissions Inventory (NEI), Version 1. The auxiliary boiler, unit 3, and unit 4 SO_2 annual emissions reported in the 2008 NEI were 0.01, 0.02, and 0.03 tons, respectively.

Other sources of SO_2 emissions in the area include the Martins Creek facility which is located approximately 10 km to the south of the Portland Plant. There are two units at Martins Creek, units 3 and 4, which averaged about 1,039 and 584 hours of operation respectively. Those units each have a capacity of 850 MW and can burn either oil or natural gas. The facility reported approximately 1,100 tons of SO_2 emissions in 2009. There are also three cement plants (Hercules, Keystone, and ESSROC) and several minor emitting units in Pennsylvania located at distances generally greater than 30 km away to the south and west of the Portland Plant. In 2009, the Pennsylvania Department of Environmental Protection emission inventory database (PADEP eFACTS) reported 1,862 tons for Hercules, 685 tons for Keystone, and 799 tons for ESSROC of SO_2 emissions respectively, all of which are relatively low compared to the SO_2 emissions from the Portland Plant.

The Delaware River transects the region, with higher terrain on either side of the river valley where the Portland Plant is located. There is elevated terrain, as high as or greater than Portland's highest stacks, which rises 400 to 500 foot (ft) above the valley floor near the Portland Plant. The 1500 ft high Kittatinny Ridge is located within 7 kilometer (km) to the north and northwest of the Portland Plant. Further south, near the Martins Creek Power Plant, major terrain features such as Scotts Mountain to the east of the Delaware River rise up to 1000 ft above the valley floor.

[6] Facility unit data is available at the EPA Clean Air Markets Division (CAMD) database available at *http://camddataandmaps.epa.gov/gdm/index.cfm?fuseaction=emissions.wizard.*

E. Sulfur Dioxide and Public Health

Current scientific evidence links health effects with short-term exposure to SO_2 ranging from 5 minutes to 24 hours. Adverse respiratory health effects include narrowing of the airways which can cause difficulty breathing (bronchoconstriction) and increased asthma symptoms. These effects are particularly important for asthmatics during periods of faster or deeper breathing (*e.g.,* while exercising or playing). Studies show an association between short-term SO_2 exposure and increased visits to emergency departments and hospital admissions for respiratory illnesses particularly in at-risk populations including children, the elderly and asthmatics. EPA's NAAQS for 1-hour SO_2 is designed to protect against exposure to the entire group of sulfur oxides (SO_X). SO_2 is the component of greatest concern and is used to represent the larger group of gaseous sulfur oxides. Other gaseous sulfur oxides (*e.g.,* SO_3) are found in the atmosphere at concentrations much lower than SO_2. Emissions that lead to high concentrations of SO_2 generally also lead to the formation of other SO_X. Control measures that reduce SO_2 can generally be expected to reduce people's exposure to all gaseous SO_X. Reducing SO_2 emissions is expected to have the important cobenefit of reducing the formation of fine sulfate particles that pose significant public health threats. SO_X can react with other compounds in the atmosphere to form small particles (*e.g.,* $PM_{2.5}$). These small particles penetrate deeply into sensitive parts of the lungs and can cause or worsen respiratory disease, such as emphysema and bronchitis, and can aggravate existing heart disease, leading to increased hospital admissions and premature death.

IV. EPA's Methodology for Making the Proposed Section 126 Finding for the Portland Plant

This section explains the analysis conducted by EPA to determine whether it would be appropriate to find, in response to the petition submitted by NJDEP, that the Portland Plant emits or would emit any air pollutant in violation of the prohibition of section 110(a)(2)(D)(i)(I) with respect to the 1-hour SO_2 NAAQS.

A. EPA's Approach for Determining Whether To Make a Section 126 Finding for the Portland Plant

1. CAA Section 126(b)

Section 126 of the CAA provides a mechanism for States and other political subdivisions to seek abatement of pollution in other States that may be affecting their air quality; however, it does not identify specific criteria or a specific methodology for the Administrator to apply when deciding whether to make a section 126 finding or deny a petition. Therefore, EPA has discretion to identify relevant criteria and develop a reasonable methodology for determining whether a section 126 finding should be made. *See, e.g., Chevron, U.S.A., Inc.* v. *NRDC,* 467 U.S. 837, 842–43 (1984); *Smiley* v. *Citibank,* 517 U.S. 735, 744–45 (1996).

As an initial matter, EPA looks to see whether a petition identifies or establishes a technical basis for the requested section 126 finding. EPA first evaluates the technical analysis in the petition to see if that analysis, standing alone, is sufficient to support a section 126 finding. EPA focuses on the analysis in the petition because the statute does not require EPA to conduct an independent technical analysis to evaluate claims made in section 126 petitions. The petitioner thus bears the burden of establishing, as an initial matter, a technical basis for the specific finding requested. EPA has no obligation to prepare an analysis to supplement a petition that fails, on its face, to include an initial technical demonstration. Such a petition, or a petition that fails to identify the specific finding requested, could be found insufficient. Nonetheless, the Agency may decide to conduct independent technical analyses when such analyses are helpful in evaluating the basis for a potential section 126 finding or developing a remedy if a finding is made. As explained later, given our view that it is necessary to make some technical adjustments to the NJDEP modeling, we determined that it was appropriate to conduct independent technical analysis to determine an appropriate remedy. Such analysis, however, is not required by the statute and may not be necessary or appropriate in other circumstances.

In this section, EPA explains the methodology used to evaluate the technical analysis presented in NJDEP's petition and to determine whether it would be appropriate to make the section 126 finding requested. This methodology was developed to address the specific allegations in the NJDEP petition and does not speak to how EPA

might evaluate petitions that raise different interstate transport issues, such as collective contributions from multiple sources, contributions to nonattainment areas in multiple States, or contributions to different NAAQS. The methodology used to assess the remedy is discussed in section VII.

2. EPA's Approach To Evaluating NJDEP's Section 126 Petition

Emissions from upwind States can, alone or in combination with local emissions, result in air quality levels that exceed the NAAQS and jeopardize the health of residents in downwind communities. Each State is required by section 110(a)(2)(D)(i)(I) to prohibit emissions from activities within that individual State that would significantly contribute to downwind nonattainment or interfere with downwind States' maintenance of the NAAQS.

Section 110(a) of the CAA assigns to each State both the primary responsibility for attaining and maintaining the NAAQS within such State, and prohibiting emissions activities within the State that will significantly contribute to nonattainment or interfere with maintenance in a downwind area. States fulfill these CAA obligations through the SIP process described in section 110(a) of the CAA. States are required to submit SIPs to prohibit those emissions that significantly contribute to nonattainment or interfere with maintenance in downwind States within 3 years of promulgation of a new or revised NAAQS. *See* 42 U.S.C. 7410(a), 7410(a)(2)(D). The prohibition on these emissions is intended to assist the downwind State as it designs strategies for ensuring that the NAAQS are attained and maintained.

The NJDEP petition asserts and presents modeling that demonstrates that emissions from one plant (the Portland Plant) by itself is sufficient to cause downwind SO_2 NAAQS violations in New Jersey. The approach described later was developed by EPA to analyze these specific claims in these particular circumstances and may not be appropriate for evaluating other claims or those arising in different circumstances for other actions.

In this case, EPA is proposing to define the Portland Plant's significant contribution to nonattainment and interference with maintenance as those emissions that must be eliminated to bring the downwind receptors in New Jersey affected by the Portland Plant into modeled attainment in the analysis year. While this approach would not be appropriate in every circumstance, EPA believes it is appropriate where, as here, the source's emissions are sufficient on their own to cause downwind NAAQS violations and background levels of the relevant pollutant are relatively low. EPA therefore developed a methodology to identify the reductions necessary to bring the downwind receptors into attainment.

EPA's methodology uses dispersion modeling to assess the impact of emissions from the Portland Plant on SO_2 concentrations at downwind receptors. EPA modeled the emissions from the Portland Plant and determined that the modeled concentrations from the Portland Plant, when combined with the relatively low background concentrations [in the manner described in section VII and in greater detail in the Modeling Technical Support Document (TSD)], cause violations of the 1-hour SO_2 NAAQS in New Jersey. We have determined it is appropriate to use modeling in this case to determine whether downwind air quality will attain the 1-hour SO_2 NAAQS in the analysis year.[7]

In the modeling analysis, thousands of receptors are placed in New Jersey to determine the area of maximum concentration from the Portland Plant emissions. A design value concentration is calculated for each receptor for comparison to the NAAQS. The design value concentration is equal to the 99th percentile (4th-highest) daily maximum 1-hour SO_2 concentration. All receptors with modeled design value concentrations that are greater than the NAAQS (196 $\mu g/m^3$) are determined to be nonattainment receptors.

To quantify the emissions that constitute the Portland Plant's significant contribution, we identify the level of emissions that need to be reduced to ensure that no modeled concentration within the affected area exceeds the level of the NAAQS (*i.e.,* the 99th percentile of the daily maximum 1-hour average of 196 $\mu g/m^3$).

The first step of the "interfere with maintenance" analysis is to identify whether there are any maintenance receptors in the relevant area. In considering maintenance, we are examining the receptors in the analysis to determine if higher modeled concentrations may exist due to variability in meteorology, emissions, and/or other factors. Nonattainment receptors are already modeled to be above the NAAQS and receptors with higher[8] concentrations attributed to variability in emissions or meteorology would be exceeding the NAAQS by an even greater amount. Therefore, nonattainment receptors are by definition also maintenance receptors. In addition to these nonattainment/maintenance receptors, we also examine receptors that are modeled to be attainment but due to variability in meteorology or emissions might be at risk for nonattainment. In that case, any identified maintenance receptors would not be nonattainment and would therefore be considered "maintenance only" receptors.

In this particular case, due to the high modeled concentrations from the Portland Plant emissions, all of the downwind modeled receptors in the modeled receptor grid in New Jersey are modeled to be nonattainment. In this application, it was not necessary to expand the modeling grid to identify additional nonattainment or "maintenance only" receptors because the modeling domain was centered on the receptors with the maximum impact from the Portland Plant. In a primary pollutant dispersion modeling application, emissions reductions from the contributing source lead to a linear reduction in downwind concentrations. Therefore, we can be certain that an emissions limit on the Portland Plant that eliminates modeled violations at the maximum concentration receptor will eliminate violations at all potential receptors. Because there are no "maintenance only" receptors in the area of concern, it was not necessary for us to consider the Portland Plant's impact on maintenance only receptors.

We next consider whether the Portland Plant should be required to make additional reductions, above and beyond those required to eliminate its significant contribution to nonattainment to ensure that it does not interfere with maintenance at the nonattainment/maintenance receptors. We identified an approach that we believe is appropriate for the specific circumstances presented here.

Among other things, we considered the nature of the modeling used to determine the appropriate remedy and the potential for SO_2 concentrations in New Jersey to be higher than those

[7] Historically, EPA has favored dispersion modeling to support SO_2 NAAQS compliance determinations for areas with sources that have the potential to cause an SO_2 NAAQS violation, and EPA explained that for an area to be designated as "attainment," dispersion modeling regarding such sources needs to show the absence of violations even if monitoring does not show a violation. This has been our general position throughout the history of implementation of the SO_2 NAAQS program. *See* 75 FR 35551.

[8] Variability of emissions and meteorology could also lead to lower concentrations; however, for purposes of identifying interference with maintenance receptors, we would only be concerned with concentrations that would be higher than those modeled.

modeled. Here are some of the relevant facts:

(1) There is only 1 year of site-specific meteorology available for this analysis, so we are not able to examine the impact of year-to-year variability of meteorology on downwind modeled concentrations.[9]

(2) The remedy modeling used allowable emissions from the Portland Plant. Since these are the highest emissions that are allowed to be emitted by the facility, higher concentrations could not be expected to occur in New Jersey due to the emissions from the Portland Plant.

(3) In the modeling analysis, we used a seasonal and hourly varying background concentration that represents the high end of the distribution (99th percentile) of hourly observed SO_2 concentrations in the area. As indicated in the trajectory analysis submitted by NJDEP, it is likely that direct SO_2 impacts from the Portland Plant contributed to high monitored concentrations at the monitor located in Chester, New Jersey (Chester monitor). Therefore, to avoid double counting of contributions from the Portland Plant through both monitored and modeled emissions, it would not be appropriate to consider higher background concentrations.

EPA believes that given the specific circumstances described previously, there is no indication that concentrations higher than those modeled from the Portland Plant would be likely to occur at the nonattainment/maintenance receptors or anywhere in New Jersey. It is therefore reasonable to conclude, under the circumstances, that any remedy that eliminates the significant contribution to nonattainment from the Portland Plant will also eliminate its interference with maintenance with respect to year-to-year variability in emissions and air quality.

As noted in the proposed Transport Rule, EPA believes that the maintenance concept has two components: Year-to-year variability in emissions and air quality, and continued maintenance of the air quality standard over time. Consistent with the approach in the Transport Rule, EPA examined both of these concepts in assessing "interfere with maintenance" for NJDEP's section 126 petition regarding the Portland Plant. Year-to-year variability is discussed above. Year-to-year variability is appropriate to consider because data demonstrates that year-to-year variations in air quality that stem from differences in weather and emissions can determine whether or not the health-based standard will be achieved in a particular location in the analyzed year.

EPA separately considered whether further emissions reductions from the Portland Plant are necessary to ensure continued lack of interference with maintenance of the NAAQS over time, and believes that the answer is no. The proposed requirements of this rule will prevent the emissions of the Portland Plant from increasing over time relative to the modeled scenario. Also, EPA does *not* have evidence that background SO_2 emissions from other sources affecting the relevant New Jersey receptors will increase in the future, which—in combination with residual Portland Plant emissions—in theory might have raised the possibility of a future maintenance issue at those receptors.

In conclusion, we are proposing to find that compliance by the Portland Plant with the emission limits proposed in this action will bring it into compliance with the prohibition on emissions that significantly contribute to nonattainment of the 1-hour SO_2 NAAQS as well as with the prohibition on emissions that interfere with maintenance in a downwind area.

EPA requests comment on our approach to address interference with maintenance with regard to this specific petition and whether the proposed emission limits are sufficient to eliminate the Portland Plant's interference with maintenance of the 1-hour SO_2 NAAQS in New Jersey.

V. Summary and Assessment of the Modeling and Other Data Relevant to EPA's Finding

A. Summary of the Modeling Submitted by NJDEP To Support the Petition

NJDEP submitted several technical analyses in support of its section 126 petition. Among the submitted materials were a summary of the NJDEP dispersion modeling results, a modeling analysis for the 1-hour SO_2 NAAQS using AERMOD, a modeling analysis for the 1-hour SO_2 NAAQS using CALPUFF,[10] and a trajectory analysis of high SO_2 episodes at a SO_2 monitor in Chester, New Jersey. In addition, the petition references a CALPUFF model validation study, which was submitted by NJDEP along with the previous (May 13, 2010) section 126 petition.

NJDEP submitted two different modeling analyses of the SO_2 impacts from the Portland Plant on New Jersey. The first analysis (Exhibit 2 to the NJDEP petition) used the AERMOD dispersion model and the second analysis (Exhibit 3 to the NJDEP petition) used the CALPUFF dispersion model. Both models were run with both actual and allowable emissions rates and CALPUFF was also run with various meteorological input data. Each NJDEP model run showed modeled violations of the 1-hour SO_2 NAAQS (*i.e.,* showed annual 99th percentile of daily maximum 1-hour SO_2 values at or above 196 $\mu g/m^3$) in New Jersey.

Table V.A–1 summarizes the CALPUFF and AERMOD 1-hour SO_2 NAAQS (196 $\mu g/m^3$, 99th percentile) modeling results submitted by NJDEP.

TABLE V.A–1—SUMMARY OF MODELING RESULTS SUBMITTED BY NJDEP

Model	Emissions	Meteorology	Maximum modeled concentration ($\mu g/m^3$)	99th Percentile (4th high) modeled concentration ($\mu g/m^3$) [11]
AERMOD	Allowable	July 1993–June 1994 [12]	3,700	1,402
AERMOD	Estimated Actual	July 1993–June 1994	1,713	467.3
CALPUFF	Allowable	2002 12km MM5	15,273	3,455

[9] Due to constraints on data availability, our analysis is appropriate in this instance; however, nothing here is intended to suggest that, where sufficient data are available to examine year-to-year variability, this should not be a relevant factor.

[10] CALPUFF is a non-steady-state puff dispersion model that was originally developed for the California Air Resources Board.

[11] NJDEP did not add background concentrations to any of the modeled concentrations in the table.

[12] Meteorological data used in the AERMOD modeling was based on the only site-specific meteorological data available for the Portland Plant, from July 1993 through June 1994, which satisfies the recommendations in Section 8.3.1 of Appendix W regarding the length of record for meteorological data.

TABLE V.A–1—SUMMARY OF MODELING RESULTS SUBMITTED BY NJDEP—Continued

Model	Emissions	Meteorology	Maximum modeled concentration ($\mu g/m^3$)	99th Percentile (4th high) modeled concentration ($\mu g/m^3$) [11]
CALPUFF	Actual	2002 12km MM5	6,740	2,194
CALPUFF	Allowable	2003 4km MM5	18,643	2,468

As can be seen in the table V.A–1, each of the modeling analyses submitted by NJDEP shows modeled violations of the 1-hour SO_2 NAAQS. The concentrations predicted by the CALPUFF model tend to be higher than those predicted by the AERMOD model. In addition, the model runs based on allowable emissions logically show higher concentrations than those based on actual emissions. The allowable emissions included in the NJDEP modeling are shown in Table V.A–2.

TABLE V.A–2

Portland Plant unit	Allowable SO_2 rate (lb/hr)	Maximum 3-hr permit limit (tons per 3 hours)
1	5,820	8.73
2	8,900	13.35

The petition also contained modeling of actual emissions for the 2002 MM5 (mesoscale meteorological model) based CALPUFF case and this modeling run showed large exceedances of the 1-hour SO_2 NAAQS. Actual emissions were also modeled with AERMOD for the 1993–1994 site-specific meteorology. As with the modeling based on allowable emissions, the AERMOD results with actual emissions were much lower than the CALPUFF results, but still showed significant exceedances of the 1-hour SO_2 NAAQS. The 2002 CALPUFF modeling with actual emissions was based on actual SO_2 emissions from CEMS data. The 1993–1994 actual emissions used with AERMOD were estimated based on monthly coal usage reports (CEMS data were not available for that period).

The modeling submitted by NJDEP indicates actual emissions from the Portland Plant alone cause air quality in New Jersey to exceed the 1-hour SO_2 NAAQS. The NJDEP modeling also indicates that the Portland Plant's allowable emissions (*i.e.,* the emissions the plant would emit if it were to emit at the level currently allowed) cause air quality in New Jersey to exceed the 1-hour SO_2 NAAQS. The NJDEP AERMOD predictions of the 4th high daily 1-hour maximum concentrations (99th percentile) based on allowable emissions show a maximum concentration in New Jersey of 1,402 $\mu g/m^3$ (located on a ridge at the Delaware Water Gap (in New Jersey) approximately 7 kilometers (km) from the Portland Plant stacks). The AERMOD modeling submitted by NJDEP also demonstrates that actual emissions from the Portland Plant are causing NAAQS exceedances in New Jersey. In addition, the CALPUFF predictions of the 4th high daily maximum 1-hour concentrations (99th percentile) based on allowable emissions are as high as 3,455 $\mu g/m^3$.

The results of the NJDEP modeling based on both allowable and actual emissions indicate that emissions reductions would be needed at the Portland Plant in order to eliminate Portland's significant contribution to nonattainment in New Jersey.

B. EPA's Assessment of Modeling Submitted by NJDEP

EPA evaluated several aspects of the NJDEP modeling to determine if the analyses followed EPA regulations and guidance for dispersion modeling. Among the key specific issues evaluated were the choice of model(s), modeling of actual vs. allowable emissions, and the application of site-specific meteorological data that were used as inputs to the AERMOD model. Additional technical details regarding the NJDEP modeling were also examined, as documented in the Modeling TSD.

1. NJDEP's Model Selection

EPA first evaluated which model is most appropriate for use in these particular circumstances. As noted previously, NJDEP submitted both AERMOD and CALPUFF model results. Given the significant differences in the magnitude of predicted impacts associated with the Portland Plant emissions based on the use of the AERMOD model versus use of the CALPUFF model, identifying the most appropriate model for use in these circumstances was a key aspect of EPA's assessment. Section 4.2.2(b) of the "Guideline on Air Quality Models," published as Appendix W to 40 CFR Part 51 (commonly referred to as "Appendix W") States that AERMOD is "the recommended model" "[f]or a wide range of regulatory applications in all types of terrain." [13] The modeling application under consideration in this section 126 petition is covered under this section of Appendix W since the transport distances of concern are less than 50 kilometers.

The NJDEP petition acknowledges that AERMOD is the preferred model for near-field applications such as this, but suggests the use of CALPUFF may be appropriate under the alternative model provisions in Section 3.2.2b of Appendix W. Section 3.2 of Appendix W lists three separate conditions under which an alternative model may be approved for use, as follows:

(1) If a demonstration can be made that the model produces concentration estimates equivalent to the estimates obtained using a preferred model;

[13] Section 4.2.2 identifies other models that are recommended for specific applications that do not apply for the Portland Plant, *e.g.,* the Buoyant Line and Point Source (BLP) dispersion model is recommended for cases where buoyant plume rise from line sources is important.

(2) If a statistical performance evaluation has been conducted using measured air quality data and the results of that evaluation indicate the alternative model performs better for the given application than a comparable model in Appendix A; or

(3) If the preferred model is less appropriate for the specific application, or there is no preferred model.

The NJDEP modeling documentation suggests that NJDEP's use of the CALPUFF model in support of this petition is based on condition (2) of Section 3.2.2b. NJDEP claims that CALPUFF was shown to have "performed better and produced predictions of greater accuracy than AERMOD,"[14] and therefore satisfies condition (2) under Section 3.2.2b of Appendix W. NJDEP also claims that the use of CALPUFF is more appropriate for the specific application due to the complex winds addressed in Section 7.2.8 of Appendix W[15] and is therefore justified under condition (3) of Section 3.2.2b.

For the reasons stated later, EPA determines that AERMOD is the appropriate modeling platform to use in these specific circumstances. This conclusion is based on the particular circumstances presented here and does not speak to whether it would be appropriate to use CALPUFF modeling in other situations.

a. CALPUFF Alternative Model Justification

EPA issued a memo on August 13, 2008, providing "Clarification of Regulatory Status of CALPUFF for Near-field Applications,"[16] (which applies to the application under review here). The key points emphasized in that memo are as follows:

1. The EPA-preferred model for near-field regulatory applications (less than 50 kilometers) for simple and complex terrain is AERMOD. The AERMOD model should be used for all near-field regulatory applications, unless an adequate determination is made that AERMOD is not appropriate for that application or is clearly less appropriate than an alternative model.

2. CALPUFF is not the EPA-preferred model for near-field applications, but may be considered as an alternative model on a case-by-case basis for near-field applications involving "complex winds," subject to approval by the reviewing authority. The approval of CALPUFF for near-field regulatory applications must be based on case-specific justification, including necessary documentation and an adequate determination that AERMOD is not appropriate or clearly less appropriate than CALPUFF.

The impacts from a source such as the Portland Plant (tall stacks with nearby terrain features) are likely to occur with "line-of-sight" impacts of the elevated plumes on nearby terrain features for which straight-line, steady-state assumptions are valid.

The AERMOD model has been evaluated for similar situations of tall stacks in complex terrain settings for at least five separate data bases and consistently shown to perform better than competing models (Perry, *et al.,* 2005;[17] EPA, 2003[18]). Therefore, EPA does not agree with the argument that CALPUFF is more appropriate in this situation due to the existence of complex winds.

We thus turn to NJDEP's assertion that the use of CALPUFF as an alternative model can be justified under condition (2) of Section 3.2.2b, based on a demonstration that CALPUFF performs better than AERMOD. To evaluate this assertion, we evaluate whether there is evidence to support NJDEP's assertion that CALPUFF performs better than AERMOD. In the September 17, 2010, petition, NJDEP references a CALPUFF validation study that was submitted with the May 13, 2010, petition. EPA believes it is appropriate to consider this study because it was explicitly referenced in the September 17, 2010, petition, and a copy was provided with the prior petition.

We note again that the AERMOD model has undergone extensive peer review and model validation as the basis for its promulgation as the preferred model for a wide range of regulatory applications in all types of terrain. Therefore, we would not determine CALPUFF to be a more appropriate model in this case absent compelling evidence that CALPUFF is clearly superior to AERMOD for this application.

Model validation is a complex process that entails several technical challenges, including uncertainties regarding the accuracy and representativeness of key input data that could affect results, as well as a wide range of statistical methods and metrics that may be applied to quantify model performance. In some cases subtle changes to the evaluation methods can markedly affect the conclusions that might be drawn from such studies. For these reasons, the importance of establishing a consistent set of objective procedures to evaluate the performance of dispersion models for use in regulatory modeling applications and of comparing the relative performance of competing models has long been recognized. Section 3.2.1 of Appendix W references EPA's "Protocol for Determining the Best Performing Model"[19] document (EPA, 1992) that states it "is available to assist in developing a consistent approach when justifying the use of other-than-preferred modeling techniques recommended in the Guideline. The procedures in this protocol provide a general framework for objective decision-making on the acceptability of an alternative model for a given regulatory application.

Although the CALPUFF validation study submitted by NJDEP with the May 13, 2010, petition cites EPA's Protocol as one of the references for its model validation procedures, there were some key changes implemented in the NJDEP model evaluation study relative to the methods recommended and used by EPA in its evaluation of AERMOD model performance. EPA's evaluation of NJDEP's changes to the protocol leads us to believe that the NJDEP methods show relatively better model performance for CALPUFF compared to AERMOD, without any clear technical basis that would justify those changes. Further details on these changes and their impacts on the results of the validations study are provided in the Modeling TSD included in the docket for this rulemaking.

Furthermore, the Quantile-Quantile (Q–Q) plots[20] included in the NJDEP validation report provide a clear visual representation of model performance that is very relevant to the regulatory application of these models. These plots suggest that the performance of the

[14] *See* September 17, 2010 petition, Section IV, page 5.

[15] *See* May 13, 2010, petition, Section V, subsection B.

[16] "Clarification of Regulatory Status of CALPUFF for Near-field Applications," memo from Richard A. Wayland, dated August 13, 2008, available at *http://www.epa.gov/ttn/scram/clarification%20of%20regulatory%20status%20of%20calpuff.pdf.*

[17] Perry, S.G., A.J. Cimorelli, R.J. Paine, R.W. Brode, J.C. Weil, A. Venkatram, R.B. Wilson, R.F. Lee, and W.D. Peters, 2005. AERMOD: A Dispersion Model for Industrial Source Applications. Part II: Model Performance against 17 Field Study Databases. *J. Appl. Meteor.,* 44, pp. 694–708.

[18] EPA, 2003. AERMOD: Latest Features and Evaluation Results. EPA–454/R–03–003. U.S. Environmental Protection Agency, Research Triangle Park, NC, available at *http://www.epa.gov/scram001/7thconf/aermod/aermod_mep.pdf.*

[19] "Protocol for Determining the Best Performing Model", EPA–454/R–92–025, December 1992. U.S. Environmental Protection Agency, Research Triangle Park, NC, available at *http://www.epa.gov/ttn/scram/guidance/guide/modleval.zip.*

[20] Quantile-Quantile (Q–Q) plots compare modeled vs. monitored concentrations on the basis of independently ranked distributions of concentration, unpaired in time and space.

CALPUFF and AERMOD models on this database is in fact quite similar, but that AERMOD shows slightly better overall agreement with observations.

Another fundamental point in relation to NJDEP's overall justification for the use of CALPUFF in this petition is that results from the model validation study are not relevant to this application of CALPUFF due to fundamental differences in the meteorological processing used in the validation study compared to the modeling submitted in support of the petition. The CALMET modeling for the validation study made use of the site-specific meteorological data collected as part of the field study so that the documented CALPUFF model performance is largely dependent on the characterization of wind fields by CALMET that are informed by that site-specific data. In contrast, the application of CALPUFF to support the petition did not use any site-specific meteorological data but relied on three different sets of MM5 prognostic meteorological data to inform the 3-dimensional wind fields generated by CALMET. Performance of the CALPUFF model in this case would rely upon the ability of the CALMET meteorological model to adequately simulate the wind fields in the absence of such site-specific data, and there have not been any such demonstrations that would be relevant to this application.

We also note that the spatial distribution of 1-hour SO_2 impacts predicted by CALPUFF (in the petition application) is very different than the impacts predicted by AERMOD. The CALPUFF modeling shows extremely high 1-hour SO_2 concentrations very close to the Portland Plant (see Figures 1, 2, and 3 of Exhibit 3). The highest impacts based on the 2002 CALPUFF modeling with allowable emissions of 3,455 $\mu g/m^3$ (99th percentile of daily maximum 1-hour values) occurs about 100 meters from units 1 and 2 at an elevation of only 3 meters above the stack base in Pennsylvania. These results are physically unrealistic for buoyant plumes from tall stacks such as units 1 and 2 at the Portland Plant, raising additional concerns regarding the appropriateness of CALPUFF for this application.

Based on the discussion previously (and additional details contained in the Modeling TSD), we conclude that NJDEP has not adequately justified the use of CALPUFF in this application under either conditions (2) or (3) of Section 3.2.2b of Appendix W, and that AERMOD is the most appropriate model for this application.[21]

2. Emissions and Source Characteristics

As noted previously, NJDEP submitted dispersion modeling results based on maximum allowable emissions as well as actual emissions. For the reasons explained later, EPA has determined that it is reasonable and appropriate to model allowable emissions when evaluating whether the source "emits or would emit" any air pollutant in violation of the prohibition of section 110(a)(2)(D)(i) under a section 126 petition. EPA interprets the term "emits or would emit" as a reference to the source's current and potential future emissions. A determination of whether the source "emits" pollutants in violation of the prohibition of section 110(a)(2)(D)(i) could be based on modeling of actual emissions. However, for the emissions the source "would emit" (*i.e.,* its potential future emissions), it is appropriate to consider the level at which the source could emit given the existing constraints on its emissions—that is, the source's allowable emissions.

For these same reasons, EPA believes it appropriate to model allowable emissions when determining the appropriate remedy to eliminate the source's significant contribution to nonattainment and interference with maintenance. In addition, as a practical matter, it would be difficult to determine an appropriate remedy under a section 126 petition based on actual emissions given the potential variability of actual emissions. Because the question posed is what additional limits must be placed on the source's emissions to eliminate its significant contribution to nonattainment and interference with maintenance, it is appropriate to consider what its emissions could be in the absence of such limits.

For these reasons, the rest of the review of NJDEP's modeling and the methodology of EPA's remedy modeling is limited to modeled results based on allowable emissions.

3. Meteorological Data

Aside from emissions data, meteorological data are the other key input to dispersion models. The NJDEP AERMOD modeling was based on 1 year of site-specific meteorological data collected from a 100-meter instrumented tower and sonic detection and ranging (SODAR) system located about 2.2 kilometers west of the Portland Plant, for the period July 1993 through June 1994.

Section 8.3 of Appendix W provides guidance regarding meteorological data for use in dispersion modeling to demonstrate compliance with the NAAQS. A key issue related to meteorological data is the representativeness of the data for the particular application, including spatial and temporal representativeness. Based on a review of the data, we believe that the meteorological data from 1993–1994 [22] meet the basic criteria for representativeness under Section 8.3.3 of Appendix W, and therefore can be considered as site-specific data for purposes of modeling impacts from the elevated stacks for the Portland Plant's units 1 and 2. The 1993–1994 data also meet the minimum criterion of at least 1 year of site-specific meteorological data recommended in Section 8.3.1.2(b) of Appendix W.

Although the Portland Plant meteorological data meet the basic criteria for representativeness, we note that there is a difference of about 100 meters between the base elevation for the meteorological tower and that of the stack base elevation. This raises concerns regarding how the meteorological data were input to the AERMOD model in the NJDEP modeling analysis, especially given that the stack heights for units 1 and 2 are about 122 meters and that plume heights of concern for units 1 and 2 are about 200 to 400 meters above stack base. The modeling submitted by NJDEP used the measurement heights above local ground for the meteorological data input to the model, effectively assuming that the measured profiles of wind, temperature and turbulence were "terrain-following."

We provide additional analysis of the impact on the tower height in the EPA remedy modeling section and in the Modeling TSD. We believe an adjustment to the meteorological data heights is warranted and EPA made these adjustments in the supplemental technical analysis it conducted to determine the appropriate remedy. These adjustments may play an

[21] EPA's discussion of the appropriate air quality model for near field applications focuses on primary emissions from a stationary source, such as the SO_2 emissions from the Portland Plant, at issue in NJDEP's petition. EPA is not suggesting that AERMOD is the appropriate model to simulate the effects of SO_2 and nitrogen oxide emissions on secondary pollutants formed in the atmosphere such as $PM_{2.5}$ and ozone. *See* 70 FR 68,234.

[22] The fact that the 1993–1994 meteorological data is nearly 20 years old is not relevant. The modeling was conducted with allowable emissions from the Portland Plant. The meteorology needs to be representative of typical meteorology that occurs in the area, regardless of time period. The allowable emissions do not vary, regardless of the meteorological data year.

important role in determining the remedy, as explained later in section VII. However, since the maximum design value concentration in the NJDEP AERMOD modeling analysis was nearly seven times the NAAQS, we do not expect these adjustments to change the overall conclusion that the Portland Plant emissions are likely to cause or contribute to violations of the 1-hour SO_2 NAAQS in New Jersey.

4. Receptor/Terrain Data

Proper treatment of terrain information is important for this analysis given the potential influence of elevated and complex terrain on the modeling results. The NJDEP analysis was based on an initial grid of coarsely spaced receptor locations across a large domain covering all potentially important impact areas associated with emissions from the Portland Plant, followed by a much smaller grid of more closely spaced receptors focused on the area of expected worst-case impacts from the plant. The initial grid included spacing of 250 meters in areas of expected high impacts with receptors spaced at 1,000 meter intervals covering the gaps between the 250-meter grids. The initial coarse receptor grid included a total of 5,189 receptors. The fine grid used by NJDEP in determining the controlling impact from the Portland Plant for purposes of this petition included a total of 121 receptors in a 10 $\times$ 10 array spaced at 100-meter intervals covering a portion of the Kittatinny Ridge on the New Jersey side of the Delaware Water Gap.

5. AERMOD Results

NJDEP's AERMOD modeling shows maximum design value impacts from the Portland Plant, based on allowable SO_2 emissions of 1402 $\mu g/m^3$ in New Jersey.[23] Since those concentrations are nearly seven times the 1-hour SO_2 NAAQS (196 $\mu g/m^3$), and since NJDEP's AERMOD modeling also showed significant exceedances of the 1-hour SO_2 NAAQS in NJ based on an estimate of actual SO_2 emissions, we conclude that the NJDEP has clearly shown that SO_2 emissions from the Portland Plant cause violations of the 1-hour SO_2 NAAQS in New Jersey.

[23] The 1402 $\mu g/m^3$ impact from the Portland Plant did not include background concentrations. In most modeling applications, a representative background concentration would be added to the modeled concentrations from the source being modeled. But since the modeled concentration from the Portland Plant exceeded the NAAQS, accounting for background does not make a difference to the finding of violations. However, assumed background concentrations are needed for the remedy modeling which is discussed in section VII.

C. Summary of NJDEP's Trajectory Analysis and the Columbia Lake Monitor

As a supplement to its supporting modeling analyses, NJDEP analyzed winds using a trajectory model on days with the highest concentrations of SO_2 at a State operated ambient air monitoring site in Chester, Morris County, New Jersey. NJDEP used the HYSPLIT [24] model to calculate the movement of air during these two episodes, which covered three days (July 17–18, 2008 and December 7, 2009). The monitoring site in Chester is about 36 kilometers east-southeast of the Portland Plant. Concentrations of SO_2 on one of these days exceeded the 1-hour SO_2 NAAQS of 75 parts per billion (ppb). The trajectories generated by HYSPLIT show that air from the Portland Plant arrives in the vicinity of Chester about the time of the highest concentrations of SO_2, shown by running the model in two modes: Forward from the facility and backward from the monitoring site. When these high concentrations occurred, a review of available emissions data showed that no other facility in the area had emissions more than 1/1,000th the emissions of the Portland Plant. NJDEP asserts that this trajectory analysis demonstrates that it is likely that the Portland Plant is largely responsible for these recorded high concentrations.

We also note that 1-hour SO_2 monitoring data have been collected since September 23, 2010, at the NJDEP Columbia Lake Wildlife Management Area (WMA) air quality monitor in Knowlton Township, Warren County, New Jersey, located about 2 km northeast of the Portland Plant, that show several exceedances of the 1-hour SO_2 NAAQS. The exceedances are shown during periods when prevailing winds (as measured at the Allentown International Airport) would disperse emissions from the Portland Plant in the general direction of the Columbia monitor.

VI. EPA's Decision on Whether To Make a Section 126 Finding or Deny the Petition

Based on the results of the NJDEP modeling described previously, EPA is proposing to grant the request in NJDEP's September 17, 2010, petition that EPA make a finding that emissions from the Portland Plant significantly contribute to nonattainment or interfere with maintenance of the 1-hour SO_2 NAAQS.

As explained previously, NJDEP conducted dispersion modeling of the 1-hour SO_2 impacts using both the CALPUFF and AERMOD dispersion models. NJDEP also submitted a trajectory analysis of two particular episodes showing that elevated 1-hour SO_2 measurements at the Chester monitor in Morris County, New Jersey, were caused primarily by the Portland Plant. For the reasons explained previously and in the TSD in the docket for this rulemaking, EPA believes that the AERMOD analysis, submitted by NJDEP, provides a reasonable basis for analyzing whether or not emissions from the Portland Plant significantly contribute to nonattainment or interfere with maintenance in Warren, Sussex, Morris, and Hunterdon Counties in New Jersey. EPA has determined that the AERMOD modeling analysis provides a more appropriate technical basis for this petition than the modeling submitted based on the CALPUFF model, as explained in this notice and in more detail in the Modeling TSD. EPA's review of the NJDEP AERMOD analysis supports a finding that SO_2 emissions contribute significantly to nonattainment and interfere with maintenance of the 1-hour SO_2 NAAQS.

In addition, the trajectory analysis submitted from NJDEP and the preliminary air quality monitoring data collected from the Columbia monitor in New Jersey are consistent with our proposed finding of significant contribution to nonattainment and interference with maintenance of the 1-hour SO_2 NAAQS in New Jersey. A detailed review of the trajectory and monitoring data is included in the Trajectory Analysis of High Sulfur Dioxide Episodes TSD, and the Columbia Monitor in Warren County TSD contained in the docket for this proposal.

VII. EPA's Proposed Remedy

A. Quantification of the Emission Reductions Necessary To Eliminate the Portland Plant's Significant Contribution

EPA next conducted analyses to determine an appropriate remedy, as required by section 126.

In the section 126 petition, NJDEP suggested that appropriate remedies for the Portland Plant might be installation of scrubbers or meeting the RACT limit that New Jersey has set for SO_2 sources in its State. EPA's authority under section 126, however, is limited to

[24] The Hybrid Single-Particle Lagrangian Integrated Trajectory (HYSPLIT) model computes simple air parcel trajectories using a three-dimensional grid. NJDEP used the HYSPLIT model using an ETA meteorological model with a 12 km horizontal grid size for the three-dimensional grid. *See http://ready.arl.noaa.gov/* for more details on the HYSPLIT.

establishing emission limits and compliance schedules (including increments of progress) as needed to bring the Portland Plant into compliance as expeditiously as practicable. EPA cannot apply New Jersey law extraterritorially in Pennsylvania. In addition, we believe it is better policy for EPA, where only directed by statute to provide emission limits and compliance schedules, to allow the source the flexibility to achieve compliance in the way it determines is most reasonable and not to require the use of a specific technology.

Because section 126 allows continued operation of a major existing source subject to a section 126 finding, only if the source complies with emission limits and compliance schedules established by EPA to bring about compliance with the requirements in sections 110(a)(2)(D)(i) and 126 as expeditiously as practicable but in no case later than 3 years after the date of the finding. Thus, to determine the appropriate remedy, EPA must quantify the reductions necessary to eliminate the Portland Plant's significant contribution to nonattainment and interference with maintenance of the 1-hour SO_2 NAAQS in New Jersey.

We previously determined that due to the magnitude of the modeled violations in the NJDEP AERMOD modeling, the NJDEP modeling was sufficient to make a finding that the Portland Plant significantly contributes to nonattainment and interferes with maintenance in New Jersey. However, we noted some technical concerns with the NJDEP modeling which may affect the degree to which emissions need to be reduced to be able to meet the 1-hour SO_2 NAAQS in New Jersey. Therefore, EPA conducted an independent modeling assessment to help determine the necessary and appropriate emissions limit for Portland units 1 and 2.

1. Summary of EPA's Remedy Modeling for 1-Hour SO_2 NAAQS

EPA completed AERMOD modeling of the Portland Plant units 1, 2, and 5 using the 1993–1994 Portland Plant on-site meteorological data. EPA made several adjustments to the meteorological inputs (compared to the NJDEP modeling) which it determined to be appropriate, as documented in the Modeling TSD. The maximum modeled design value impact from the Portland Plant in New Jersey based on EPA's modeling was 851.1 $\mu g/m^3$. This included an impact from the Portland Plant of 811.8 $\mu g/m^3$ plus a background concentration of 39.3 $\mu g/m^3$. The details of the modeling setup are summarized later and in greater detail in the Modeling TSD, which is in the docket for this proposal.

2. Model Selection

As discussed in Section V.B of this notice, Appendix W, Section 4.4.2(b) states that AERMOD is "the recommended model" "[f]or a wide range of regulatory applications in all types of terrain." The modeling application under consideration in this section 126 petition is generally covered under this section of Appendix W since the transport distances of concern are less than 50 kilometers. Therefore, EPA used AERMOD to determine the necessary remedy to eliminate the significant contribution to nonattainment and interference with maintenance in New Jersey.

3. Meteorological Data

Similar to the NJDEP AERMOD application, the EPA AERMOD modeling was based on 1 year of site-specific meteorological data collected from a 100-meter instrumented tower and SODAR located about 2.2 kilometers west of the Portland Plant, for the period July 1993 through June 1994. This is the same meteorological database used in the NJDEP AERMOD analysis.

As noted earlier, there is a difference of about 100 meters between the base elevation for the meteorological tower and the Portland Plant stack base elevation. This raises concerns regarding how the meteorological data should be input to the AERMOD model, especially given that the stack heights for units 1 and 2 are about 122 meters and that plume heights of concern for units 1 and 2 are about 300 to 400 meters above stack base. Given that the vertical variability of wind directions in the Portland Plant area documented in Exhibit 11 submitted with NJDEP's May 13, 2010, petition, a key component of the modeling analysis is the representativeness of the site-specific winds for transport and dispersion of the Portland Plant emissions. Therefore, to address the issues of representativeness for this application, EPA made several adjustments to the meteorological data for the EPA remedy modeling, compared to the data used by NJDEP.

Specifically, we made some adjustments to the measurement heights for the Portland Plant site-specific meteorological data. Given that the local terrain relief is about 100 meters, and assuming that local terrain effects on flow would extend up to about 3 times the height of the "obstacles", we conclude that we should apply a simple adjustment based on the 100-meter difference in base elevations to measurement heights at or above 300 meters. It is reasonable to assume that little or no adjustment should be applied to the lowest level winds due to the dominance of surface drag and other local influences. In addition to the height adjustment, several other changes were made to the meteorological data inputs (*see* the Modeling TSD for additional details).

4. Receptor/Terrain Data

As noted in section V, EPA examined the terrain and receptor processing from the NJDEP AERMOD analysis and concluded that NJDEP's processing of terrain data based on several 7.5-minute (30-meter) DEM terrain files and two 1-degree (90-meter) DEM files for use in AERMOD was appropriate. However, EPA's AERMOD modeling was based on the application of the AERMAP terrain processor using the National Elevation Dataset (NED) format (USGS, 2002), which reflects updates to the older DEM terrain data. Additional details can be found in the Modeling TSD.

5. Portland Plant Emissions and Source Characteristics

The EPA AERMOD analysis used allowable SO_2 emissions rates for Portland Plant units 1, 2, and 5 along with stack parameters shown in Table VII.A–1 [25]:

TABLE VII.A–1

Source	Permitted emission rate (g/s)	Stack height (m)	Stack diameter (m)	Stack temperature (K)	Stack velocity (m/s)
Portland Plant Coal Unit 1	733.3	121.92	2.84	403.0	43.3

[25] The allowable emissions and stack parameters in Table VII.A–1 for units 1 and 2 are the same as used by NJDEP. The allowable emissions and stack parameters for unit 5 are based on a 2010 report regarding the Portland Plant prepared for RRI Energy.

TABLE VII.A–1—Continued

Source	Permitted emission rate (g/s)	Stack height (m)	Stack diameter (m)	Stack temperature (K)	Stack velocity (m/s)
Portland Plant Coal Unit 2	1,121.0	121.72	3.79	406.0	36.2
Portland Plant Turbine 5	12.0	42.7	6.1	821.5	36.6

6. Identification of Background Concentration To Use in the Remedy Analysis

The dispersion modeling submitted by NJDEP with the September 17, 2010, petition only included emissions from units 1 and 2 at the Portland Plant, and did not account for background concentrations of SO_2 from other sources. NJDEP did not offer any rationale regarding the exclusion of any contribution from background concentrations in the modeling.[26] Therefore, we address it here.

Section 8.2 of Appendix W provides guidance regarding the inclusion of background concentrations in dispersion modeling demonstrations of compliance with the NAAQS under PSD regulations. Appendix W defines "background air quality" as including "pollutant concentrations due to: (1) Natural sources; (2) nearby sources other than the one(s) currently under consideration; and (3) unidentified sources." *See* Section 8.2.1a. EPA recently issued additional clarification regarding application of Appendix W guidance for the 1-hour NO_2 NAAQS,[27] indicating that portions of that guidance are equally applicable to the 1-hour SO_2 NAAQS. Two topics addressed in the March 1, 2011, guidance that are relevant here are the determination of background concentrations and combining modeled results with monitored background concentrations to determine cumulative impacts. While the guidance does not explicitly address dispersion modeling analyses in the context of a section 126 petition, we believe that the guidance provides an appropriate basis for the modeling conducted for the Portland Plant in support of this action.

A review of SO_2 emission sources within 50 km of the Portland Plant identified 10 sources, located mostly in Pennsylvania southwest of the Portland Plant. One of the closest sources is the PPL Martins Creek Plant located about 14 km south-southwest of the Portland Plant. Martins Creek emitted around 1,000 tons per year of SO_2 in 2009. The next closest sources with SO_2 emissions of at least 2,000 tpy are two cement plants located in the Lehigh Valley about 25–30 km southwest of the Portland Plant. A more detailed discussion of nearby sources is provided in the Modeling TSD.

Of the SO_2 emission sources identified for possible inclusion in the modeling analysis, the Martins Creek Plant is the only source that is large enough and close enough to the Portland Plant to be considered for inclusion in the modeling analysis. However, the SO_2 emissions from the Martins Creek Plant are somewhat intermittent (as noted earlier, Martins Creek units 3 and 4 averaged about 1,039 and 584 hours of operation per year respectively). Even more fundamentally, the purpose of this modeling is to determine the impact of the Portland Plant itself on the downwind nonattainment areas. Any intermittent impacts from Martins Creek would be in addition to the impacts from the Portland Plant and the Portland Plant would have no obligation to remedy any violations associated solely with those emissions. This modeling uses actual monitored background levels of SO_2 such that it is reasonable to expect that the contribution of intermittent emissions from Martins Creek and other nearby sources is accounted for in EPA's analysis. This approach is also consistent with the modeling analysis conducted by NJDEP. Further details regarding our assessment of nearby SO_2 sources are provided in the Modeling TSD.

There are currently three operating SO_2 monitors within 50 km of the Portland Plant, including the Chester monitor located about 36 km southeast of the Portland Plant in Morris County, New Jersey, the Easton monitor located about 27 km southeast in Northampton County, Pennsylvania, and the Columbia Lake WMA monitor located about 2 km northeast in Warren County, New Jersey. The Columbia monitor has only been in operation since September 23, 2010, while the Chester and Easton(2) monitors have been in operation for several years.

Of the two long term SO_2 monitors, the ambient SO_2 data from the Chester, New Jersey, monitor provides the most representative background concentrations for this analysis since the distribution of sources impacting the Chester monitor is more similar to the distribution of sources around the Portland Plant. While the Easton(2), Pennsylvania, monitor is better situated to capture background concentrations upwind in relation to Portland Plant impacts in New Jersey, the Easton(2) monitor is close enough to the Lehigh Valley Cement Plants and other SO_2 sources that monitored SO_2 levels at Easton(2) would overestimate background concentrations applicable to this analysis.

The Columbia monitor data period is too short to serve as a source of monitored background concentrations for this application. Given its proximity to the Portland Plant, it is likely to capture ambient SO_2 impacts associated with the Portland Plant emissions under appropriate meteorological conditions. The location of the Columbia monitor also suggests that it may provide some useful insight into background concentration levels within the area by examining the concentration distribution during periods that are not affected by emissions from the Portland Plant.

Based on an assessment of the available SO_2 monitoring data, we determined that the Chester monitor is the most appropriate monitor to account for background SO_2 concentrations for the Portland Plant. Consistent with the March 1, 2011, guidance, we included monitored concentrations based on the 99th-percentile by season and hour-of-day from the Chester data for 2007 through 2009 (the most recent data available) to account for background concentrations. These background SO_2 concentrations by season and hour-of-day varied from 13 $\mu g/m^3$ to 60 $\mu g/m^3$. Examination of hourly SO_2 concentrations for both the Chester monitor and the available data from the Columbia monitor indicates very low concentrations (less than 3 ppb) during

[26] Arguably, since the NJDEP modeling showed modeled violations of the NAAQS without background concentrations, it was not necessary for them to identify and/or add background concentrations to the results. However, in order to develop a remedy, it is necessary to consider background concentrations.

[27] "Additional Clarification Regarding Application of Appendix W Modeling Guidance for the 1-hour NO_2 National Ambient Air Quality Standard." Memorandum from Tyler Fox, OAQPS/AQAD, dated March 1, 2011.

the majority of the hours. However, we consider the background concentrations used in our analysis (13 μg/m³ to 60 μg/m³) to be appropriate for this application given that no other emission sources were explicitly modeled. A more detailed discussion of our assessment and use of monitored SO_2 concentrations for this analysis are provided in the Modeling TSD.

7. Summary of EPA's Modeling Results

The results of the AERMOD model runs relied on by EPA to determine the appropriate remedy are described later and fully documented in the Modeling TSD which is included in the docket.

EPA's modeling based on the NJDEP coarse receptor grids resulted in a 1-hour SO_2 modeled design value of 841 μg/m³ (about 321 ppb) at a receptor located about 3 kilometers north-northeast of the Portland Plant. Compared to the initial coarse grid analysis conducted by NJDEP, EPA's modeled design value is about 32 percent lower (compared to 1,236 μg/m³) and occurs at a different location within the modeling domain. While EPA's modeling showed peak impacts much lower than NJDEP's peak design value, we note that EPA's modeled peak design value of 841 μg/m³ is about 90 percent higher than NJDEP's modeled impact at EPA's peak receptor location. These differences are likely due to the adjustments in the processing of meteorological data input to the model. The adjustments to the measurement heights could result in significant differences in the transport direction for particular hours, as well as somewhat lower wind speeds. Both of these factors could shift the modeled impact area away from the higher terrain around the Delaware Water Gap toward a different part of the domain. The inclusion of observed σ_w data (standard deviation of the vertical velocity fluctuations) from the SODAR in the EPA modeling could also account for this shift in the maximum impact area from the Portland Plant. If observed σ_w values are higher than the reference values used in AERMOD in the absence of observations, then modeled impacts near the Delaware Water Gap, which are associated with direct plume impaction on the complex terrain, could be significantly lower. In contrast, larger σ_w values would tend to increase concentrations in the lower terrain, northeast of the Portland Plant, by mixing the plume to the ground faster. This would result in maximum impacts closer to the source.

Based on the results from the initial coarse grid analysis, EPA developed a finer resolution receptor network that included two separate grids with 100-meter horizontal resolution. The smaller of the two fine resolution grids covers the impact area near the Delaware Water Gap to the northwest, and is similar to NJDEP's 100-meter fine grid, but is extended an additional 500 meters to the north and east. The larger fine resolution grid is focused on the area surrounding the maximum design value from the EPA's initial coarse grid model run, and extends about 5 km north, 4 km east, 1 km south and 2 km west of the Portland Plant.

EPA's modeling based on the 100-meter fine receptor grids resulted in modeled design value (including background) of 851.1 μg/m³ (about 325 ppb). The total concentration of 851.1 μg/m³ consists of the contribution from the Portland Plant of 811.8 μg/m³ plus 39.3 μg/m³ from background. This result is slightly higher than (and near the location of) the controlling coarse grid result.

a. Calculation of Emissions Limits Based on Maximum Modeled Impacts From Units 1 and 2 Plus Background

As detailed previously, the modeled maximum 99th percentile (4th-highest) daily maximum 1-hour SO_2 concentration (including monitored background) from the Portland Plant in New Jersey was 851.1 μg/m³. Table VII.A–2 shows the contribution from each of the Portland Plant units to the design value concentration.

TABLE VII.A–2

Unit 1	Unit 2	Unit 5	Background	Total
371.7 μg/m³	439.2 μg/m³	0.91 μg/m³	39.3 μg/m³	851.1 μg/m³.

Based on this result, EPA calculated the emissions reduction needed to eliminate the Portland Plant's significant contribution to nonattainment in New Jersey. The calculation is relatively simple in this case because emissions from the Portland Plant alone cause violations of the 1-hour SO_2 NAAQS in New Jersey and background levels of SO_2 are very low. If the modeled concentration from the Portland Plant plus background is reduced to a level that is below the 1-hour SO_2 NAAQS, then there will be no modeled violations of the NAAQS in New Jersey.

Based on the EPA modeling results, an 81 percent reduction in allowable SO_2 emissions from Portland Plant units 1 and 2 is needed to reduce the Portland Plant contribution plus background to below the NAAQS. The calculation is as follows: (Total modeled concentration)—(NAAQS—background)/(total modeled concentration). This calculation recognizes that the assumed background concentration cannot be reduced. The actual calculation based on Table VII.A–2 is (811.8) − (196–39.3)/811.8. This results in a reduction of 80.7 percent, which we round to 81 percent.

In this calculation, the contribution from all modeled sources (units 1, 2, and 5) is included in the total contribution. However, the contribution from unit 5 is only 0.1 percent of the total contribution (0.91 μg/m³ contribution to the design value). A reduction in the unit 5 contribution would provide a negligible reduction to the modeled design value. Therefore, it can be assumed that unit 5 emissions do not need to be reduced, and therefore can be added to the irreducible background value. This alternative calculation gives an emissions reduction of 80.8 percent (which is essentially the same as the previous 80.7 percent calculation). Therefore, we conclude that only emissions reductions from units 1 and 2 are needed in order to ensure that the downwind area in New Jersey will be able to attain the NAAQS and will not have maintenance problems and that a revised emissions limit is not needed for unit 5.

While a total emissions reduction of 81 percent for both units 1 and 2 eliminates all modeled violations in New Jersey, an additional question remains. Can the emissions limit be met by over controlling one unit (by more than 81 percent) and under controlling the other unit (by less than 81 percent)? Based on our analysis, there are many different combinations of emissions limits for units 1 and 2 that would eliminate violations of the SO_2 NAAQS in New Jersey. However, the stack parameters (exit velocity and stack diameter) of units 1 and 2 are slightly different, which causes the maximum downwind impacts from each unit to occur at slightly different locations at

different times. Therefore, the emissions limit has to be assigned to each individual unit and cannot be a combined limit. There are many different combinations of emissions limits for units 1 and 2 that would eliminate violations of the SO_2 NAAQS in New Jersey, but we are not able to examine an unlimited number of combinations. Therefore we are proposing an emissions limit based on an 81 percent reduction in allowable emissions at both units 1 and 2. This leads to a proposed SO_2 emissions limit for unit 1 of 1105 lbs/hr (5820*0.19) and a proposed SO_2 emissions limit for unit 2 of 1691 lbs/hr (8900*0.19).

As a final check on the remedy, EPA ran AERMOD again with the above emissions limits on the Portland Plant's units 1 and 2 (and current allowable emissions from unit 5). At these proposed emissions levels, all receptors in New Jersey were below the 1-hour SO_2 NAAQS. The modeled 99th percentile (4th-highest) daily maximum 1-hour SO_2 concentration was 192.2 $\mu g/m^3$ (including a background concentration of 41.9 $\mu g/m^3$).

EPA is requesting comment on other possible combinations or approaches in setting limits that are no less stringent than the proposed limits, but also result in elimination of the modeled violations while allowing for operating flexibility and load shifting. For example, a combined limit could be set for both units 1 and 2, in conjunction with individual limits, such as those proposed, for units 1 and 2. Similarly, a limit could be set for emissions from all relevant units at the plant accompanied by individual limits for units 1 and 2. EPA also requests comment on the proposed emissions limit calculations.

VIII. Proposed Emission Limits and Compliance Schedules

A. Statutory Requirements for Sources for Which EPA Makes a Section 126(b) Finding

Section 126(c) initially makes it unlawful for any major existing source to operate more than 3 months after a section 126 finding has been made with respect to it; yet also gives the Administrator authority to permit continued operation under certain conditions. Specifically, the statute provides that the Administrator "may permit the continued operation" of such a source beyond the end of the three month period "if such source complies with such emission limitations and compliance schedules (containing increments of progress) as may be provided by the Administrator to bring about compliance with the requirements contained in section 7410(a)(2)(D)(i) of this title or this section as expeditiously as practicable, but in no case later than three years after the date of such finding." 72 U.S.C. 7426(c). Thus, unless the Administrator affirmatively decides to permit continued operation of the source and establishes emission limitations and compliance schedules, an existing major source subject to a section 126 finding must shut down in three months. However, if the source complies with the emission limitations and compliance schedules established by the Administrator, it may continue operation.

Section 126, however, does not give the Administrator unlimited discretion when establishing emission limitations and compliance schedules. Instead, the statute provides that the emission limitations and compliance schedules must bring about compliance with the requirements of section 110(a)(2)(D)(i) of the Act "as expeditiously as practicable" but in no case later than 3 years from the date of the finding. The use of the phrase "as expeditiously as practicable" allows for consideration of the time needed to implement a compliance option in setting a compliance schedule. However, the length of time needed to implement any given compliance option depends on the compliance option to be implemented. Furthermore, EPA recognizes that in some instances a source may choose to cease operation as its method of compliance. EPA is therefore requesting comment on the meaning of as "expeditious as practicable" in this context.

EPA recognizes both that the statute requires that any compliance schedule ensure compliance as "expeditiously as practicable" and also that while the statute directs EPA to establish emission limits and compliance schedules, it does not foreclose EPA from allowing the source to select a compliance option. EPA thus seeks to balance the statutory requirement of compliance as "expeditiously as practicable" with the goal of ensuring that the regulation does not unnecessarily limit the options available to the source to achieve compliance within the statutorily mandated timeframe. For these reasons, EPA has determined that it would be reasonable to interpret the statute as allowing EPA to develop different compliance schedules for different compliance options. By doing so, EPA can both give flexibility to the source to select an appropriate compliance option and ensure that compliance is achieved as "expeditiously as practicable." As discussed later, EPA is also explicitly requesting comment on how to interpret the term "as expeditiously as practicable" when the method of compliance selected is to cease operations.

B. Proposed Emission Limits

As explained in this subsection, EPA is proposing specific emission limitations and a specific compliance schedule that would apply unless the Portland Plant decides to cease operation as its method of compliance. EPA requests comment on all aspects of the emission limits and compliance schedule discussed later.

Based on the NJDEP AERMOD dispersion modeling analysis and EPA's independent assessment, EPA proposes to allow the continued operation of the Portland Plant beyond the three months, provided that the Portland Plant complies with a SO_2 emission limit of 1105 lbs/hr for unit 1, and 1691 lbs/hr for unit 2, representing an 81 percent reduction from currently allowable SO_2 emissions for each unit, to eliminate its significant contribution to nonattainment and prevent it from interfering with maintenance of the 1-hour SO_2 NAAQS in New Jersey. The source would be required to comply with this emission limit and the compliance deadlines and schedules (including increments of progress) set by EPA in the final rulemaking. EPA's proposed compliance schedules are discussed in more detail in sections C and D of this section.

EPA believes that these proposed emission limits for units 1 and 2 are appropriate since AERMOD modeling performed as described in section VII of this notice and in the TSD demonstrates that the Portland Plant must reduce its SO_2 emissions to these levels in order to reduce the modeled SO_2 concentration in New Jersey below the 1-hour SO_2 NAAQS level of 196 $\mu g/m^3$. As also discussed previously, EPA believes this is the appropriate remedy in this particular circumstance where the modeling shows that emissions from a single plant (the Portland Plant) are, by themselves, causing NAAQS exceedances downwind and background concentrations of the relevant pollutant are low. EPA requests comment on the emission limits proposed for units 1 and 2.

EPA is not proposing to revise emission limits on the Portland Plant's smaller units (*i.e.,* units 3, 4, 5, and the auxiliary boiler). Based on our review of their emissions, EPA proposes revised emission limits are not needed at units 3, 4, 5, and the auxiliary boiler. Portland Plant units 3, 4, 5, and the auxiliary boiler have very small emissions, in comparison to units 1 and 2. EPA's

modeling of unit 5 found a total contribution of only 0.1 percent (*i.e.,* 0.91 μg/m^3 contribution to the design value) so that reductions in its contribution would provide a negligible reduction to the modeled design value and thus do not need to be reduced. Annual SO_2 emissions reported in the 2008 NEI, Version 1 for the auxiliary boiler, unit 3 and unit 4 were 0.01, 0.02, and 0.03 tons, respectively. Therefore, given the negligible modeled contribution from unit 5, it can be assumed that emissions from these units do not need to be reduced. Therefore, units 3, 4, 5, and the auxiliary boiler can continue to operate at their previous emissions limit. EPA requests comment on its proposed determination not to establish emission limits for units 3, 4, 5, and the auxiliary boiler.

C. Proposed Compliance Schedules

Section 126 allows the Administrator to permit the continued operation of a source if the source complies with emission limitations and compliance schedules (including increments of progress) to bring about compliance as expeditiously as practicable but in no case later than 3 years after the date of the finding. *See* 42 U.S.C. 7426(c). EPA proposes in this section the compliance schedule that would apply unless the source opts to cease operation of the units subject to emission limits. In subsection D later, EPA is requesting comment on an alternate compliance schedule that would apply if the source opts to cease operations at units subject to emission limits as its method of compliance. As part of that, we are asking for comment on what would constitute compliance "as expeditiously as practicable" if the source decides to cease operation of the units subject to emission limits as its method of compliance. The proposed compliance schedule and increments of progress discussed in this subsection were developed based on the assumption that the plant would need time to install controls to reduce its emissions. They would not apply if the compliance option selected is to cease operation of the units subject to emission limits.

EPA proposes to require compliance with the emission limits described in subsection VIII.B no later than 3 years from the effective date of the section 126 finding. EPA is asking for comment on whether 3 years from the effective date of the section 126 finding is "as expeditious as practicable." In addition, EPA proposes a schedule of interim reduction steps that will provide incremental progress toward eventual compliance with the requirements of section 110(a)(2)(D)(i)(I) and a schedule of milestones that must be achieved to provide assurance that the source is on track to achieve full compliance as expeditiously as practicable and no later than the 3 year deadline.

EPA is proposing to include an interim reduction requirement because section 126 calls for the establishment of a compliance schedule "including increments of progress," 42 U.S.C. 7426, and interim reduction requirements constitute important increments of progress towards full compliance. More specifically, EPA is proposing to require the source to meet an SO_2 emission limit of 2910 lbs/hr for unit 1 and 4450 lbs/hr for unit 2, representing a 50 percent reduction from allowable SO_2 emissions, after 1 year. EPA is proposing this interim reduction because, as explained previously in further detail, EPA's analysis supports that the Portland Plant's Units 1 and 2 are significantly contributing to nonattainment or interfering with maintenance of the 1-hour SO_2 NAAQS in New Jersey. EPA has evaluated the emission reduction options available and has determined that several potentially available options could provide incremental reductions such as reagent injection, switching to lower sulfur coal and load shifting. Information from the U.S. Department of Interior, U.S. Geological Survey indicates lower sulfur coal may be available in Pennsylvania.[28] EPA's analysis of available control technologies for coal-fired electric generating units and experience with coal-fired electric generating units also support that reagent injection can achieve emissions reductions at coal-fired electric generating units in excess of fifty percent and can be installed and operational on coal-fired electric generating units in less than 12 months.[29] EPA requests comment on the proposed interim reduction requirements for units 1 and 2, including achievability of limits in the time proposed, and the impact of the reductions on the reliability of the electric grid.

EPA also proposes to establish the following milestones that the source would be required to meet to demonstrate that it is on track to achieving full compliance as expeditiously as practicable and no later than the 3 year deadline.

(1) Within 3 months of EPA's finding, the Portland Plant shall notify EPA whether it will continue to operate subject to the emission limitations and compliance schedules established by EPA herein, whether under the proposed emissions limits or under an alternative where the plant would cease operation, such as the alternative compliance option presented for comment later in this notice, in which the plant could chooses to cease operation by a date certain, and meet certain interim milestones for reducing emissions. If the plant plans to continue to operate subject to emissions limits, the plant shall also indicate how the plant intends to achieve full compliance with the emission limits established in this notice. Specifically, the plant must indicate whether it intends to cease or reduce operation at any emission unit subject to emission limits as its method of compliance with such limits. The Portland Plant must also include in this notice what physical or operational changes, if any, the plant will implement as its method of compliance with the emission limits and compliance schedules EPA will establish in the section 126 finding, including predicted emissions reductions and emission rates after changes are implemented. EPA requests comment on all aspects of this proposed requirement, including on what specific information should be included in this notification and the appropriate level of detail that should be required.

(2) If the notice required by paragraph (1) above indicates that the plant intends to continue operation of the plant past the three month period, the plant must also comply with the requirements in paragraphs (3)–(7) later.

(3) No later than 3 months from the date of the section 126 finding, the Portland Plant shall submit to EPA a modeling protocol, consistent with EPA's Guideline on Air Quality Models, which is codified at 40 CFR Part 51, Appendix W and other relevant modeling guidance issued to support regulatory programs, for air modeling of the selected remedy. The air modeling to be conducted by the source will need

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[28] *See* information from the *U.S. Department of the Interior, U.S. Geological Survey* at *http://pubs.usgs.gov/of/1998/of98–763/#fig2.*

[29] *See* Summary Report, *Trona Injection Tests, Mirant Potomac River Station, Unit 1,* November 12- December 23, 2005 at *http://www.oe.energy.gov/DocumentsandMedia/mirant_012006_g.pdf;* Kong, Yougen and Davidson, Heidi, *Dry Sorbent Injection of Sodium Sorbents for SO_2, HCl, and Mercury Mitigation,* May 11–13, 2010 at *http://www.seas.columbia.edu/earth/wtert/sofos/nawtec/nawtec18/nawtec18-3560.pdf;* ADA–ES, Inc, *TOXECON™ Retrofit for Multi-Pollutant Control on Three 90–MW Coal-Fired Boilers, Topical Report: Performance and Economic Assessment of Trona-Based SO_2/NO_X Removal at the Presque Isle Power Plant Prepared for We Energies and DOE/NETL, August 25, 2008 at http://www.netl.doe.gov/technologies/coalpower/cctc/ccpi/pubs/SOx-Ox%20Reduction%20at%20PIPP%20-20Topical%20Report%20Final.pdf;* and ENSR Corporation, *BART Analysis for the Kincaid Power Plant Prepared for Dominion Energy, Inc.,* January 2009 at *http://www.epa.state.il.us/air/drafts/regional-haze/bart-kincaid.pdf.*

to demonstrate that, when that remedy is implemented, the Portland Plant will no longer significantly contribute to nonattainment or interfere with maintenance in New Jersey with respect to the 1-hour SO_2 NAAQS. All units at the Portland Plant (*i.e.,* units 1 thru 5 plus the auxiliary boiler) shall be included in the modeling analysis, in order to demonstrate that emissions from the Portland Plant will not significantly contribute to nonattainment or interfere with maintenance with respect to the 1-hour SO_2 NAAQS.

(4) If EPA identifies deficiencies in the modeling protocol submitted by the source, the Portland Plant will have 15 business days to submit a revision to correct any deficiencies identified by EPA.

(5) No later than 6 months from the date of the section 126 finding, Portland Plant shall submit a modeling analysis for the selected remedy performed in accordance with the modeling protocol.

(6) Beginning 6 months after the section 126 finding and continuing every 6 months until the final compliance date, the Portland Plant shall submit to EPA a progress report on the implementation of the remedy, including status of design, technology selection, development of technical specifications, awarding of contracts, construction, shakedown, and compliance demonstration.

(7) No later than 3 years following EPA's final rulemaking, the Portland Plant shall submit a final project report which demonstrates compliance with the emission limits in the final rulemaking. The final report shall include the date when full operation of controls was achieved at the Portland Plant after shakedown; as well as a minimum of 1 month of CEMS data demonstrating compliance with the emission limits in the final rulemaking.

EPA requests comment on all aspects of this proposed compliance schedule and the proposed increments of progress. Key issues EPA is requesting comment on include: Whether the compliance schedule is sufficient to achieve compliance as expeditiously as practicable; whether additional increments of progress are necessary and, if so, what they should be; what level of detail should be required in the notices the Portland Plant will be required to submit; whether the deadline for each increment of progress is appropriate or should be sooner or later; whether continued periodic progress reports should be required after the final compliance date; and whether the required progress reports and final project reports are sufficient to document and demonstrate compliance.

D. Alternate Compliance Schedule

As noted previously, EPA is also requesting comment on how to interpret the phrase "compliance as expeditiously as practicable" when the source has selected to cease operation of either unit as its method of compliance with the emission limit for that unit and cessation cannot occur within 3 months of EPA's finding. If EPA determines that it is appropriate to do so, EPA will include in the final rule a compliance schedule and increments of progress that would apply only if the source opts to cease operations at either unit subject to an emission limit as its method of compliance with the limit. EPA, therefore, is also requesting comment on what an appropriate compliance schedule would be, what factors EPA should consider in setting the compliance schedule, and what form the increments of progress should take. Though not an exhaustive list of relevant factors, EPA is taking comment on the following factors for determining what "compliance as expeditiously as practicable" means when compliance with an emission limit is to be achieved by ceasing to operate the unit subject to the limit: Electricity grid reliability issues; contracts that the source has with the electric utility independent service operator (ISO); other contractual obligations that the source has that would be impacted by a shutdown; whether the source is designated as a reliability must-run unit for any purpose by the ISO; whether some amount of electricity generating capacity at the source could be shut down in a shorter time period without creating reliability issues for the grid; what types of actions are required to address grid reliability (if there are any such issues), such as transmission line upgrades; how long it would take to address reliability issues (if there are any such issues); and the continued impact of interstate transport of emissions from the source on air quality in the affected State. EPA is also taking comment on whether other factors should be considered, and requests that commenters identify any additional relevant factors. In light of the factors enumerated previously as well as any other relevant factors, EPA is requesting comment on what would be an appropriate compliance schedule, that is as expeditious as practicable but no later than 3 years after the date of such finding, if compliance with the requirements of section 110(a)(2)(D)(i) is to be achieved by ceasing operations of the unit subject to the limit and cessation of operations cannot occur within 3 months of EPA's finding.

In addition to these factors, EPA also requests comment on what increments of progress should be established as part of the compliance schedule discussed previously. EPA specifically requests comment on the relevant milestones that should be included in a compliance schedule. At a minimum the interim milestones discussed in paragraphs (1) through (4) of section VIII.C would apply. That is, the Portland Plant would be required to notify EPA whether it will cease to operate within 3 months of EPA's finding or whether it will continue to operate subject to the emission limitations and compliance schedules established by EPA herein. The Portland Plant would also need to submit a protocol for and later submit air quality modeling sufficient to demonstrate that emissions from the plant, after implementation of the remedy, will no longer significantly contribute to nonattainment or interfere with maintenance of the 1-hour SO_2 NAAQS in New Jersey. This requirement would be waived only if the source opted to cease operation of all emitting units at the Portland Plant.

EPA also specifically requests comment as to whether to include interim emission reductions during the period of time that the plant continues to operate after such a finding until the eventual shutdown. And if so, EPA requests comment as to the appropriate level of emission reductions.

IX. Statutory and Executive Order Reviews

A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review

This proposed action is not a "significant regulatory action" under the terms of Executive Order (EO) 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011) and is therefore not subject to review under EO 12866 or EO 13563.

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.,* because this proposed rule, if finalized, under section 126 of the CAA will not in-and-of itself create any new information collection burdens but simply establishes a SO_2 emission limit at the Portland Plant. Burden is defined at 5 CFR 1320.3(b).

C. Regulatory Flexibility Act (RFA)

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

For purposes of assessing the impacts of this rule on small entities, small entity is defined as: (1) A small business as defined by the Small Business Administration's (SBA) regulations 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 proposed rule on small entities, I certify that this action will not have a significant economic impact on a substantial number of small entities. The SO_2 emission limits for the Portland Plant being proposed in this notice do not impose any new requirements on small entities.

We continue to be interested in the potential impacts of the proposed rule on small entities and welcome comments on issues related to such impacts.

D. Unfunded Mandates Reform Act

This rule does not contain a Federal mandate that may result in expenditures of $100 million or more for State, local, and Tribal governments, in the aggregate, or the private sector in any 1 year. The costs necessary to comply with the emission limit proposed in this notice are not expected to exceed $100 million or more for State, local, and Tribal governments, in aggregate, or the private sector in any 1 year. Thus, this rule is not subject to the requirements of sections 202 or 205 of UMRA.

This rule is also not subject to the requirements of section 203 of UMRA because it contains no regulatory requirements that might significantly or uniquely affect small governments. The requirements for compliance in this action will be borne by a single, privately owned source.

E. Executive Order 13132: Federalism

This action 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. The proposed rule primarily affects private industry, and does not impose significant economic costs on State or local governments. Thus, Executive Order 13132 does not apply to this action.

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

This action does not have Tribal implications, as specified in Executive Order 13175 (65 FR 67249, November 9, 2000). It will not have a substantial direct effect on Tribal governments, on the relationship between the Federal government and Indian Tribes, or the distribution of power and responsibilities between the Federal government and Indian Tribes. Thus, Executive Order 13175 does not apply to this action.

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

EPA interprets Executive Order 13045 (62 FR 19885, April 23, 1997) as applying to those regulatory actions that concern health or safety risks, such that the analysis required under section 5–501 of the Order has the potential to influence the regulation. This action is not subject to Executive Order 13045 because it proposes to improve a State action for the implementation of a previously promulgated health or safety based Federal standards. EPA believes that the proposed emissions reductions in this rule will further improve air quality and will further improve children's health.

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

This action is not subject to Executive Order 13211 (66 FR 28355 (May 22, 2001)), because it is not a significant regulatory action under Executive Order 12866.

I. National Technology Transfer and Advancement Act

Section 12(d) of the National Technology Transfer and Advancement Act of 1995 ("NTTAA"), Public Law 104–113, 12(d) (15 U.S.C. 272 note) 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. NTTAA directs EPA to provide Congress, through OMB, explanations when the Agency decides not to use available and applicable voluntary consensus standards.

This proposed rulemaking does not involve technical standards. Therefore, EPA is not considering the use of any voluntary consensus standards.

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

Executive Order 12898 (59 FR 7629, February 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, if finalized, will not have disproportionately high and adverse human health or environmental effects on minority or low-income populations because it increases the level of environmental protection for all affected populations without having any disproportionately high and adverse human health or environmental effects on any population, including any minority or low-income population. This proposed rule limits emissions of SO_2 from the Portland Plant located in Northampton County, Pennsylvania.

List of Subjects in 40 CFR Part 52

Administrative practice and procedure, Air pollution control, Intergovernmental relations, Reporting and recordkeeping requirements, Sulfur dioxide.

Dated: March 31, 2011.

Lisa P. Jackson,

Administrator.

For the reasons set forth in the preamble part 52 of chapter I of title 40

of the Code of Federal regulations are proposed to be 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 NN— Pennsylvania

2. Section 52.2039 is added to read as follows:

§ 52.2039 Interstate transport.

EPA has made a finding pursuant to section 126 of the Clean Air Act that emissions of sulfur dioxide (SO_2) from the Portland Generating Station in Northampton County, Upper Mount Bethel Township, Pennsylvania significantly contribute to nonattainment and interfere with maintenance of the 1-hour SO_2 national ambient air quality standard (NAAQS) in New Jersey. The owners and operators of the Portland Generating Station shall either cease operations no later than 90 days from the effective date of the section 126 finding or comply with the requirements in paragraphs (b) through (e) of this section.

(a) No later than 90 days from the effective date of the section 126 finding, the owners and operators of the Portland Generating Station shall notify EPA whether the owners and operators will operate the Portland Generating Station after the date 90 days after the effective date of the section 126 finding in compliance with the requirements in paragraphs (b) through (e) of this section. If the owners and operators will operate the Portland Generating Station after such date, such notice must also specify the methods to be used to ensure compliance with the emission limits in paragraphs (b) and (c) of this section.

(b) The owners and operators of Portland Generating Station in Upper Mount Bethel Township, Northampton County, Pennsylvania, shall not, at any time later than three years after the effective date of the section 126 finding, emit SO_2 (as determined in accordance with part 75 of this chapter) in excess of the following limits:

(1) 1,105 pounds per hour ("lbs/hr") for unit 1 (identified with source ID 031 in Title V Permit No. 48–0006) and

(2) 1,691 lbs/hr for unit 2 (identified with source ID 032 in Title V Permit No. 48–0006).

(c) The owners and operators of the Portland Generating Station in Upper Mount Bethel Township, Northampton County, Pennsylvania, shall not, at any time later than one year after the effective date of the section 126 finding, emit SO_2 (as determined in accordance with part 75 of this chapter) in excess of the following limits:

(1) 2,910 lbs/hr for unit 1 (identified with source ID 031 in Title V Permit No. 48–0006); and

(2) 4,450 lbs/hr for unit 2 (identified with source ID 032 in Title V Permit No. 48–0006);

(3) Provided that the limits in paragraphs (c)(1) and (c)(2) of this section shall not apply if the notice required by paragraph (a) of this section indicates that the owners and operators of the Portland Generating Station have decided to completely and permanently cease operation of unit 1 (identified with source ID 031 in Title V Permit No. 48–0006) and unit 2 (identified with source ID 032 in Title V Permit No. 48–0006) as the method of compliance with the emission limits in paragraph (b) of this section.

(d) The owners and operators of the Portland Generating Station shall comply with the following requirements:

(1) Perform air modeling to demonstrate that, starting no later than three years after the effective date of the section 126 finding, emissions from the Portland Generating Station will not significantly contribute to nonattainment or interfere with maintenance of the 1-hour SO_2 NAAQS in New Jersey, in accordance with the following requirements:

(i) No later than 90 days after the effective date of the section 126 finding, submit to EPA a modeling protocol that is consistent with EPA's Guideline on Air Quality Models, as codified at 40 CFR Part 51, Appendix W, and that includes all units at the Portland Generating Station in the modeling.

(ii) Within 15 business days of receipt of a notice from EPA of any deficiencies in the modeling protocol under paragraph (d)(1)(i) of this section, submit to EPA a revised modeling protocol to correct any deficiencies identified in such notice.

(iii) No later than 180 days after the effective date of the section 126 finding, submit to EPA a modeling analysis, performed in accordance with the modeling protocol under paragraphs (d)(1)(i) and (d)(1)(ii) of this section, for the compliance methods identified in the notice required by paragraph (a) of this section.

(2) Starting 180 days after the effective date of the section 126 finding and continuing every six months until the date three years after the effective date of the section 126 finding, submit to EPA progress reports on the implementation of the methods of compliance identified in the notice required by paragraph (a) of this section, including status of design, technology selection, development of technical specifications, awarding of contracts, construction, shakedown, and compliance demonstration. These reports shall include:

(i) An interim project report, submitted no later than one year after the effective date of the section 126 finding, that demonstrates compliance with the emission limits in paragraph (c) of this section.

(ii) A final project report, submitted no later than three years after the effective date of the section 126 finding, that demonstrates compliance with the emission limits in paragraph (b) of this section and that includes the date when full operation of controls was achieved at the Portland Generating Station after shakedown.

(3) The requirements in paragraphs (d)(1) and (d)(2) of this section shall not apply if the notice required by paragraph (a) of this section indicates that the owners and operators of the Portland Generating Station have decided to completely and permanently cease operation of unit 1 (identified with source ID 031 in Title V Permit No. 48–0006) and unit 2 (identified with source ID 032 in Title V Permit No. 48–0006) as the method of compliance with the emission limits in paragraph (b) of this section.

(e) If the notice required by paragraph (a) of this section indicates that the owners and operators of the Portland Generating Station have decided to completely and permanently cease operation of unit 1 (identified with source ID 031 in Title V Permit No. 48–0006) and unit 2 (identified with source ID 032 in Title V Permit No. 48–0006) as the method of compliance with the emission limits in paragraph (b) of this section, the owners and operators shall meet the following requirements:

(1) No later than 90 days after the effective date of the section 126 finding, submit to EPA an analysis of the time required to completely and permanently cease operations at unit 1 (identified with source ID 031 in Title V Permit No. 48–0006) and unit 2 (identified with source ID 032 in Title V Permit No. 48–0006) as expeditiously as practicable.

(2) Within 15 business days of receipt of notice from EPA of any deficiencies in the analysis under paragraph (e)(1) of this section, submit to EPA a revised analysis to correct any deficiencies identified by EPA.

(3) Completely and permanently cease operation of unit 1 (identified with source ID 031 in Title V Permit No. 48–0006) by the date that achieves, as determined by the Administrator,

expeditious as practicable cessation of operation.

(4) Completely and permanently cease operation of unit 2 (identified with source ID 032 in Title V Permit No. 48–0006) by the date that achieves, as determined by the Administrator, expeditious as practicable cessation of operation.

[FR Doc. 2011–8166 Filed 4–6–11; 8:45 am]

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