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DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 97

[Docket No. 30881; Amdt. No. 3516]

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

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This rule establishes, amends, suspends, or revokes Standard Instrument Approach Procedures (SIAPs) and associated Takeoff Minimums and Obstacle Departure Procedures for operations at certain airports. These regulatory actions are needed because of the adoption of new or revised criteria, or because of changes occurring in the National Airspace System, such as the commissioning of new navigational facilities, adding new obstacles, or changing air traffic requirements. These changes are designed to provide safe and efficient use of the navigable airspace and to promote safe flight operations under instrument flight rules at the affected airports.

DATES: This rule is effective January 25, 2013. The compliance date for each SIAP, associated Takeoff Minimums, and ODP is specified in the amendatory provisions.

The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of January 25, 2013.

ADDRESSES: Availability of matter incorporated by reference in the amendment is as follows:

For Examination—

1. FAA Rules Docket, FAA Headquarters Building, 800 Independence Avenue SW., Washington, DC 20591;
2. The FAA Regional Office of the region in which the affected airport is located;
3. The National Flight Procedures Office, 6500 South MacArthur Blvd., Oklahoma City, OK 73169 or,
4. The National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.*

Availability—All SIAPs are available online free of charge. Visit *nfdc.faa.gov* to register. Additionally, individual SIAP and Takeoff Minimums and ODP copies may be obtained from:

1. FAA Public Inquiry Center (APA–200), FAA Headquarters Building, 800 Independence Avenue SW., Washington, DC 20591; or
2. The FAA Regional Office of the region in which the affected airport is located.

FOR FURTHER INFORMATION CONTACT: Richard A. Dunham III, Flight Procedure Standards Branch (AFS–420) Flight Technologies and Programs Division, Flight Standards Service, Federal Aviation Administration, Mike Monroney Aeronautical Center, 6500 South MacArthur Blvd., Oklahoma City, OK 73169 (Mail Address: P.O. Box 25082 Oklahoma City, OK 73125) telephone: (405) 954–4164.

SUPPLEMENTARY INFORMATION: This rule amends Title 14, Code of Federal Regulations, Part 97 (14 CFR part 97) by amending the referenced SIAPs. The complete regulatory description of each SIAP is listed on the appropriate FAA Form 8260, as modified by the National Flight Data Center (FDC)/Permanent Notice to Airmen (P–NOTAM), and is incorporated by reference in the amendment under 5 U.S.C. 552(a), 1 CFR part 51, and § 97.20 of Title 14 of the Code of Federal Regulations.

The large number of SIAPs, their complex nature, and the need for a special format make their verbatim publication in the **Federal Register** expensive and impractical. Further, airmen do not use the regulatory text of the SIAPs, but refer to their graphic depiction on charts printed by publishers of aeronautical materials. Thus, the advantages of incorporation by reference are realized and publication of the complete description of each SIAP contained in FAA form documents is unnecessary. This amendment provides the affected CFR sections and specifies the types of SIAP and the corresponding effective dates. This amendment also identifies the airport and its location, the procedure and the amendment number.

The Rule

This amendment to 14 CFR part 97 is effective upon publication of each separate SIAP as amended in the transmittal. For safety and timeliness of change considerations, this amendment incorporates only specific changes contained for each SIAP as modified by FDC/P–NOTAMs.

The SIAPs, as modified by FDC P–NOTAM, and contained in this amendment are based on the criteria contained in the U.S. Standard for Terminal Instrument Procedures (TERPS). In developing these changes to SIAPs, the TERPS criteria were applied only to specific conditions existing at the affected airports. All SIAP amendments in this rule have been previously issued by the FAA in a FDC NOTAM as an emergency action of immediate flight safety relating directly to published aeronautical charts. The circumstances which created the need for all these SIAP amendments requires making them effective in less than 30 days.

Because of the close and immediate relationship between these SIAPs and safety in air commerce, I find that notice and public procedure before adopting these SIAPs are impracticable and contrary to the public interest and, where applicable, that good cause exists for making these SIAPs effective in less than 30 days.

Conclusion

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore—(1) Is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. For the same reason, the

FAA certifies that this amendment will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR part 97:

Air Traffic Control, Airports, Incorporation by reference, and Navigation (Air).

Issued in Washington, DC, on January 4, 2013.

John M. Allen,

Director, Flight Standards Service.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me, Title 14, Code of Federal Regulations, Part 97, 14 CFR part 97, is amended by amending Standard Instrument Approach Procedures, effective at 0901 UTC on the dates specified, as follows:

PART 97—STANDARD INSTRUMENT APPROACH PROCEDURES

■ 1. The authority citation for part 97 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40103, 40106, 40113, 40114, 40120, 44502, 44514, 44701, 44719, 44721–44722.

§§ 97.23, 97.25, 97.27, 97.29, 97.31, 97.33, 97.35 [Amended]

■ 2. Part 97 is amended to read as follows:

By amending: § 97.23 VOR, VOR/DME, VOR or TACAN, and VOR/DME or TACAN; § 97.25 LOC, LOC/DME, LDA, LDA/DME, SDF, SDF/DME; § 97.27 NDB, NDB/DME; § 97.29 ILS, ILS/DME, MLS, MLS/DME, MLS/RNAV; § 97.31 RADAR SIAPs; § 97.33 RNAV SIAPs; and § 97.35 COPTER SIAPs, Identified as follows:

** * *Effective Upon Publication*

AIRAC date	State	City	Airport	FDC No.	FDC date	Subject
7–Feb–13	NY	Schenectady	Schenectady County	2/2338	12/14/12	This NOTAM, published in TL 13–03, is hereby rescinded in its entirety.
7–Feb–13	TX	Fort Worth	Bourland Field	2/4285	12/19/12	VOR/DME–A, Orig-A.
7–Feb–13	IA	Des Moines	Des Moines Intl	2/4286	12/19/12	RNAV (GPS) RWY 31, Amdt 1B.
7–Feb–13	MI	Detroit	Detroit Metropolitan Wayne County.	2/4300	12/19/12	ILS OR LOC RWY 21L, Amdt 10B.
7–Feb–13	MI	Detroit	Detroit Metropolitan Wayne County.	2/4301	12/19/12	ILS PRM RWY 21L (SIMULTANEOUS CLOSE PARALLEL), Orig-B.
7–Feb–13	IL	Olney-Noble	Olney-Noble	2/4348	12/19/12	NDB RWY 3, Amdt 13.
7–Feb–13	IL	Olney-Noble	Olney-Noble	2/4349	12/19/12	RNAV (GPS) RWY 3, Orig.
7–Feb–13	IL	Olney-Noble	Olney-Noble	2/4350	12/19/12	RNAV (GPS) RWY 11, Orig.
7–Feb–13	IL	Olney-Noble	Olney-Noble	2/4351	12/19/12	LOC RWY 11, Amdt 5.
7–Feb–13	IL	Olney-Noble	Olney-Noble	2/4352	12/19/12	VOR/DME–A, Amdt 9.
7–Feb–13	KS	Johnson	Stanton County Muni	2/4396	12/19/12	RNAV (GPS) RWY 35, Amdt 1.
7–Feb–13	KS	Johnson	Stanton County Muni	2/4397	12/19/12	NDB RWY 17, Amdt 2.
7–Feb–13	KS	Johnson	Stanton County Muni	2/4398	12/19/12	RNAV (GPS) RWY 17, Amdt 1.
7–Feb–13	MN	Hutchinson	Hutchinson Muni-Butler Field.	2/4961	12/19/12	RNAV (GPS) RWY 15, Orig.
7–Feb–13	MI	Hastings	Hastings	2/4992	12/19/12	VOR RWY 12, Orig-C.
7–Feb–13	IL	Morris	Morris Muni—James R. Washburn Field.	2/5085	12/19/12	RNAV (GPS) RWY 18, Orig-B.
7–Feb–13	CO	Denver	Centennial	2/6105	01/02/13	ILS OR LOC RWY 35R, Amdt 9.
7–Feb–13	CA	Atwater	Castle	2/6114	01/02/13	ILS OR LOC/DME RWY 31, Amdt 2C.
7–Feb–13	CO	Denver	Denver Intl	2/6120	01/02/13	ILS OR LOC RWY 34L, Amdt 2.
7–Feb–13	NY	Schenectady	Schenectady County	2/6912	12/27/12	RNAV (GPS) RWY 10, Orig-A.
7–Feb–13	MI	Flint	Bishop Intl	3/0134	01/02/13	VOR RWY 27, Orig.

[FR Doc. 2013–01385 Filed 1–24–13; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 97

[Docket No. 30880; Amdt. No. 3515]

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

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This rule establishes, amends, suspends, or revokes Standard Instrument Approach Procedures (SIAPs) and associated Takeoff Minimums and Obstacle Departure Procedures for operations at certain airports. These regulatory actions are needed because of the adoption of new or revised criteria, or because of changes occurring in the National Airspace System, such as the commissioning of new navigational facilities, adding new obstacles, or changing air traffic requirements. These changes are designed to provide safe and efficient use of the navigable airspace and to promote safe flight operations under instrument flight rules at the affected airports.

DATES: This rule is effective January 25, 2013. The compliance date for each SIAP, associated Takeoff Minimums, and ODP is specified in the amendatory provisions.

The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of January 25, 2013.

ADDRESSES: Availability of matters incorporated by reference in the amendment is as follows:

For Examination—

1. FAA Rules Docket, FAA Headquarters Building, 800 Independence Avenue SW., Washington, DC 20591;

2. The FAA Regional Office of the region in which the affected airport is located;

3. The National Flight Procedures Office, 6500 South MacArthur Blvd., Oklahoma City, OK 73169 or,

4. The National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.*

Availability—All SIAPs and Takeoff Minimums and ODPs are available online free of charge. Visit *http://www.nfdc.faa.gov* to register. Additionally, individual SIAP and Takeoff Minimums and ODP copies may be obtained from:

1. FAA Public Inquiry Center (APA–200), FAA Headquarters Building, 800 Independence Avenue SW., Washington, DC 20591; or

2. The FAA Regional Office of the region in which the affected airport is located.

FOR FURTHER INFORMATION CONTACT: Richard A. Dunham III, Flight Procedure Standards Branch (AFS–420), Flight Technologies and Programs Divisions, Flight Standards Service, Federal Aviation Administration, Mike Monroney Aeronautical Center, 6500 South MacArthur Blvd., Oklahoma City, OK 73169 (Mail Address: P.O. Box 25082, Oklahoma City, OK 73125) Telephone: (405) 954–4164.

SUPPLEMENTARY INFORMATION: This rule amends Title 14 of the Code of Federal Regulations, Part 97 (14 CFR part 97), by establishing, amending, suspending, or revoking SIAPS, Takeoff Minimums and/or ODPS. The complete regulators description of each SIAP and its associated Takeoff Minimums or ODP for an identified airport is listed on FAA form documents which are incorporated by reference in this amendment under 5 U.S.C. 552(a), 1 CFR part 51, and 14 CFR 97.20. The applicable FAA Forms are FAA Forms 8260–3, 8260–4, 8260–5, 8260–15A, and 8260–15B when required by an entry on 8260–15A.

The large number of SIAPs, Takeoff Minimums and ODPs, in addition to their complex nature and the need for a special format make publication in the **Federal Register** expensive and impractical. Furthermore, airmen do not use the regulatory text of the SIAPs, Takeoff Minimums or ODPs, but instead refer to their depiction on charts printed by publishers of aeronautical materials. The advantages of incorporation by reference are realized and publication of the complete description of each SIAP, Takeoff Minimums and ODP listed on FAA forms is unnecessary. This amendment provides the affected CFR sections and specifies the types of SIAPs and the effective dates of the, associated Takeoff Minimums and ODPs. This amendment also identifies the airport and its location, the procedure, and the amendment number.

The Rule

This amendment to 14 CFR part 97 is effective upon publication of each separate SIAP, Takeoff Minimums and ODP as contained in the transmittal. Some SIAP and Takeoff Minimums and textual ODP amendments may have been issued previously by the FAA in a Flight Data Center (FDC) Notice to Airmen (NOTAM) as an emergency action of immediate flight safety relating directly to published aeronautical charts. The circumstances which created the need for some SIAP and Takeoff Minimums and ODP amendments may require making them effective in less than 30 days. For the remaining SIAPS and Takeoff Minimums and ODPS, an effective date at least 30 days after publication is provided.

Further, the SIAPs and Takeoff Minimums and ODPS contained in this amendment are based on the criteria contained in the U.S. Standard for Terminal Instrument Procedures (TERPS). In developing these SIAPS and Takeoff Minimums and ODPs, the TERPS criteria were applied to the conditions existing or anticipated at the affected airports. Because of the close and immediate relationship between these SIAPs, Takeoff Minimums and ODPs, and safety in air commerce, I find that notice and public procedures before adopting these SIAPS, Takeoff Minimums and ODPs are impracticable and contrary to the public interest and, where applicable, that good cause exists for making some SIAPs effective in less than 30 days.

Conclusion

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore—(1) Is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule '' under DOT Regulatory Policies and Procedures (44 FR 11034; February 26,1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. For the same reason, the FAA certifies that this amendment will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 97

Air Traffic Control, Airports, Incorporation by reference, and Navigation (Air).

Issued in Washington, DC, on January 4, 2013.

John M. Allen,

Director, Flight Standards Service.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me, Title 14, Code of Federal Regulations, Part 97 (14 CFR part 97) is amended by establishing, amending, suspending, or revoking Standard Instrument Approach Procedures and/or Takeoff Minimums and/or Obstacle Departure Procedures effective at 0902 UTC on the dates specified, as follows:

PART 97—STANDARD INSTRUMENT APPROACH PROCEDURES

■ 1. The authority citation for part 97 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40103, 40106, 40113, 40114, 40120, 44502, 44514, 44701, 44719, 44721–44722.

■ 2. Part 97 is amended to read as follows:

** * * Effective 7 FEBRUARY 2013*

Canon City, CO, Fremont County, GPS RWY 29, Orig, CANCELED
Canon City, CO, Fremont County, RNAV (GPS) Y RWY 29, Orig
Canon City, CO, Fremont County, RNAV (RNP) RWY 11, Orig
Canon City, CO, Fremont County, RNAV (RNP) Z RWY 29, Orig
Canon City, CO, Fremont County, Takeoff Minimums and Obstacle DP, Amdt 1
Hillsboro, OH, Highland County, NDB RWY 23, Amdt 5
Hillsboro, OH, Highland County, RNAV (GPS) RWY 23, Orig
Hillsboro, OH, Highland County, VOR/DME OR GPS–A, Amdt 1B, CANCELED
Indiana, PA, Indiana County/Jimmy Stewart FLD/, LOC RWY 28, Orig-B

** * * Effective 7 MARCH 2013*

Anaktuvuk Pass, AK, Anaktuvuk Pass, RNAV (GPS)–A, Amdt 1
Jonesboro, AR, Jonesboro Muni, ILS OR LOC RWY 23, Amdt 2
Jonesboro, AR, Jonesboro Muni, VOR RWY 23, Amdt 11
Melbourne, AR, Melbourne Muni—John E Miller Field, RNAV (GPS) RWY 3, Amdt 1
Melbourne, AR, Melbourne Muni—John E Miller Field, RNAV (GPS) RWY 21, Amdt 1
Aspen, CO, Aspen-Pitkin CO/Sardy Field, RNAV (GPS)–F, Orig–A
Lakeland, FL, Lakeland Linder Rgnl, RNAV (GPS) RWY 5, Orig–B

Lakeland, FL, Lakeland Linder Rgnl, RNAV (GPS) RWY 9, Amdt 1
Lakeland, FL, Lakeland Linder Rgnl, RNAV (GPS) RWY 23, Orig–A
Lakeland, FL, Lakeland Linder Rgnl, RNAV (GPS) RWY 27, Amdt 1
Lakeland, FL, Lakeland Linder Rgnl, VOR RWY 9, Amdt 4B
Lakeland, FL, Lakeland Linder Rgnl, VOR RWY 27, Amdt 7D
St Petersburg, FL, Albert Whitted, RNAV (GPS) RWY 7, Amdt 3
Tampa, FL, Tampa Intl, VOR RWY 10, Amdt 9, CANCELED
Toccoa, GA, Toccoa RG Letourneau Field, RNAV (GPS) RWY 20, Amdt 1
Canton, IL, Ingersoll, RNAV (GPS) RWY 18, Amdt 1
Canton, IL, Ingersoll, RNAV (GPS) RWY 36, Amdt 1
Chicago/West Chicago, IL, Dupage, Takeoff Minimums and Obstacle DP, Amdt 1A
Macomb, IL, Macomb Muni, RNAV (GPS) RWY 9, Amdt 1
Macomb, IL, Macomb Muni, RNAV (GPS) RWY 27, Amdt 1
Macomb, IL, Macomb Muni, VOR/DME–A, Amdt 8B, CANCELED
Olney-Noble, IL, Olney-Noble, RNAV (GPS) RWY 11, Amdt 1
Marion, KY, Marion-Crittenden County, RNAV (GPS) RWY 7, Amdt 1
Marion, KY, Marion-Crittenden County, RNAV (GPS) RWY 25, Amdt 1
Marion, KY, Marion-Crittenden County, Takeoff Minimums and Obstacle DP, Amdt 1
Oakland, MD, Garrett County, VOR RWY 27, Amdt 5
Escanaba, MI, Delta County, LOC/DME BC RWY 27, Amdt 1
Houghton Lake, MI, Roscommon County-Blodgett Memorial, RNAV (GPS) RWY 9, Amdt 2
Houghton Lake, MI, Roscommon County-Blodgett Memorial, RNAV (GPS) RWY 27, Amdt 1
Houghton Lake, MI, Roscommon County-Blodgett Memorial, VOR RWY 9, Amdt 5
Houghton Lake, MI, Roscommon County-Blodgett Memorial, VOR RWY 27, Amdt 4
Mason, MI, Mason Jewett Field, GPS RWY 27, Orig, CANCELED
Mason, MI, Mason Jewett Field, RNAV (GPS) RWY 10, Orig
Mason, MI, Mason Jewett Field, RNAV (GPS) RWY 28, Orig
Mason, MI, Mason Jewett Field, VOR–A, Amdt 5
Aitkin, MN, Aitkin Muni-Steve Kurtz Field, NDB RWY 16, Amdt 5
Aitkin, MN, Aitkin Muni-Steve Kurtz Field, RNAV (GPS) RWY 16, Orig
Aitkin, MN, Aitkin Muni-Steve Kurtz Field, RNAV (GPS) RWY 34, Orig
Aitkin, MN, Aitkin Muni-Steve Kurtz Field, Takeoff Minimums and Obstacle DP, Amdt 3
Rolla, MO, Rolla Downtown, Takeoff Minimums and Obstacle DP, Amdt 1, CANCELED
Rolla, MO, Rolla Downtown, VOR/DME OR GPS–A, Amdt 2A, CANCELED
Atlantic City, NJ, Atlantic City Intl, RNAV (GPS) RWY 4, Amdt 2
Atlantic City, NJ, Atlantic City Intl, RNAV (GPS) RWY 22, Amdt 4
Lakeview, OR, Lake County, GPS RWY 34, Orig–A, CANCELED
Lakeview, OR, Lake County, RNAV (GPS) RWY 17, Orig
Lakeview, OR, Lake County, RNAV (GPS) RWY 35, Orig
Lakeview, OR, Lake County, Takeoff Minimums and Obstacle DP, Amdt 3
Philipsburg, PA, Mid-State, Takeoff Minimums and Obstacle DP, Amdt 2
Madisonville, TN, Monroe County, RNAV (GPS) RWY 5, Amdt 2
Madisonville, TN, Monroe County, RNAV (GPS) RWY 23, Amdt 2
Tooele, UT, Bolinder Field-Tooele Valley, ILS OR LOC/DME RWY 17, Amdt 2
Tooele, UT, Bolinder Field-Tooele Valley, NDB RWY 17, Amdt 1A, CANCELED
Tooele, UT, Bolinder Field-Tooele Valley, RNAV (GPS) RWY 17, Amdt 3
Danville, VA, Danville Rgnl, RNAV (GPS) RWY 31, Orig
Jonesville, VA, Lee County, RNAV (GPS) RWY 7, Amdt 1
Wilbur, WA, Wilbur, WIPES ONE, Graphic DP

[FR Doc. 2013–01388 Filed 1–24–13; 8:45 am]
BILLING CODE 4910–13–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

18 CFR Part 11

[Docket No. RM11–6–000; Order No. 774]

Annual Charges for Use of Government Lands

AGENCY: Federal Energy Regulatory Commission, DOE.

ACTION: Final rule.

SUMMARY: In this Final Rule, the Commission revises its regulations for assessing the annual charge for use of government lands by hydropower licensees. Each year, the Commission will create an annual per-acre fee schedule by county using a formula with four components: a per-acre land value by county based on a publicly available index of land values; an encumbrance factor; a rate of return; and, an inflation adjustment.

DATES: *Effective Date:* This rule will become effective February 25, 2013.

FOR FURTHER INFORMATION CONTACT:

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Norman Richardson (Technical Information), Office of the Executive Director, Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426, (202) 502–6219, *Norman.Richardson@ferc.gov.*

SUPPLEMENTARY INFORMATION:

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Before Commissioners: Jon Wellinghoff, Chairman; Philip D. Moeller, John R. Norris, Cheryl A. LaFleur, and Tony T. Clark.

Final Rule

Issued January 17, 2013

1. This Final Rule amends Part 11 of the Commission's regulations and implements a new methodology for the calculation of annual charges for the use of government lands. Annually, the Commission will create a per-acre fee schedule by county that will be published in Appendix A of Part 11 of the Commission's regulations. The formula to create the fee schedule has four components: a per-acre land value by county based on a publicly available index of land values; an encumbrance factor; a rate of return; and, an annual inflation adjustment. In this Final Rule, all charges for the occupancy of government lands by hydropower projects will be calculated based on the fee schedule rate. A discount will be applied to all applicable licensees for the first year of this rule's implementation.

I. Background

2. Section 10(e)(1) of the Federal Power Act (FPA) requires the hydropower licensees occupying federal lands to:

> pay to the United States reasonable annual charges in an amount to be fixed by the Commission * * * for recompensing [the United States] *for the use, occupancy, and enjoyment of its lands or other property* * * * and in fixing such charges the Commission shall seek to avoid increasing the price to the consumers of power by such charges, and any such charges may be adjusted from time to time by the Commission as conditions may require * * *.[1]

In other words, where licensees use and occupy federal lands for project purposes, they must compensate the United States through payment of an annual fee, to be established by the Commission.[2]

A. History of Annual Charges for Use of Government Lands

3. Since its inception, the Commission has used or considered a number of methodologies to effectuate this statutory directive. From 1937 to 1942, the Commission based annual charges for the use of federal lands by hydropower licensees on individual land appraisals for each project.[3] In 1942, the Commission rejected this approach in favor of a single national average per-acre land value because it determined that project-by-project appraisals were more costly to administer than the value collected in rent, the values for inundated lands would become distorted, the values could only be maintained with reappraisals, and disputes over values may lead to costly litigation.[4] In 1986, the Commission also rejected use of a single national average per-acre land value because this methodology resulted in an under-collection of over $15 million per year due to the use of outdated land values.[5]

1. 1987 BLM Fee Schedule

4. In 1987, the Commission adopted use of a fee schedule developed by the U.S. Department of the Interior's Bureau of Land Management (BLM) and the U.S. Department of Agriculture's Forest Service (Forest Service) that identified per-acre rental rates by county for linear rights-of-way on federal lands.[6] The BLM and Forest Service produced the fee schedule by taking a survey of market values by county for the various types of land the agencies had allowed to be occupied by linear rights-of-way.[7] The BLM divided the range of per-acre land values into eight zones with the following per-acre values: $50, $100, $200, $300, $400, $500, $600, and $1000. To calculate the rental rate in the fee schedule, the per-acre zone value was multiplied by an encumbrance factor of 70 percent,[8] a rate of return of 6.41 percent,[9] and an annual inflation adjustment factor.[10] The resulting fee schedule assigned all counties to one of eight rental rates.[11]

5. In adopting the 1987 BLM fee schedule, the Commission found that the methodology promulgated by the BLM and Forest Service for linear rights-of-way was the ''*best approximation available* of the value of lands used for transmission line rights-of-way.'' [12] Therefore, the Commission assessed the BLM-generated schedule rate for transmission line rights-of-way on federal lands, and doubled this rate for federal lands occupied by other project works (e.g., dams, powerhouses,

[1] 16 U.S.C. 803(e)(1) (2006) (emphasis added). Section 10(e)(1) also requires licensees to reimburse the United States for the costs of administering Part I of the FPA. These charges are calculated and billed separately from the land use charges, and are not the subject of this Final Rule.

[2] Pursuant to section 17(a) of the FPA, 16 U.S.C. 810(a) (2006), the fees collected for the use of government lands are allocated as follows: 12.5 percent is paid into the U.S. Treasury, 50 percent is paid into the federal reclamation fund, and 37.5 percent is paid into the treasuries of the states in which particular projects are located. No part of the fees discussed in this Final Rule are used to fund the Commission's operations.

[3] *Order Prescribing Amendment to Section 11.21 of the Regulations Under the Federal Power Act,* 56 FPC 3860, at 3863 (1976).

[4] *Id.* at 3863–64.

[5] *See* Assessment of Charges under the Hydroelectric Program, DOE/IG Report No. 0219 (September 3, 1986); *see also* More Efforts Needed to Recover Costs and Increase Hydropower Charges, U.S. General Accounting Office Report No. RCED–87–12 (November 1986). The single national average land value per acre in 1942 was $50 per acre, and by 1976, the value was $150 per acre. 56 FPC 3860.

[6] *Revision of the Billing Procedures for Annual Charges for Administering Part I of the Federal Power Act and to the Methodology for Assessing Federal Land Use Charges,* Order No. 469, FERC Stats. & Regs. ¶ 30,741, at 30,584 (1987).

[7] *Notice of Adoption of Rental Fee Schedule,* 51 FR 44014 (Dec. 5, 1986). BLM explained that the value of timber had not been included, and that the values were not for urban or suburban residential areas, industrial parks, farms or orchards, recreation properties or other such types of land. The agencies tried to avoid using attractive public use areas such as lakeshores, streamsides, and scenic highway frontage.

[8] The encumbrance factor reflects the degree that a particular type of facility encumbers the right-of-way area or excludes other types of land uses. If the encumbrance factor is 100 percent, the right-of-way facility (and its operation) encumbers the right-of-way area to the exclusion of all other uses.

[9] This number was the 1-year Treasury Securities ''Constant Maturity'' rate for June 30, 1986.

[10] The fee schedule was adjusted annually by the change in the Implicit Price Deflator for the Gross National Product index from the second quarter to the second quarter.

[11] In 1987, the per-acre rental fee under the 1987 BLM fee schedule ranged from $2.24 to $44.87. By 2008, due to the inflation adjustments, the per-acre rental fee under the 1987 fee schedule ranged from $3.76 to $75.23.

[12] Order No. 469, FERC Stats. & Regs. ¶ 30,741 at 30,588 (1987) (emphasis added).

reservoirs) because the Forest Service indicated that its methodology was intended for transmission line rights-of-way, and its market value figures reflected strips of land used for limited purposes, but that reservoirs, streambeds, and other typical hydropower sites should have a higher value.[13]

6. In the 1987 proceeding, the Commission rejected arguments that it should intentionally establish low charges for the use of government lands based on the public benefits provided by hydropower projects. The Commission explained that the public benefits provided by licensed projects are considered in the licensing decision, and these benefits are the *quid pro quo* for the ability to operate the project in a manner consistent with the needs of society. In contrast, the purpose of the rental fee is to establish a fair market rate for the use of government land.[14]

7. The Commission also found no merit to claims that charging fair market value for federal lands is prohibited by the FPA:

> All increases in charges will result in some impact on consumers. The statutory provision bars the Commission from assessing unreasonable charges that would be passed along to consumers. Reasonable annual charges are those that are proportionate to the value of the benefit conferred. Therefore, a fair market approach is consistent with the dictates of the Act. Furthermore, as land values have not been adjusted in over ten years, an adjustment upwards is warranted and overdue.[15]

8. In adopting the 1987 BLM fee schedule, the Commission again rejected a proposal to use individual project appraisals because such appraisals would be too costly and result in time-consuming litigation.[16]

9. From 1987 to 2007, the Commission assessed annual charges for the use of government lands according to the BLM fee schedule. Each year, BLM adjusted the fee schedule for inflation, and each year the Commission published notice of the updated schedule.[17]

2. 2008 BLM Fee Schedule

10. In 2005, Congress passed the Energy Policy Act (EPAct 2005), which required BLM ''to update [the fee schedule] to revise the per acre rental fee zone value schedule * * * to reflect current values of land in each zone.''[18] Congress further directed that ''the Secretary of Agriculture shall make the same revision for linear rights-of-way * * * on National Forest System land.''[19]

11. On October 31, 2008, BLM issued a Final Rule promulgating its updated rental schedule for linear rights-of-way to satisfy the congressional mandate in EPAct 2005,[20] and the Forest Service subsequently adopted the 2008 BLM fee schedule.[21] As had been the case with the methodology underlying the 1987 BLM fee schedule, the updated 2008 fee schedule is based on a formula with four components: (1) An average per-acre land value by county (grouped into zones); (2) an encumbrance factor reduction; (3) a rate of return; and (4) an annual adjustment factor for inflation.[22]

12. The per-acre land value for counties (or other geographic regions) is based on 80 percent of the average per-acre land and building value published in the Census of Agriculture (Census) by the National Agricultural Statistics Service (NASS).[23] Updates to the per-acre land values will occur every five years following publication of the NASS Census.[24] The annual adjustment factor will be updated every 10 years, with the first 10-year period occurring from 2006 through 2015. For Puerto Rico, the average per-acre farmland value for the entire Commonwealth of Puerto Rico is used as the per-acre land value. For Alaska, the 2008 BLM rule uses the NASS Census designation Aleutian Islands Area for all lands within the Aleutian Islands Chain; Fairbanks Area for all lands within the BLM Fairbanks District boundaries; Kenai Peninsula Area for all lands within the BLM Anchorage District boundaries excluding the Aleutian Islands Chain, the Anchorage Area, and the Juneau Area; Anchorage Area for all lands within the Municipality of Anchorage; and Juneau Area for all lands within downtown Juneau (i.e., Juneau voting precincts 1, 2, and 3).

13. In addition to the source of the per-acre land values, BLM made additional changes to the components of the formula used to calculate the fee schedule. BLM reduced the encumbrance factor from 70 percent to 50 percent after a review of public comments, industry practices in the private sector, and the Department of the Interior's appraisal methodology for right-of-way facilities on federal lands.[25] BLM revised the fixed rate of return downward from 6.41 percent to 5.27, which it stated was the most recent 10-year average (1998–2007) of the 30-year and 20-year Treasury bond yield rate.[26] To stay current with inflationary or deflationary trends, BLM applied an annual adjustment factor, which is currently 1.9 percent, to the per-acre rental rate in the fee schedule for all years in a 10-year period except the base year.[27] The annual adjustment factor is based on the average annual change in the Implicit Price Deflator for the Gross Domestic Product (IPD–GDP) for the 10-year period immediately preceding the year that the NASS Census data become available.[28] The BLM rule makes clear that the fee schedule is the only basis for determining an annual rental fee for rights-of-way on federal lands.[29]

14. On February 17, 2009, the Commission issued notice (February 17 Notice) of the 2008 BLM fee schedule that had been created from the revised methodology, as it had done for every annual update to the 1987 fee schedule.[30] Because of the land value revisions and methodology adjustments in response to EPAct 2005, the 2008 BLM fee schedule resulted, in some cases, in significantly higher annual charge assessments for Commission licensees.[31]

15. On March 6, 2009, a group of licensees requested rehearing of the February 17 Notice, which the Commission denied.[32] The licensees

[13] *Id.* at 30,589.

[14] *Id.* at 30,587.

[15] *Id.* at 30,589 (footnotes omitted).

[16] *Id.* at 30,590.

[17] *See, e.g., Update of the Federal Energy Regulatory Commission's Fee Schedule for Annual Charges for the Use of Government Lands,* 73 FR 3626 (Jan. 22, 2008), FERC Stats. & Regs. ¶ 31,262 (2008).

[18] 42 U.S.C. 15925 (2006).

[19] *Id.*

[20] *Update of Linear Right-of-Way Rent Schedule,* 73 FR 65,040 (Oct. 31, 2008).

[21] *See Fee Schedule for Linear Rights-of-Way Authorized on National Forest System Lands,* 73 FR 66591 (November 10, 2008). The Forest Service noted it had given notice, in the preambles to BLM's proposed and final rules, that it would adopt BLM's revised fee schedule.

[22] 43 CFR 2806.20(b) (2012).

[23] 43 CFR 2806.21 (2012).

[24] *Update of Linear Right-of-Way Rent Schedule,* 73 FR 65040, at 65047 (2008).

[25] *Id.* at 65,047.

[26] *Id.* at 65,049. A calculation of the 10-year average of the 30-year and 20-year Treasury bond yield rates for 1998–2007 results in a rate of return of 5.77 percent.

[27] *Id.* at 65,050. The base year is the first year updated per-acre values are applied based on the most recent NASS Census data.

[28] The annual adjustment factor will be updated every 10 years.

[29] If lands are to be transferred out of federal ownership, BLM allows a right-of-way occupier to submit an appraisal report to determine a one-time rental payment for perpetual linear grants or easements.

[30] *Update of the Federal Energy Regulatory Commission's Fees Schedule for Annual Charges for the Use of Government Lands,* FERC Stats. & Regs. ¶ 31,288 (2009); 74 FR 8184 (Feb. 24, 2009).

[31] However, a handful of licensees, in geographical locations throughout the country, had reduced rates.

[32] *Update of the Federal Energy Regulatory Commission's Fees Schedule for Annual Charges for the Use of Government Lands,* 129 FERC ¶ 61,095 (2009).

petitioned for review of the Commission's orders in the United States Court of Appeals for the District of Columbia Circuit. On January 4, 2011, the Court granted the petition for review and vacated the Commission's February 17 Notice.[33] The D.C. Circuit found that the Commission is required by the Administrative Procedure Act to seek notice and comment on the methodology used to calculate annual charges because the Commission's fee schedule is based on the BLM fee schedule, and BLM made changes to the methodology underlying its fee schedule.

B. Notice of Inquiry

16. On February 17, 2011, the Commission issued a Notice of Inquiry (NOI) soliciting comments on its procedures for assessing annual charges for the use of government lands by hydropower licensees.[34] The NOI specifically sought information about existing indices that could be used as the basis for establishing annual land use charges, the adequacy of such indices, and how any new or modified proposed methodology for calculating an annual charge is consistent with five objectives. The methodology must be uniformly applicable to all licensees occupying federal lands, administration of the methodology should not impose exorbitant costs on the Commission, the methodology should not be subject to review on an individual case-by-case basis, the methodology must reflect reasonably accurate land valuations, and the methodology should avoid an unreasonable increase in the price to consumers of power.[35]

17. In response to the NOI, comments were filed by eight entities representing licensees, industry trade groups, and federal agencies. No commenters offered an alternative, existing index to the NASS Census identified in the NOI to determine per-acre rental rates by county. Instead, most commenters proposed modifications or adjustments to the values and components in the 2008 BLM fee schedule.

18. The Forest Service recommended adoption of the 2008 BLM fee schedule because it would result in consistent application of linear rights-of way rental values among federal agencies, parity in rental rates for projects licensed or exempted from licensing under the FPA, and reduced administrative burden because BLM maintains and updates the fee schedule, with periodic revisions.

19. One commenter suggested that even though BLM and Forest Service have updated their fee schedules, for hydropower licensees, the Commission should retain the 1987 fee schedule with annual adjustments for inflation.

20. A number of commenters recommended reducing the NASS Census per-acre land values for counties (or other geographic regions). The proffered suggestions included reducing the NASS Census land values by 50 percent, rather than the 20 percent reduction incorporated into the BLM fee schedule, rejecting the zone system implemented by BLM, or using the ''pastureland'' values from the NASS Census, which commenters advocated would result in reduced land values. A number of commenters also advocated for an opportunity for licensees to conduct individual appraisals to independently determine the fair market value of the federal lands occupied by a hydropower project, but one commenter objected to individual appraisals on a case-by-case basis because of the potential for increased costs in the administration of Part I of the FPA.[36] Commenters also recommended reducing the encumbrance factor significantly to reflect the fact that project lands often incorporate multiple uses, many of which benefit the public at a cost to the licensee.

21. Commenters objected to the Commission's longstanding practice of automatically doubling the linear rights-of-way fee for non-transmission line project lands. Some commenters also proposed specific adjustments to the rate of return and annual adjustment factor components of the annual fee calculation. Several commenters requested that the annual fee resulting from any new methodology be phased-in or discounted initially.

C. Notice of Proposed Rulemaking (NOPR)

22. In the NOPR, the Commission proposed to adopt the 2008 BLM methodology for creating a fee schedule, with some modifications, to assess annual charges for the use, occupancy, and enjoyment of federal lands by hydropower licensees.[37] Like the methodology set forth in the 2008 BLM rule, the formula proposed in the NOPR had four components: (1) An average per-acre land value by county, based on the ''land and buildings'' category from the NASS Census; (2) an encumbrance factor of 50 percent; (3) a rate of return; and (4) an annual adjustment factor.

23. The Commission proposed to use this formula to create its own schedule because it agreed with the underlying premise of the change in the BLM fee schedule that the 1987 fee schedule no longer reflected fair market land values. Thus, the NOPR proposed to use the NASS Census—the only index proferred by commenters—which includes land values from around the country as a basis for the per-acre land values. However, the Commission agreed with commenters that BLM's ''zone system'' inflates the values of all counties in a zone except the highest valued county.

24. Except for rejecting the zone system, the Commission proposed to adopt all other aspects of the BLM methodology for producing a fee schedule to assess rental rates for the use of federal lands, including the encumbrance factor, the rate of return, the annual adjustment factor, and assignment of non-county geographical areas in Alaska and Puerto Rico.

25. The proposed rule eliminated the Commission's longstanding practice of doubling the fee schedule rate for non-transmission line lands. In promulgating the 1987 fee schedule, the Forest Service indicated that its methodology at the time was intended for transmission line rights-of-way, and its market value figures reflected strips of land used for limited purposes, but that reservoirs, streambeds, and other typical hydropower sites should have a higher value.[38] In contrast, the land values in the formula proposed in the NOPR are based on the NASS Census, which is a survey of land values for areas of land rather than strips of land used for limited purposes. Thus, as proposed in the NOPR, it would no longer be necessary to double the fee schedule for non-linear strips of land.

26. The proposed rule did not include a graduated phase-in period for the new fee schedule.

II. Discussion

A. Part 11 Fee Schedule

27. In this Final Rule, the Commission adopts a methodology for creating an annual fee schedule for the use, occupancy, and enjoyment of government lands by hydropower licensees, and amends Part 11 of its

[33] *City of Idaho Falls, Idaho* v. *FERC,* 629 F.3d 222 (D.C. Cir. 2011).

[34] *Annual Charges for Use of Government Lands,* 134 FERC ¶ 61,111 (2011).

[35] *Id.* P 19.

[36] The annual charge for use of government lands is one component of a licensee's annual charges. Another component of the annual charge is the Commission's costs for administering Part I of the FPA, which are allocated, with certain exceptions, among licensees and exemptees according to installed capacity. *See* 18 CFR 11.1 (2012).

[37] *Annual Charges for the Use of Government Lands,* FERC Stats. & Regs ¶ 32,684; 137 FERC ¶ 61,139 (2011).

[38] Order No. 469, FERC Stats. & Regs. ¶ 30,741 at 30,589 (1987).

regulations accordingly. This methodology is largely based on the methodology proposed in the NOPR, which in turn is based on the methodology expounded in the 2008 BLM rule adopting an updated fee schedule for linear rights-of-way.

28. The fee schedule will be based on a formula with four inputs: (1) An adjusted per-acre land value by county or geographic area; (2) an encumbrance factor; (3) a rate of return; and (4) an annual inflation adjustment. The product of the formula's components will result in a fee for each county or geographic area and will be noticed and published annually as a fee schedule in Appendix A to Part 11 of the Commission's regulations. The Commission will compute a licensee's annual charge for the use of government lands by multiplying the applicable county or geographical area fee in the fee schedule by the number of federal acres reported by a licensee.

1. Projects Occupying Multiple Counties, States, or Geographical Areas

29. Several commenters requested clarification regarding the application of the fee schedule to hydropower projects that occupy multiple counties. If a licensed project occupies multiple counties, states, or geographical areas, the Commission will perform a separate calculation for the proportional amount of acres in each county, state, or geographical area.[39] As discussed more fully below, this includes proportional application of the state-specific reduction to remove the value of irrigated lands from the value of all farmlands reported in the NASS Census.

2. Transmission Line Acres

30. This Final Rule retains the NOPR's proposal to eliminate the Commission's practice of doubling the fee schedule rate for non-transmission line lands. In other words, all federal hydropower project lands will be charged at the fee schedule rate.

31. A number of commenters agreed with the Commission's proposal to eliminate its longstanding practice of automatically doubling the linear fee schedule rate for non-transmission line lands (i.e., non-linear acres). However, Pacific Gas and Electric Company (PG&E) commented that the Commission should reduce a licensee's charges under the Final Rule by 50 percent for federal lands occupied by transmission lines and similar project works (e.g., roads) because the rationale for the Commission's decision to reject doubling of the annual fee for the use of government lands dictates that the Commission accordingly reduce the charges when they are applied to transmission lines.

32. We disagree. As explained above, from 1942 to 1986, the Commission used a national per-acre average land value as the basis for assessing rent for the use of government lands. Throughout this period, the Commission adopted the view that fees for right-of-way usage of federal lands would be less than those for other project uses because land so used remained available for multiple uses.[40] In adopting a new methodology for creating a fee schedule for the use of government lands in 1986, the Commission considered whether to eliminate the practice of charging a lower rate for the use of federal lands occupied by transmission lines than for lands occupied by other project features.[41] The Forest Service commented that its methodology was intended for transmission line rights-of-way, its market value figures reflected strips of land used for limited purposes, and therefore it suggested that reservoirs, streambeds, and other typical hydropower sites should have a higher rental value.[42] Thus, in adopting the 1987 fee schedule, the Commission found that the Forest Service's and BLM's methodology was ''the *best approximation available* of the value of lands used for transmission line rights-of-way,'' applied the 1987 fee schedule rate for transmission line lands, and doubled this rate for other hydropower sites, because, while the existence of transmission lines did not completely preclude other uses, features such as dams and powerhouses did.[43]

33. Both previous methodologies (i.e., the national per-acre average, and the 1987 fee schedule based on surveys of linear rights-of-way) were estimates of the value of lands occupied by hydropower projects based on the data available at that time. Thus, in adopting the 1987 fee schedule, it was reasonable for the Commission to attempt to account for the presumption that more uses could be permitted on linear rights-of-way than on other hydropower sites and the attendant presumption that the lands underlying linear rights-of-way are of lesser value than the lands underlying other hydropower sites.

34. However, we find that this conflates two aspects of the formula for creating the fee schedule. The extent to which a hydropower facility *encumbers* federal lands, or precludes other uses on such lands, is reflected in the encumbrance factor component of the formula. As discussed below, this Final Rule reduces the encumbrance factor from 70 percent (the encumbrance factor used in the 1987 fee schedule) to 50 percent, which lowers the rent for licensees, in recognition of the various degrees of encumbrance caused by different hydropower facilities (e.g., powerhouses, dams, reservoirs, roads, penstocks, or transmission lines). However, the underlying land value component of the formula is independent of the type of infrastructure (transmission line, reservoir, penstock, road) occupying the land. The specificity and detail of the NASS Census allows the Commission to more accurately value parcels of land in particular counties or geographic areas. Thus, it is no longer necessary to rely on the ''best approximation available,'' and the attendant estimated adjustments to discount lands perceived to have differing degrees of encumbrance. Accordingly, the Final Rule makes this distinction and eliminates the rudimentary practice of simply doubling the linear fee schedule rate for non-transmission line lands.

3. Phase-In Period

35. The NOPR did not propose to include a phase-in period for the new schedule of annual charges because licensees have been on notice since issuance of the 2008 BLM rule that the fee schedule would be updated. In response to the NOPR, six commenters requested a 25 percent reduction in the annual charge calculated under any new methodology because of the anticipated higher rates that may result from the Final Rule. Because of the uncertainty about the actual rates that would be charged under the new fee schedule, we agree that a 25 percent reduction in the annual charge for the use of government lands will be applied to all licensees for the first year under this rule.

[39] Throughout this order, any reference to a county or state also applies to the regions termed ''geographical areas,'' even if this term is not explicitly used.

[40] *See, e.g.,* Order No. 560, 56 F.P.C. 3860 (1976).

[41] *Revisions to the Billing Procedures for Annual Charges for Administering Part I of the Federal Power Act and to the Methodology for Assessing Federal Land Use Charges,* 51 FR 211 (January 3, 1986), FERC Stats. & Regs., Proposed Regulations ¶ 33,278, at 33,282 (1986).

[42] Order No. 469, FERC Stats. & Regs. ¶ 30,741 at 30,588 (1987).

[43] *Id.* (emphasis added).

B. Components of the Fee Schedule

1. Per-Acre Land Value

36. The NOPR proposed to base the per-acre land value on the applicable county ''land and buildings'' category [44] from the NASS Census, adjusted downward by 20 percent to remove the value of irrigated lands and buildings,[45] and updated with current land values from the NASS Census every five years. This Final Rule changes the adjustment downward in the proposed per-acre value to a state-specific reduction that removes the value of irrigated lands on a state-by-state basis rather than a national basis, plus a seven percent reduction to remove the value of buildings or other improvements.

37. The NASS Census is conducted every five years and there is an 18-month delay before NASS publishes the Census data. The 2008 BLM rule incorporates another 18-month delay to allow notice of any changes in applicable land values. This Final Rule adopts the NOPR's proposed schedule, which is consistent with BLM's implementation of its rule. Thus, the Commission's 2011–2015 fee schedules will be based on data from the 2007 NASS Census, the 2016–2020 fee schedules will be based on data from the 2012 NASS Census, the 2021–2025 fee schedules will be based on data from the 2017 NASS Census, and so on. State-specific adjustments to the per-acre land value will be performed in the first year that the most recent NASS Census data are used in the formula, and remain the same until the next round of NASS Census data are used.

38. To determine the downward adjustment of 20 percent to the per-acre land and buildings value, BLM consulted with NASS on an appropriate methodology to reduce the average per-acre land and building value by an amount that reflects the value of irrigated cropland and land encumbered by buildings.[46] NASS advised BLM that this calculation could be accomplished by comparing the total value of irrigated acres and the acres in the ''other'' category [47] to the total value of all farmland acres. This resulted in a 13 percent reduction for all irrigated acres and a seven percent reduction for all lands in the ''other'' category, for a total 20 percent reduction in the per-acre land value to eliminate the value of all land that could possibly be encumbered by buildings or which could possibly have been developed, improved, or irrigated.[48]

39. In response to the NOPR, seven commenters argued that the per-acre county land values should be reduced by more than 20 percent. Several of these commenters argued that such a further downward adjustment is appropriate because the lands where hydropower projects are located tend to be rocky, steep-sloped, and with little soil, and therefore of lesser value than ''agricultural'' lands. The Federal Lands Group,[49] in particular, believes the per-acre county land values should be reduced by 50 percent to reflect the fundamental difference in character and quality between agricultural lands and hydropower lands. Placer County Water Agency (PCWA) argues that the 13 percent reduction for irrigated cropland, which reflected the national ratio of irrigated croplands to all farmlands in the 2008 BLM rule, should be performed individually for each state because the value of irrigated lands relative to all farmlands varies drastically from state to state. Similarly, Idaho Power argues that a blanket 20 percent reduction is inequitable and overestimates the per-acre land value in the states with a large percentage of irrigated cropland.

40. We agree with PCWA and Idaho Power that the use of a national ratio to remove the value of irrigated lands from the per-acre country value is disproportionate. In this Final Rule, the per-acre value by county or other geographic area will be reduced by a state-specific factor to remove the value of irrigated lands from the per-acre land value. This will be accomplished by comparing the total value of irrigated lands in each state to the total value of all farmlands in each state. For all counties or geographical areas within a particular state, the per-acre land value will be reduced by this state-specific ratio to remove the value of irrigated lands. This state-specific reduction will be performed every five years, or on the same schedule as the introduction of the updated NASS Census values.[50] Appendix A to this order includes a table demonstrating this calculation for each state under the 2007 NASS Census. For each subsequent NASS Census, a table identifying the state-specific factor will be available on the Commission's Web site.

41. In its 2008 rule, BLM specifically consulted with NASS on an appropriate methodology to reduce the average per acre ''land and buildings'' category by an amount that reflects the value of irrigated cropland because BLM- and Forest Service-administered lands generally do not include these land categories. We agree with this assessment and concur that hydropower projects, particularly those occupying BLM- and Forest Service-administered lands, generally do not include irrigated croplands.[51] Thus, it is reasonable to remove the value of irrigated croplands from the per-acre county land value assessment in the NASS Census. Furthermore, using a state-specific ratio to remove the increased value of irrigated lands from the per-acre county land values results in a fairer representation of the value of county lands. Commission staff found that performing such a calculation every five years is administratively feasible. Therefore, in the Final Rule, the per-acre land value from the NASS Census' ''land and buildings'' category will be adjusted individually for each state.

42. Once this percent is determined for each state, the per-acre land value will be reduced by an additional seven percent. According to the BLM rule, the additional seven percent reduction reflects the value added to the ''lands and buildings'' category by buildings and other improvements, as reflected in the ''other'' category. In its rule, BLM acknowledged that seven percent was likely a slight overestimate, but that neither it nor NASS knew of any way to separate out the components of the ''other'' category, which included

[44] The ''land and buildings'' category is a combination of all the land categories in the NASS Census, and includes croplands (irrigated and non-irrigated), pastureland/rangeland, woodland, and ''other'' (roads, ponds, wasteland, and land encumbered by non-commercial/non-residential buildings).

[45] Twenty percent is the sum of a 13 percent reduction to remove the value of irrigated lands based on national averages and a 7 percent reduction to remove the value of lands in the ''other'' category, which include buildings and improvements.

[46] 73 FR 65040, at 65043 (2008).

[47] The ''other'' category includes all improved land or land encumbered by buildings.

[48] 73 FR 65040, at 65043 (2008).

[49] The Federal Lands Group is composed of the following licensees: Bradley Lake Project Management Committee; City of Idaho Falls, Idaho; City of Seattle, Washington; City and Borough of Sitka, Alaska; City of Tacoma, Washington; El Dorado Irrigation District; Eugene Water and Electric Board; PacifiCorp; Portland General Electric Company; Public Utility District No. 1 of Chelan County, Washington; Puget Sound Energy, Inc.; Sacramento Municipal Utility District; Public Utility District No. 1 of Snohomish County; Southeast Alaska Power Agency; Kodiak Electric Association; and Turlock Irrigation District.

[50] The 2007 NASS Census will be applicable through 2015, data from the 2012 NASS Census will apply beginning in 2016, data from the 2017 NASS Census will apply beginning in 2021, etc.

[51] However, this is not always the case. Commenters focused exclusively on licensed hydropower projects in the western United States to argue that hydropower lands are often on steep, rocky, and soilless lands that are fundamentally different than agricultural lands. This is sometimes the case, but it is also true that many licensed hydropower reservoirs are located in the heart of agricultural areas. Therefore, we disagree with the assertion that, by their very nature, lands used for hydropower projects are fundamentally different from those used for agriculture.

buildings and other improvements, but also included wastelands. Because no commenters offered a viable critique or alternative to the calculation for the seven percent reduction to remove the value of buildings and improvements, we retain and find reasonable this reduction as presented in the BLM rule.

a. Per-Acre Land Values for Alaska

43. In the NOPR, the Commission proposed to retain BLM's approach to Alaska per-acre land values such that lands in Alaska would be designated as part of one of the NASS Census geographic area identifiers. Under the 2008 BLM rule, the Aleutian Islands Area includes all lands within the Aleutian Islands chain; the Fairbanks Area includes all lands within the BLM Fairbanks District boundaries; the Kenai Peninsula Area includes all lands within the BLM Anchorage District excluding the Aleutian Islands Chain, the Anchorage Area, and the Juneau Area; the Anchorage Area for all lands within the Municipality of Anchorage, and the Juneau Area for all lands within downtown Juneau (i.e., voting precincts 1, 2, and 3). Currently, Commission-licensed projects occupying federal lands are located only in the Kenai Peninsula Area, as defined above, although there are outstanding preliminary permits for projects that would occupy federal lands in the Fairbanks Area.

44. A number of commenters argued that Alaska should be assessed a per-acre statewide value, which is also a category reported by the NASS Census. Commenters asserted that regional values for Alaska are inappropriate because Alaska does not use the administrative designation of county, the number of farms surveyed for the NASS Census in the entire state of Alaska is less than the number of farms surveyed in most counties in the lower-48 states, and certain per-acre land values near Anchorage and Juneau are very high and result in a substantial increase in annual charges for the use of government lands by hydropower licensees. Despite these objections and concerns, commenters offered no explanation as to why it was appropriate to use a statewide value for Alaska, but not the smallest NASS Census defined area, which in Alaska's case is the geographic area identifier.

45. This Final Rule retains the proposal in the NOPR, but clarifies that the Anchorage Area and the Juneau Area will not be used to assess annual charges for the use of government lands because these high, urban-based rates would not reasonably reflect the value of government lands on which hydropower projects are located.[52] Thus, for purposes of determining a per-acre land value, projects in Alaska will be assessed the Aleutian Islands Area per-acre land value if located in the Aleutian Islands Chain, the Fairbanks Area per-acre land value if located in the Fairbanks BLM district, or the Kenai Peninsula Area land value if located in the Anchorage BLM district, but excluding the Aleutian Islands Area. As with the other states, the Alaska per-acre geographic area values will be reduced to remove the value of irrigated lands and building or improvements.

46. While the NASS Census is based on farmland values—which include pasturelands, woodlands, and other wastelands—and there is a low concentration of farms in Alaska, the NASS Census remains a useful indication of land values. Even under the 1987 fee schedule, projects in Alaska were charged a unique rate that was not the result of surveyed lands. Because this rate was artificially low, the current adjustment is aligning Alaska's charges with the methodology applied to all other licensees. Furthermore, in adopting application of the NASS Census values for the Alaska geographical areas, BLM found that the fee schedule rates under the formula promulgated in its 2008 rule are consistent with the general fee schedule previously developed by the Department of the Interior's Appraisal Services Directorate, Alaska, for the BLM and the U.S. Fish and Wildlife Service. Thus, while the increase to Alaska licensees in annual charges for the use of government lands may seem significant, this is in large part due to the arbitrarily low rate assessed under the 1987 fee schedule. No commenters have proferred a meaningful justification for treating federal lands in Alaska any differently from federal lands administered by the same land management agencies throughout the country.

b. Per-Acre Land Values for Puerto Rico

47. Except for excluding the use of BLM's zone system, the NOPR proposed to adopt all other aspects of the 2008 BLM rule with respect to the components of the formula for creating a fee schedule. Under the 2008 BLM schedule, the Forest Service proposed to use $5,866 as the per-acre land value for projects occupying Forest Service lands in Puerto Rico,[53] which is the NASS average farmland value for the entire Commonwealth Puerto Rico.

48. No comments were received regarding the application of the proposed rule to Puerto Rico. We find the Forest Service's proposal reasonable because Puerto Rico has no counties, and the NASS Census surveys do not convey the same information in the same units and categories as those presented in the NASS Census state tables. The Final Rule will use the NASS average farmland value, adjusted by 20 percent to remove the value of irrigated lands and buildings,[54] as the per-acre value component of the fee schedule formula.

c. Individual Appraisals

49. The NOPR did not propose to allow licensees to challenge an annual charge by presenting independent appraisals based on the Commission's longstanding disfavor of any annual charges methodology that would rely on individual appraisals. A number of commenters objected to this preference and recommended that the Commission should allow licensees to submit individual appraisals at a licensee's expense. One commenter opposed the use of individual appraisals because it may increase the administrative charges for all licensees.

50. This Final Rule does not include a provision for independent appraisals. The adjustments made to this rule ensure that the annual charges are reasonable because they are based on a market value index that surveys down to the county level, adjusts for state-specific increases in value based on the ratio of irrigated lands in each state, and is further reduced by an encumbrance factor that fairly reflects the occupation of federal lands that are also used for multiple purposes. Moreover, the total amount collected by the Commission in annual charges for the use of government lands is less than a one percent increase.[55] We recognize that for some licensees the annual charge for the use of government lands will

[52] As noted, there are no Commission-licensed projects in these geographic areas, as defined in the 2008 BLM rule. However, even if there were projects in these locations in the future, such projects would be assessed annual charges for the use of government lands using the Kenai Peninsula per-acre value.

[53] Puerto Rico has one licensed project that occupies approximately two acres of lands managed by the Forest Service. Under the 2007 NASS Census, the base per-acre land value is $8,829.

[54] The NASS Census information reported for Puerto Rico is not presented in the same units and categories as the information presented for other states. As such, it is not possible to perform the state-specific reduction to remove the value of irrigated lands. Therefore, this Final Rule retains the 2008 BLM rule's adjustment of 20 percent to remove the value of irrigated lands and building and improvements from the per-acre land value.

[55] Under the 1987 fee schedule, 2013 collections were estimated to be $8,227,851. Under the Final Rule, 2013 collections are estimated to be $10,270,471.

increase, but this is because annual charges have not been updated to reflect changes in land values since 1987.[56] We continue to believe that allowing individual appraisals of a licensee's lands would significantly increase the Commission's administrative burden, cause delay in the final determination of annual charges, result in increased costs in the administration of Part I of the FPA, and could lead to unnecessary litigation.

2. Encumbrance Factor

51. The NOPR proposed to adopt a 50 percent encumbrance factor.[57] In response to the NOPR, a number of commenters argued that the encumbrance factor should be less than 50 percent in recognition of the public benefits and enhancements provided by hydropower projects. Specifically, the Federal Lands Group argues that the encumbrance factor should be 30 percent to reflect the actual, physical encumbrance of federal lands, the multiple, non-project uses of federal lands at licensed projects, and the public benefits licensees provide. Similarly, the National Hydropower Association (NHA) and Edison Electric Institute (EEI) assert that the record in this proceeding demonstrates that federal lands at hydropower projects are often used by federal land management agencies for non-project purposes.

52. We disagree and retain the 50 percent encumbrance factor in this Final Rule. The 50 percent encumbrance factor in this Final Rule is a reduction from the 70 percent encumbrance factor incorporated into the 1987 fee schedule. In promulgating its 2008 fee schedule, BLM revisited its survey of the degrees of encumbrance presumed by utility facilities and infrastructure, and determined that 50 percent was more reasonable than 70 percent because lands often can be used for other purposes. BLM made this change as a result of comments received on its proposed rule, a review of industry practices in the private sector, and a review of the Department of Interior's appraisal methodology for right-of-way facilities located on federal lands.[58]

53. A 50 percent encumbrance factor partially reflects commenters' suggestion that hydropower projects are used for non-power purposes. However, the Commission's position remains unchanged in that public benefits provided by licensed projects are considered in the licensing decision, and these benefits are the quid pro quo for the ability to operate the project in a manner consistent with the needs of society. In combination with the decision not to double the fee schedule for non-transmission line lands, and the fact that the different components of hydropower projects represent varying levels of encumbrance on federal lands, on balance, a 50 percent encumbrance factor is reasonable.

3. Rate of Return

54. The rate of return component of the formula converts the adjusted per-acre land value into an annual rental value. The NOPR proposed a rate of return of 5.27 percent, which is the rate of return adopted in the 2008 BLM rule. BLM described 5.27 percent as the most current 10-year average (1998–2007) of the 30-year and 20-year Treasury bond yield rate.[59]

55. In response to the NOPR, Southern California Edison (SCE) commented that the 10-year average of these Treasury bond yield rates will result in no greater certainty than the a one-point-in-time Treasury bond yield rate. SCE proposes that, rather than using a 10-year average, the Commission should use the most recent 30-year Treasury bond yield rate to determine the applicable rate of return for annual charges.[60]

56. In deciding to use the Treasury bond yield rate as a basis for a rate of return, BLM reviewed a number of appraisal reports that indicated the rate of return for land can vary from 7 to 12 percent, and is typically around 10 percent. BLM acknowledged that these rates take into account certain risk considerations, and do not normally include an allowance for inflation. BLM determined that it should use a ''safe rate of return,'' that is, the prevailing rate on insured savings accounts or guaranteed government securities that include an allowance for inflation, because any risk of non-payment is reduced because BLM requires a potential right-of-way holder to show that it is financially able to construct and operate the facility.

57. We agree that, because the annual charge for use of government land is a required payment as a term of a hydropower license, using a ''safe'' rate of return is appropriate. Therefore, as in the 2008 BLM rule, our Final Rule will convert the adjusted per-acre land value into an annual rental value using a rate of return pegged to the 30-year Treasury bond yield rate. Hydropower licenses generally are issued for a period of 30 to 50 years, and the Treasury bond yield rate should match that time frame as closely as possible. The longest bond yield rate available from the Treasury is 30 years. We also agree with BLM's reasoning in its 2008 rule that a 10-year average eliminates a ''one-point-in-time'' high or low rate, and thus we will not adopt SCE's proposal that we use a one-point-in-time Treasury bond yield rate. Therefore, in this Final Rule, the rate of return will be the 10-year average of the 30-year Treasury bond yield rate for the 10 years immediately preceding the most recent NASS Census.[61] The 10-year average (2002–2011) of the 30-year Treasury bond yield rate for the 10 years immediately preceding the 2012 NASS Census is 5.77 percent.[62] Therefore, the applicable interest rate will be 5.77 percent for years 2013 through 2025.[63]

58. Further, for the sake of administrative efficiency, the 10-year adjustments will occur in tandem with the annual adjustment factor, which is also adjusted on a decadal basis. As a result, the 5.77 percent rate of return will apply for 13 years, or through 2025. Both the rate of return and the annual adjustment factor will be recalculated for years 2026 through 2035, and will remain fixed through the 10-year period.

4. Annual Adjustment Factor

59. The annual adjustment factor adjusts the fee schedule annually to reflect inflationary or deflationary trends. The NOPR proposed an annual adjustment factor of 1.9 percent, as adopted in the 2008 BLM rule, which would be adjusted every 10 years.[64] The NOPR proposed to base the annual adjustment factor on the average annual

[56] Based on land trends since 1987, we would expect to see increases in some western states, in suburban areas adjacent to cities, and in Alaska because of the artificially low rate assessed under the 1987 fee schedule.

[57] The encumbrance factor is a measure of the degree to which a particular type of facility encumbers a right-of-way or excludes other types of land uses.

[58] 73 FR 65040, at 65047.

[59] The longest term treasury bond is a 30-year bond. However, from 2003–2005, 30-year treasury bonds were discontinued, and the longest term treasury bond was the 20-year bond.

[60] This rate is 3.91 percent for 2011.

[61] Between 2003 and 2005, the U.S. Treasury Department did not publish a 30-year Treasury bond yield rate. For these years, the 20-year Treasury bond yield rate is used. Should the U.S. Treasury Department discontinue publishing the 30-year Treasury bond yield rate, the longest term bond yield available will be used for applicable years to calculate the rate of return.

[62] Data to derive these calculations is available from the Federal Reserve Web site. This Final Rule uses the nominal 30-year Treasury constant maturity rate available on an annualized basis from the Federal Reserve Web site.

[63] For the years 2026–2035, the rate of return will be the 10-year average of the 30-year Treasury bond yield rate for the 10 years (2012–2021) preceding the 2022 NASS Census.

[64] The first 10-year period will not be a full period so as to ensure that the 10-year track the five year census data updates. Thus, the annual adjustment factor of 1.9 percent would be applied for each calendar year through 2015.

change from second quarter to second quarter in the IPD–GDP for the 10-year period immediately preceding the year (2004) that the 2002 NASS Census data became available. The NOPR proposed to adopt BLM's decadal updates to the annual adjustment factor.[65] BLM chose to use the IPD–GDP over the Consumer Price Index—for all Urban Consumers (CPI–U) because the IPD–GDP index tracks increases in land values as well as, if not better than, the CPI–U, and the IPD–GDP tracks a broader range of economic indicators than does the CPI–U, and can be tracked on an annual basis. BLM chose to update the IPD–GDP every ten years to provide predictability so that rental fees could be anticipated.

60. In response to the NOPR, no comments were received on the proposal to adopt the BLM methodology of using the IPD–GDP for the 10-year period immediately preceding the issuance of the NASS Census data, and updating the annual adjustment factor every 10 years. The IPD–GDP was used from 1987 to 2007 to adjust the fee schedule for the use of government lands without complaint, it is an easily identifiable number for use by the public and federal agencies, and, as explained by BLM, it better aligns with actual inflationary trends when contrasted to the CPI–U. Therefore, the ten-year IPD–GDP for the period immediately preceding issuance of the NASS Census data is a reasonable factor to adjust for inflationary or deflationary trends in the per-acre land values.

61. Through 2015, a 1.9 percent annual adjustment factor will be applied each calendar year. This is the annual change in the IPD–GDP index for the ten-year period immediately preceding the year (2004) that the 2002 NASS Census data became available. For the next ten-year period (2016–2025), the annual adjustment factor will be based on the average annual change in the IPD–GDP for the ten-year period immediately preceding the year (2014) that the 2012 NASS Census data becomes available. The annual adjustment factor will be adjusted in the same manner for subsequent ten year periods.

C. Summary of Schedule

62. Fee schedules through 2015 will be based on data from the 2007 NASS Census, and all adjustments and components identified in this order apply through 2015 (i.e., the per-acre land value adjustment, the 50 percent encumbrance factor, the 5.77 percent rate of return, and the 1.9 percent inflation adjustment).

63. Fee schedules for years 2016–2020 will be based on data from the 2012 NASS Census. The state-specific adjustment to the per-acre land values will be performed for the 2016 base year, the rate of return will remain at 5.77 percent, and the inflation adjustment will be recalculated.

64. For years 2021–2025, the per-acre land value will be based on data from the 2017 NASS Census, the state-specific adjustments will be recalculated, the rate of return will be 5.77 percent, and the inflation adjustment will match that used in years 2016–2020.

65. A schedule of adjustments to the fee schedule is provided in Appendix B to this order, and will be available on the Commission's Web site.

D. Changes to Proposed Regulations

66. The NOPR proposed to retain the general structure of section 11.2 by referring to the completed fee schedule created based on the components described in the rule promulgating the 1987 regulations. However, in response to comments on the NOPR and to reduce the risk of ambiguity, the regulations promulgated by this Final Rule include a description of the individual components of the formula used to create the fee schedule. Furthermore, the first sentence of section 11.2(a) will not be deleted because it helps to clarify the relationship of annual charges for the use of government lands to the annual charges for the use of government dams.

III. Regulatory Requirements

A. Information Collection Statement

67. The Office of Management and Budget (OMB) regulations require OMB to approve certain reporting, record keeping, and public disclosure requirements (collections of information) imposed by an agency.[66] This rule does not contain any information collection requirements and compliance with the OMB regulations is thus not required. The Commission anticipates this rulemaking will make no change in current filing requirements, since licensees already must report to the Commission annually the number of acres per county a licensed project occupies. In addition, this Final Rule does not make any substantive or material changes to requirements specified in the NOPR, where the Commission similarly found no information collection requirements. The Commission will submit a copy of this Final Rule to OMB for information purposes only.

B. Environmental Analysis

68. The Commission is required to prepare an Environmental Assessment or an Environmental Impact Statement for any action that may have a significant adverse effect on the human environment.[67] The Commission has categorically excluded certain actions from these requirements as not having a significant effect on the human environment.[68] The actions taken here fall within categorical exclusions in the Commission's regulations for actions concerning annual charges.[69] Therefore, an environmental review is unnecessary and has not been prepared in this rulemaking.

C. Regulatory Flexibility Act

69. The Regulatory Flexibility Act of 1980 (RFA)[70] generally requires a description and analysis of final rules that will have significant economic impact on a substantial number of small entities. The RFA mandates consideration of regulatory alternatives that accomplish the stated objectives of a rulemaking while minimizing any significant economic impact on a substantial number of small entities. The Small Business Administration's (SBA) Office of Size Standards develops the numerical definition of a small business.[71] The SBA has established a size standard for electrical utilities stating that a firm is small if, including its affiliates, it is primarily engaged in the transmission, generation and/or distribution of electric energy for sale and its total electric output for the preceding twelve months did not exceed four million megawatts.[72]

70. Section 10(e)(1) of the FPA requires that the Commission fix a reasonable annual charge for the use, occupancy, and enjoyment of federal lands by hydropower licensees.[73] The Commission currently assesses annual charges to 253 licenses for projects that occupy federal lands, which represent

[65] BLM will recalculate the annual adjustment factor in 2014, based on the average annual change in the IPD–GDP from 2004 to 2013 (the 10-year period immediately preceding the year (2014) when the 2012 NASS Census data will become available) and will apply it annually to the fee schedule for years 2016 through 2025.

[66] 5 CFR 1320.12 (2012).

[67] *Regulations Implementing the National Environmental Policy Act,* Order No. 486, 52 FR 47897 (Dec. 17, 1987), FERC Stats. & Regs. ¶ 30,783 (1987).

[68] 18 CFR 380.4 (2012).

[69] 18 CFR 380.4(1) (2012).

[70] 5 U.S.C. 601–612 (2006).

[71] 13 CFR 121.101 (2012).

[72] 13 CFR 121.201, Sector 22 Utilities & n.1 (2012).

[73] 16 U.S.C. 803(e)(1) (2006).

135 discrete licensees, who will be impacted by this Final Rule. The Final Rule adopts a methodology promulgated by BLM, based on the NASS Census data, to determine the annual charge for the use of federal lands. The methodology for assessing this annual charge under the previous regulations is based on land values from 1987, whereas this Final Rule incorporates current land values, and would update those values every five years. As a result, some of the 135 licensees may experience a one-time increase in their annual charge for the use of federal lands.

71. Nevertheless, based on a review of the licensees with federal lands that will be impacted by the Final Rule, we estimate that less than 10 percent are small entities under the SBA definition. The affected licensees represent utilities, cities, and private and public companies in 30 states or territories. Many of the utilities which may seem to be under the four million megawatt hours per year threshold are also engaged in electricity production through other forms of generation, such as coal or natural gas, or also provide other utility services such as natural gas or water delivery. Similarly, many licensees that are small hydropower generators are affiliated with a larger entity or entities in other industries. Therefore, we estimate that less than 10 percent of the impacted licensees are actually small, unaffiliated entities who are primarily engaged in hydropower generation and whose total electrical output through transmission, generation, or distribution is less than four million megawatt hours per year.

72. Any impact on these small entities would not be significant. Under the Final Rule, there may be a one-time increase for some licensees in the annual charge for the use of federal lands, but because the new methodology for calculating the annual charge will be updated every five years, any future increases or decreases will be incremental.[74] In addition, small, unaffiliated entities generally occupy less federal lands than larger projects that generate more power. Therefore, as a class of licensees, small entities would be less impacted by an annual charge for the use of federal lands. Furthermore, this Final Rule does not incur any additional compliance or recordkeeping costs on any licensees occupying federal lands. Consequently, the Final Rule should not impose a significant economic impact on small entities.

73. Based on this understanding, the Commission certifies that the Final Rule will not have a significant economic impact on a substantial number of small entities. Accordingly, no regulatory flexibility analysis is required.

D. Document Availability

74. In addition to publishing the full text of this document, except for the Appendices, in the **Federal Register**, the Commission provides all interested persons an opportunity to view and/or print the contents of this document via the Internet through the Commission's Home Page (*http://www.ferc.gov*) and in the Commission's Public Reference Room during normal business hours (8:30 a.m. to 5:00 p.m. Eastern time) at 888 First Street NE., Room 2A, Washington, DC 20426.

75. From the Commission's Home Page on the Internet, this information is available on eLibrary. The full text of this document, including the Appendices, is available on eLibrary in PDF and Microsoft Word format for viewing, printing, and/or downloading. To access this document in eLibrary, type the docket number excluding the last three digits of this document in the docket number field.

76. User assistance is available for eLibrary and the Commission's Web site during normal business hours from Commission's Online Support at 202–502–6652 (toll free at 1–866–208–3676) or email at *ferconlinesupport@ferc.gov*, or the Public Reference Room at (202) 502–8371, TTY (202) 502–8659. Email the Public Reference Room at *public.referenceroom@ferc.gov*.

E. Effective Date and Congressional Notification

77. These regulations are effective February 25, 2013. The Commission has determined, with the concurrence of the Administrator of the Office of Information and Regulatory Affairs of OMB, that this rule is not a ''major rule'' as defined in section 251 of the Small Business Regulatory Enforcement Fairness Act of 1996.[75] This rule is being submitted to the Senate, House, Government Accountability Office, and the Small Business Administration.

List of Subjects in 18 CFR Part 11

Public Lands.

By the Commission.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

In consideration of the foregoing, the Commission amends part 11, Chapter I, Title 18 of the Code of Federal Regulations, as follows.

PART 11—ANNUAL CHARGES UNDER PART I OF THE FEDERAL POWER ACT

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

Authority: 16 U.S.C. 792–828c; 42 U.S.C. 7101–7352.

■ 2. Revise § 11.2 to read as follows:

§ 11.2 Use of Government lands.

(a) Reasonable annual charges for recompensing the United States for the use, occupancy, and enjoyment of its lands (other than lands adjoining or pertaining to Government dams or other structures owned by the United States Government) or its other property, will be fixed by the Commission.

(b) *General rule.* Annual charges for the use of government lands will be payable in advance, and will be set on the basis of an annual schedule of per-acre rental fees, as set forth in Appendix A of this part. The Executive Director will publish the updated fee schedule in the **Federal Register**.

(c) The annual per-acre rental fee is the product of four factors: the adjusted per-acre value multiplied by the encumbrance factor multiplied by the rate of return multiplied by the annual adjustment factor.

(1) *Adjusted per-acre value.* (i) Counties (or other geographical areas) are assigned a per-acre value based on their average per-acre land and building value published in the Census of Agriculture (Census) by the National Agricultural Statistics Service (NASS). The adjusted per-acre value is computed by reducing the NASS Census land and building value by the sum of a state-specific modifier and seven percent. A table of state-specific adjustments will be available on the Commission's Web site.

(ii) The state-specific modifier is a percentage reduction applicable to all counties or geographic areas in a state (except Puerto Rico), and represents the ratio of the total value of irrigated farmland in the state to the total value of all farmland in the state. The state-specific modifier will be recalculated every five years beginning in payment year 2016.

(iii) The state-specific modifier for Puerto Rico is 13 percent.

(2) *Encumbrance factor.* The encumbrance factor is 50 percent.

[74] Alaska Electric Light and Power Company (AEL&P) commented that it was a small business that would be significantly impacted by the proposed rule because its charges for the Project No. 2307 would rise from approximately $10,000 annually to over $1 million. In fact, under this Final Rule, AEL&P's charges for the use of government lands would be approximately $30,000.

[75] 5 U.S.C. 804 (2006).

(3) *Rate of return.* The rate of return is 5.77 percent through payment year 2025. The rate of return will be adjusted every 10 years thereafter, and will be based on the 10-year average of the 30-year Treasury bond yield rate immediately preceding the applicable NASS Census. For example, for years 2026 through 2035, the rate of return will be based on the 10-year average (2012–2021) of the 30-year Treasury bond yield rate immediately preceding the 2022 NASS Census. If the 30-year Treasury bond yield rate is not available, the next longest term Treasury bond available should be used in its place.

(4) *Annual adjustment factor.* The annual adjustment factor is 1.9 percent through payment year 2015. For years 2016 through 2025, the annual adjustment factor is the annual change in the Implicit Price Deflator for the Gross Domestic Product (IPD–GDP) for the ten years (2014–2023) preceding issuance (2024) of the most recent NASS Census (2022). Each subsequent ten year adjustment will be made in the same manner.

(d) The annual charge for the use of Government lands for 2013 will be reduced by 25 percent for all licensees subject to this section.

(e) The minimum annual charge for the use of Government lands under any license will be $25.

Note: Appendix A will not be published in the *Code of Federal Regulations.*

APPENDIX A

State	All Farms 2007 (per acre value)	Irrigated Farms All harvested cropland irrigated 2007 (per acre value)	All Farms 2007 (acres)	Irrigated Farms All harvested cropland irrigated 2007 (acres)	Total Farm Est Mkt Value (per acre all farms value × all farms acres)	Total Harvested Irrigated Cropland Est Mkt Value (irrigated farms acres × irrigated farms per acre value)	% Reduction of Irrigated cropland	% Reduction of irragated cropland + 7% Building
Alabama	2,292	4,406	9,033,537	94,995	20,704,866,804	418,547,970	2.02	9.02
Alaska	391	766	881,585	55,673	344,699,735	42,645,518	12.37	19.37
Arizona	748	4,828	26,117,899	1,983,172	19,536,188,452	9,574,754,416	49.01	56.01
Arkansas	2,343	2,144	13,872,862	1,930,505	32,504,115,666	4,139,002,720	12.73	19.73
California	6,408	9,636	25,364,695	11,417,202	162,536,965,560	110,016,158,472	67.69	74.69
Colorado	1,046	1,426	31,604,911	7,235,306	33,058,736,906	10,317,546,356	31.21	38.21
Connecticut	12,667	25,138	405,616	13,457	5,137,937,872	338,282,066	6.58	13.58
Delaware	10,347	15,326	510,253	10,949	5,279,587,791	167,804,374	3.18	10.18
Florida	5,639	6,583	9,231,570	2,497,529	52,056,823,230	16,441,233,407	31.58	38.58
Georgia	3,117	3,091	10,150,539	500,841	31,639,230,063	1,548,099,531	4.89	11.89
Hawaii	7,688	7,873	1,121,329	264,215	8,620,777,352	2,080,164,695	24.13	31.13
Idaho	1,972	2,374	11,497,383	4,990,872	22,672,839,276	11,848,330,128	52.26	59.26
Illinois	3,792	6,244	26,775,100	43,999	101,531,179,200	274,729,756	0.27	7.27
Indiana	3,583	6,615	14,773,184	29,987	52,932,318,272	198,364,005	0.37	7.37
Iowa	3,388	5,501	30,747,550	14,798	104,172,699,400	81,403,798	0.08	7.08
Kansas	911	976	46,345,827	581,943	42,221,048,397	567,976,368	1.35	8.35
Kentucky	2,682	4,537	13,993,121	55,937	37,529,550,522	253,786,169	0.68	7.68
Louisiana	2,058	1,777	8,109,975	502,057	16,690,328,550	892,155,289	5.35	12.35
Maine	2,203	6,109	1,347,566	23,145	2,968,687,898	141,392,805	4.76	11.76
Maryland	7,034	10,102	2,051,756	31,095	14,432,051,704	314,121,690	2.18	9.18
Massachusetts	12,313	15,069	517,879	47,956	6,376,644,127	722,648,964	11.33	18.33
Michigan	3,409	6,940	10,031,807	144,741	34,198,430,063	1,004,502,540	2.94	9.94
Minnesota	2,569	3,791	26,917,962	100,603	69,152,244,378	381,385,973	0.55	7.55
Mississippi	1,870	1,972	11,456,241	238,386	21,423,170,670	470,097,192	2.19	9.19
Missouri	2,179	3,267	29,026,573	186,134	63,248,902,567	608,099,778	0.96	7.96
Montana	775	1,179	61,388,462	8,244,973	47,576,058,050	9,720,823,167	20.43	27.43
Nebraska	1,159	1,234	45,480,358	4,122,912	52,711,734,922	5,087,673,408	9.65	16.65
Nevada	613	542	5,865,392	4,197,712	3,595,485,296	2,275,159,904	63.28	70.28
New Hampshire	4,929	12,537	471,911	7,834	2,326,049,319	98,214,858	4.22	11.22
New Jersey	15,346	16,131	733,450	83,573	11,255,523,700	1,348,116,063	11.98	18.98
New Mexico	337	609	43,238,049	8,328,784	14,571,222,513	5,072,229,456	34.81	41.81
New York	2,275	12,676	7,174,743	58,992	16,322,540,325	747,782,592	4.58	11.58
North Carolina	4,096	6,923	8,474,671	221,134	34,712,252,416	1,530,910,682	4.41	11.41
North Dakota	771	1,470	39,674,586	46,390	30,589,105,806	68,193,300	0.22	7.22
Ohio	3,528	10,297	13,956,563	27,239	49,238,754,264	280,479,983	0.57	7.57
Oklahoma	1,157	1,102	35,087,269	439,262	40,595,970,233	484,066,724	1.19	8.19
Oregon	1,890	1,648	16,399,647	5,528,995	30,995,332,830	9,111,783,760	29.40	36.40
Pennsylvania	4,775	18,011	7,809,244	35,549	37,289,140,100	640,273,039	1.72	8.72
Rhode Island	16,828	15,665	67,819	6,749	1,141,258,132	105,723,085	9.26	16.26
South Carolina	2,858	4,269	4,889,339	84,908	13,973,730,862	362,472,252	2.59	9.59
South Dakota	896	667	43,666,403	422,908	39,125,097,088	282,079,636	0.72	7.72
Tennessee	3,378	6,291	10,969,798	55,112	37,055,977,644	346,709,592	0.94	7.94
Texas	1,270	1,329	130,398,753	5,146,796	165,606,416,310	6,840,091,884	4.13	11.13
Utah	1,249	1,959	11,094,700	3,751,452	13,857,280,300	7,349,094,468	53.03	60.03
Vermont	2,903	7,011	1,233,313	8,724	3,580,307,639	61,163,964	1.71	8.71
Virginia	4,213	7,062	8,103,925	50,527	34,141,836,025	356,821,674	1.05	8.05
Washington	1,992	3,029	14,972,789	3,284,122	29,825,795,688	9,947,605,538	33.35	40.35
West Virginia	2,385	5,283	3,697,606	6,109	8,818,790,310	32,273,847	0.37	7.37
Wisconsin	3,225	4,586	15,190,804	247,792	48,990,342,900	1,136,374,112	2.32	9.32
Wyoming	513	592	30,169,526	10,496,772	15,476,966,838	6,214,089,024	40.15	47.15
United States	1,892	2,757	922,095,840	87,900,817	1,744,605,329,280	242,342,552,469	13.89	20.89

Note: Appendix B will not be published in the *Code of Federal Regulations.*

APPENDIX B—ADJUSTMENT SCHEDULE FOR FORMULA COMPONENTS

Payment year	Per-acre adjustments		Rate of return adjustments	Inflation adjustments
2013	2007 NASS Census	state-specific adjustment	rate of return update (10-year average of annualized 30-year T-bill yield for years 2002–2011).	
2014				
2015				
2016	2012 NASS Census	updated state-specific adjustment.		inflation update (average IPD–GDP for 2004–2013, 2Q–2Q).
2017				
2018				
2019				
2020				
2021	2017 NASS Census	updated state-specific adjustment.		
2022				
2023				
2024				
2025				
2026	2022 NASS Census	updated state-specific adjustment.	rate of return update (10-year average of annualized 30-year T-bill yield for 2012–2021).	inflation update (average of IPD–GDP for 2014–2023, 2Q–2Q).
2027				
2028				
2029				
2030				
2031	2027 NASS Census	updated state-specific adjustment.		
2032				
2033				
2034				
2035				
2036	2032 NASS Census	updated state-specific adjustment.	rate of return update (10-year average of annualized 30-year T-bill yield for 2022–2031).	inflation update (average of IPD–GDP for 2024–2033, 2Q–2Q).
2037				
2038				
2039				
2040				
2041	2037 NASS Census	updated state-specific adjustment.		
2042				
2043				
2044				
2045				
2046	2042 NASS Census	updated state-specific adjustment.	rate of return update (10-year average of annualized 30-year T-bill yield for 2032–2041).	inflation update (average of IPD–GDP for 2034–2043, 2Q–2Q).
2047				
2048				
2049				
2050				
2051	2047 NASS Census	updated state-specific adjustment.		

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DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

18 CFR Parts 2 and 35

[Docket Nos. AD12–9–000 and AD11–11–000]

Allocation of Capacity on New Merchant Transmission Projects and New Cost-Based, Participant-Funded Transmission Projects; Priority Rights to New Participant-Funded Transmission

AGENCY: Federal Energy Regulatory Commission, Energy.

ACTION: Final Policy Statement.

SUMMARY: The Commission issues this final policy statement to clarify and refine its policies governing the allocation of capacity for new merchant transmission projects and new nonincumbent, cost-based, participant-funded transmission projects. Under this policy statement, the Commission will allow developers of such projects to select a subset of customers, based on not unduly discriminatory or preferential criteria, and negotiate directly with those customers to reach agreement on the key rates, terms, and conditions for procuring up to the full amount of transmission capacity, when the developers broadly solicit interest in the project from potential customers, and demonstrate to the Commission that the developer has satisfied the solicitation, selection and negotiation process criteria set forth herein. The Commission is making these clarifications and refinements to fulfill its statutory responsibility of preventing undue discrimination and undue preference while providing developers the ability to bilaterally negotiate rates, terms, and conditions for the full amount of transmission capacity with potential customers. These clarifications and refinements will be implemented within the Commission's existing four-factor analysis used to evaluate requests for negotiated rate authority for transmission service. The Commission will apply this policy statement on a prospective basis to filings received after this issuance.

DATES: These policies became effective January 17, 2013.

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SUPPLEMENTARY INFORMATION:

Before Commissioners: Jon Wellinghoff, Chairman; Philip D. Moeller, John R. Norris, Cheryl A. LaFleur, and Tony T. Clark.

Final Policy Statement

(Issued January 17, 2013)

I. Introduction

1. The Commission issues this final policy statement to clarify and refine its policies governing the allocation of capacity for new merchant transmission projects and new nonincumbent, cost-based, participant-funded transmission projects. Under this policy statement, the Commission will allow developers of such projects to select a subset of customers, based on not unduly discriminatory or preferential criteria, and negotiate directly with those customers to reach agreement on the key rates, terms, and conditions for procuring up to the full amount of transmission capacity, when the developers (1) broadly solicit interest in the project from potential customers, and (2) demonstrate to the Commission that the developer has satisfied the solicitation, selection and negotiation process criteria set forth herein. The Commission is making these clarifications and refinements to fulfill its statutory responsibility of preventing undue discrimination and undue preference while providing developers the ability to bilaterally negotiate rates, terms, and conditions for the full amount of transmission capacity with potential customers. These clarifications and refinements will be implemented within the Commission's existing four-factor analysis used to evaluate requests for negotiated rate authority for transmission service.[1] The Commission will apply this policy statement on a prospective basis to filings received after this issuance.

II. Background

2. The Commission first granted negotiated rate authority to a merchant transmission project developer over a decade ago, finding that merchant transmission can play a useful role in expanding competitive generation alternatives for customers.[2] Unlike traditional utilities recovering their costs-of-service from captive and wholesale customers, investors in merchant transmission projects assume the full market risk of development.[3] Over the course of a number of early proceedings, the Commission developed ten criteria to guide its analysis in making a determination as to whether negotiated rate authority would be just and reasonable for a given merchant transmission project.[4] Two of these criteria were that (1) an open season process should be employed to initially allocate all transmission capacity and (2) the results of the open season should be posted on an Open Access Same-Time Information System (OASIS) and filed in a report with the Commission.[5]

3. In recent years, a number of merchant and nontraditional transmission developers have sought guidance from the Commission regarding application of open access principles to new transmission facilities through petitions for declaratory orders. As the Commission addressed these requests, its policies evolved over time to provide potential customers adequate opportunities to obtain service while also providing transmission developers adequate certainty to assist with financing transmission projects. As a result of these evolving policies,

[1] *See infra* note 6 and P 15.

[2] *TransEnergie U.S., Ltd.,* 91 FERC ¶ 61,230, at 61,838 (2000) (*TransEnergie*).

[3] *Id.* at 61,836.

[4] *Id.; Neptune Regional Transmission System, LLC,* 96 FERC ¶ 61,147, at 61,633 (2001) (*Neptune*); *Northeast Utilities Service Co.,* 97 FERC ¶ 61,026, at 61,075 (2001) (*Northeast Utilities I*); *Northeast Utilities Service Co.,* 98 FERC ¶ 61,310, at 62,327 (2002) (*Northeast Utilities II*).

[5] The ten criteria were: (1) The merchant transmission facility must assume full market risk; (2) the service should be provided under the open access transmission tariff (OATT) of the Independent System Operator (ISO) or Regional Transmission Organization (RTO) that operates the merchant transmission facility and that operational control be given to that ISO or RTO; (3) the merchant transmission facility should create tradable firm secondary transmission rights; (4) an open season process should be employed to initially allocate transmission rights; (5) the results of the open season should be posted on the OASIS and filed in a report to the Commission; (6) affiliate concerns should be adequately addressed; (7) the merchant transmission facility not preclude access to essential facilities by competitors; (8) the merchant transmission facilities should be subject to market monitoring for market power abuse; (9) physical energy flows on merchant transmission facilities should be coordinated with, and subject to, reliability requirements of the relevant ISO or RTO; and (10) merchant transmission facilities should not impair pre-existing property rights to use the transmission grids of inter-connected RTOs or utilities. *E.g., Northeast Utilities I,* 97 FERC ¶ 61,026 at 61,075.

different rules have been adopted regarding capacity allocation for merchant transmission projects and nonincumbent, cost-based, participant-funded transmission projects.

4. In *Chinook,* the Commission refined its approach to evaluating merchant transmission by adopting a four-factor analysis.[6] Under this analysis, the Commission continues to rely upon an open season and a post-open season report as a means to provide transparency in the allocation of initial transmission capacity and ensure against undue discrimination among potential customers in the award of transmission capacity. Specifically, the Commission evaluates the terms and conditions of the open season as part of ensuring no undue discrimination (second factor),[7] and uses the open season as an added protection in overseeing any affiliate participation, to ensure no undue preference or affiliate concerns (third factor).

5. The *Chinook* order also marked a change in Commission policy on capacity allocation, as in that order the Commission for the first time authorized developers to allocate some portion of capacity through anchor customer presubscription, while requiring that the remaining portion be allocated in a subsequent open season. The Commission implemented this policy to achieve the dual goals of requiring an open season process that ensures capacity on a merchant transmission project is allocated transparently in an open, fair, and not unduly discriminatory manner, while permitting an anchor customer model that enables developers of merchant transmission projects to meet the financial challenges unique to merchant transmission development.[8] Since the *Chinook* order, the Commission has issued orders on several new merchant and other nontraditional transmission development proposals, including granting requests to allocate up to 75 percent of a transmission project's capacity to anchor customers.[9]

6. The Commission also has received proposals from transmission developers regarding the allocation of capacity on cost-based, participant-funded transmission projects. These proceedings involved incumbent transmission developers,[10] while one involved a nonincumbent transmission developer.[11] In *NU/NSTAR,* the Commission approved the structure of a transaction whereby a customer was granted usage rights to transmission capacity in exchange for funding the transmission expansion, under the reasoning that any potential transmission customer has the right to request transmission service expansion from a transmission owning utility, and that utility is obligated to make any necessary system expansions and offer service at the higher of an incremental cost or an embedded cost rate to the transmission customer. More recently, in *National Grid,* the Commission found again that participant funding of transmission projects by incumbent transmission providers is not inconsistent with the Commission's open access requirements.[12] Cost-based participant-funded projects are similar to merchant projects in that both involve willing customers assuming part of the risk of a transmission project in return for defined capacity rights; i.e., there is no direct assignment of costs to captive customers. Cost-based participant-funded projects differ between incumbents and nonincumbents, in that incumbent transmission providers have a clearly defined set of existing obligations under their tariffs for the expansion of their existing transmission facilities, whereas nonincumbents have no existing obligation to build any transmission facilities.

A. Technical Conference and Workshop

7. To gain feedback regarding the Commission's capacity allocation policies, the Commission held a technical conference in March 2011 to discuss the extent to which nonincumbent developers of transmission should be provided flexibility in the allocation of rights to use transmission facilities developed on a cost-of-service or negotiated rate basis.[13] Participants at that conference and subsequent commenters acknowledged the value in widely soliciting new customers, but they also expressed the desire to be able to allocate 100 percent of their projects' capacity through bilateral negotiations with identified customers.[14] Based on these comments, the Commission held a follow up workshop in February 2012 to obtain input on potential reforms to the Commission's capacity allocation policies.[15] Many participants at the 2012 workshop emphasized that a bilateral exchange of information is necessary to address the unique needs of developers and their potential customers, and that a rigid open season process does not allow for bilateral exchanges. However, other commenters at the 2012 workshop voiced concerns with the merchant transmission model in general, and discouraged the Commission from pursuing policies that enable anchor customers to exclude or burden generation competitors or engage in other abusive practices the Commission sought to eradicate in Order No. 888.

B. Proposed Policy Statement

8. Informed by the discussion at the workshop and technical conference and by comments filed afterwards, the Commission in July 2012 issued a proposed policy statement on the allocation of capacity on new merchant transmission projects and new cost-based, participant-funded transmission projects. The Commission proposed to allow developers of new merchant transmission projects and new nonincumbent cost-based, participant-funded transmission projects to select a subset of customers, based on not unduly discriminatory or preferential criteria, and negotiate directly with those customers to reach agreement on the rates, terms, and conditions for procuring capacity. The proposed policy would allow such direct negotiations

[6] The four factors are: (1) The justness and reasonableness of rates; (2) the potential for undue discrimination; (3) the potential for undue preference, including affiliate preference; and (4) regional reliability and operational efficiency requirements. *E.g., Chinook Power Transmission, LLC,* 126 FERC ¶ 61,134, at P 37 (2009) (*Chinook*).

[7] Also, the Commission looks to a developer's own OATT commitments or its commitment to turn operational control over to an RTO or ISO. *See id.* P 40. Guidance given in this policy statement with regards to satisfying the second factor is directed at the open season requirement; the Commission will continue to require merchant and other transmission developers either to file an OATT or to turn over control to an RTO or ISO.

[8] *See id.* P 46.

[9] *See, e.g., Champlain Hudson Power Express, Inc.,* 132 FERC ¶ 61,006 (2010); *Rock Island Clean Line LLC,* 139 FERC ¶ 61,142 (2012); *Southern Cross Transmission LLC,* 137 FERC ¶ 61,207 (2011).

[10] *See, e.g., Northeast Utilities Service Company, NSTAR Electric Company,* 127 FERC ¶ 61,179 (2009) (*NU/NStar*), *order denying reh'g and clarification,* 129 FERC ¶ 61,279 (2009); *National Grid Transmission Services Corporation and Bangor Hydro Electric Company,* 139 FERC ¶ 61,129 (2012) (*National Grid*).

[11] *See Grasslands Renewable Energy, LLC,* 133 FERC ¶ 61,225 (2010).

[12] *National Grid,* 139 FERC ¶ 61,129 at P 29.

[13] ''Priority Rights to New Participant-Funded Transmission,'' Docket No. AD11–11–000, March 15, 2011. This technical conference also addressed generator lead lines, but those facilities are not the subject of this proposed policy statement.

[14] *See, e.g.,* Clean Line Energy Partners May 5, 2011 Comments at 7; LS Power Transmission, LLC May 5, 2011 Comments at 3–4; Transmission Developers, Inc. May 5, 2011 Comments at 4–5; Western Independent Transmission Group May 5, 2011 Comments at 6; and Tonbridge Power Inc. April 19, 2011 Comments at 2.

[15] ''Allocation of Capacity on New Merchant Transmission Projects and New Cost-Based, Participant-Funded Transmission Projects,'' Docket No. AD12–9–000 (February 28, 2012).

when the developers (1) broadly solicit interest in the project from potential customers, and (2) demonstrate to the Commission that the developer has satisfied the solicitation, selection, and negotiation process criteria set forth in the proposed policy statement. Such proposed policy would also allow the developer to allocate up to 100 percent of the capacity on a transmission project to a single customer, including an affiliate, if the developer has satisfied the obligations set forth in the proposed policy statement.

9. The Commission received comments on the proposed policy statement from 18 entities.[16] As a general matter, the proposed policy statement received broad support in the comments received, albeit there were some comments in opposition. In addition, the Commission received requests to clarify the policies articulated in the proposed policy statement. We summarize here the general comments in support and in opposition to the proposed policy statement, with comments requesting clarification noted in the discussion of specific elements of this final policy statement.

10. Many commenters broadly support the proposed policy statement.[17] WITG asserts that the proposed policy statement will give new transmission development momentum by allowing transmission developers to discuss contractual arrangements, technical specifications and project timing with prospective customers.[18] WITG asserts that, under the proposed policy statement, a transmission developer will be more able to ''right-size'' its project based on market interest for the project.[19] AWEA and NYTO similarly suggest that the proposed policy statement will allow merchant transmission developments to be tailored to the needs of the market.[20] EEI asserts that the proposed policy statement will allow transmission developers to identify viable transmission customers early in the process, and suggests that the flexibility allowed for in the proposed policy statement will aid funding and enable construction on a timely basis.[21] Duke Energy also asserts that the bilateral negotiation process allowed for in the proposed policy statement will provide the most efficient and effective way of ensuring that commercial transmission projects are successfully completed.[22]

11. AWEA emphasizes the importance of merchant transmission development in removing barriers to the development of renewable energy.[23] AWEA notes that the proposed policy statement will allow transmission developers to provide incentives to first-movers, which should encourage potential transmission customers to negotiate with developers early in the development process. In contrast, AWEA asserts that, under current Commission policy, ''a prospective transmission customer has no economic incentive to commit to a capacity allocation early during the development process because that customer can obtain the same terms, and conditions during the open season auction without taking any development risk.'' [24]

12. However, APPA, NRECA, NJ Rate Counsel and TAPS argue that changes to our capacity allocation policies are unnecessary, run counter to our open access principles, and are inconsistent with our obligations under the Federal Power Act (FPA). These commenters argue that the Commission's proposal to allow allocation of 100 percent of a merchant's capacity through bilateral negotiations is counter to the Commission's core obligation under sections 205, 206, and 217(b)(4) [25] of the FPA, compromises the open access principles at the core of Order Nos. 888,[26] 890 [27] and 1000,[28] and will result in an unjust, unreasonable, and unduly discriminatory paradigm.[29] For example, TAPS argues that the Commission should not relax its merchant policies but should instead continue to require a substantial portion of the capacity to be made available to other customers, through an open season, on the same rates and terms as are applied to the anchor customer(s).[30]

13. APPA and NRECA assert that our existing policies already provide substantial flexibility and have not prevented the development of merchant transmission projects.[31] They argue that the incentives inherent in the Commission's proposed policy statement are poorly aligned with the Commission's goals. TAPS similarly refutes the claim that developers have an inherent incentive to widely solicit interest in merchant transmission projects, arguing that once a developer takes on an anchor customer, its opportunity and incentives align with that customer.[32]

14. Further, NJ Rate Counsel argues that the proposed policy statement may have the unintended consequence of reducing competition in the long run and thus ultimately increasing the delivered cost of electricity.[33] NJ Rate Counsel and TAPS both argue that the Commission has long recognized that

[16] American Antitrust Institute (AAI); American Electric Power Services Corporation (AEP); American Public Power Association (APPA); American Wind Energy Association (AWEA); Clean Line Energy Partners, LLC (Clean Line); Duke Energy Corporation (Duke); Edison Electric Institute (EEI); LSP Transmission Holdings, LLC (LSP Transmission); National Grid USA; National Rural Electric Cooperative Association (NRECA); New Jersey Division of Rate Counsel (NJ Rate Counsel); New York Transmission Owners (NYTO); Northeast Utilities Service Company (Northeast Utilities); Pattern Transmission, LP; Transmission Access Policy Study Group (TAPS); Transmission Developers, Inc. (TDI); TransWest Express, LLC; and Western Independent Transmission Group (WITG).

[17] AEP; AWEA; Clean Line; Duke; EEI; LSP Transmission; NYTO; National Grid USA; Northeast Utilities; Pattern Transmission, LP; TDI; TransWest Express, LLC; and WITG.

[18] WITG at 3.

[19] WITG at 4.

[20] AWEA at 3; NYTO at 2.

[21] EEI at 5.

[22] Duke at 3.

[23] AWEA at 6.

[24] AWEA at 6.

[25] APPA and NRECA argue the Commission has ignored its statutory obligation under FPA section 217(b)(4) that directs the Commission to facilitate the planning and expansion of transmission facilities to meet the reasonable needs of load-serving entities to satisfy their service obligations. APPA at 12; NRECA at 11–12.

[26] *Promoting Wholesale Competition Through Open Access Non-Discriminatory Transmission Services by Public Utilities; Recovery of Stranded Costs by Public Utilities and Transmitting Utilities,* Order No. 888, FERC Stats. & Regs. ¶ 31,036 (1996), *order on reh'g,* Order No. 888–A, FERC Stats. & Regs. ¶ 31,048, *order on reh'g,* Order No. 888–B, 81 FERC ¶ 61,248 (1997), *order on reh'g,* Order No. 888–C, 82 FERC ¶ 61,046 (1998), *aff'd in relevant part sub nom. Transmission Access Policy Study Group v. FERC,* 225 F.3d 667 (DC Cir. 2000), *aff'd sub nom. New York v. FERC,* 535 U.S. 1 (2002).

[27] *Preventing Undue Discrimination and Preference in Transmission Service,* Order No. 890, FERC Stats. & Regs. ¶ 31,241, *order on reh'g,* Order No. 890–A, FERC Stats. & Regs. ¶ 31,261 (2007), *order on reh'g,* Order No. 890–B, 123 FERC ¶ 61,299 (2008), *order on reh'g,* Order No. 890–C, 126 FERC ¶ 61,228 (2009), *order on clarification,* Order No. 890–D, 129 FERC ¶ 61,126 (2009).

[28] *Transmission Planning and Cost Allocation by Transmission Owning and Operating Public Utilities,* Order No. 1000, FERC Stats. & Regs. ¶ 31,323 (2011), *order on reh'g,* Order No. 1000–A, 139 FERC ¶ 61,132, *order on reh'g,* Order No. 1000–B, 141 FERC ¶ 61,044 (2012).

[29] APPA at 3; NJ Rate Counsel at 4–9; NRECA at 4–9, 12; and TAPS at 10. TAPS argues that the Commission's proposed policy statement will (1) result in undersized, single-purpose merchant transmission facilities with restricted access, (2) undermine regional transmission planning processes, (3) balkanize the grid and impair competitive wholesale markets, and (4) hamstring access to competitive generation and transmission development. TAPS at 1–5.

[30] TAPS at 10.

[31] APPA at 4; NRECA at 5.

[32] TAPS at 6–7, 9.

[33] NJ Rate Counsel at 4.

transmission is a natural monopoly and that ''the most likely route to market power in today's electric utility industry lies through ownership or control of transmission facilities.'' [34] TAPS and NRECA underscore concerns over transmission siting fatigue [35] and right-of-way limitations, arguing that a small wind developer excluded from a merchant project is unlikely to be able to reach the market.[36]

III. Final Policy Statement

A. Need for Refined Policies Regarding Allocation of Capacity on Transmission Projects

15. The fundamental concern underlying the second and third factor of the Commission's four-factor analysis for negotiated rate authority is that new transmission capacity should be allocated in a not unduly discriminatory or preferential manner. Based on the Commission's experience with new merchant transmission projects and on the comments received in this proceeding, the Commission believes that it can provide more flexibility in the capacity allocation process for customers and transmission developers, while still ensuring that the resulting allocation of new transmission capacity is not unduly discriminatory or preferential. By adopting the policies herein, the Commission seeks to encourage merchant transmission developers intending to seek negotiated rate authority to utilize the guidelines discussed herein. To the extent the Commission determines that a merchant transmission developer complies with such policies, the Commission will find that the developer has satisfied the second (undue discrimination) and third (undue preference) factors of the four-factor analysis.[37]

16. The Commission therefore refines its capacity allocation policies to allow the developer of a new merchant transmission project to select a subset of customers, based on not unduly discriminatory or preferential criteria, and negotiate directly with those customers to reach agreement on the key rates, terms, and conditions for procuring up to the full amount of transmission capacity, when the developer (1) broadly solicits interest in the project from potential customers and (2) demonstrates to the Commission that the developer has satisfied the solicitation, selection and negotiation process criteria set forth herein. This capacity allocation process also will apply to the developer of a new nonincumbent, cost-based, participant-funded project.

17. With regard to concerns raised by commenters that the policies described in the proposed policy statement may compromise open access, balkanize the grid, or otherwise impair competition, these comments were taken into account in our development of the capacity allocation policies set forth herein. We believe that the allocation process outlined herein will provide the same protections as a formal open season process, i.e., that a broad notice at the early stages of project development and rigorous demonstration after the selection of transmission customers will mirror our earlier requirements. Therefore, the Commission disagrees that the refinements to our capacity allocation policies reflected herein are a departure from the Commission's fundamental policies governing open access and encouraging competition. Retaining and refining the process by which capacity is allocated on such projects will increase, rather than impair, opportunities for customers in need of new transmission service.

18. Specifically, under this final policy statement the Commission will allow merchant transmission developers to allocate up to 100 percent of their projects' capacity through bilateral negotiations. The Commission will also allow capacity allocation to affiliates, when done in a transparent manner with the transparency protections adopted in this final policy statement, so that other interested parties can voice concern if they believe the affiliate was treated preferentially at the expense of another party.

19. The flexibility we afford under the policy outlined below is complemented by the emphasis on additional detail the Commission will expect from transmission project developers concerning the process they utilize to allocate project capacity. The Commission agrees with commenters that each merchant transmission project has unique project-specific characteristics that warrant providing such developers flexibility in negotiating risk-sharing and other details. The Commission likewise acknowledges that merchant transmission developers have inherent incentives to solicit interest widely in a potential project. However, the Commission also appreciates commenter concerns that counter-incentives may exist that could motivate a developer to unduly prefer one or more customers. To protect against undue discrimination and undue preference, the Commission will expect merchant transmission developers to engage in an open solicitation to identify potential transmission customers, and to demonstrate to the Commission that the processes leading to the identification of customers and execution of relevant capacity arrangements are consistent with our policies herein and our open access principles. The Commission believes that this approach, when coupled with the existing section 206 protections against undue discrimination and undue preference, serves the interest of customers and developers alike.[38]

20. We recognize that a developer's incentives may change once it has contracted with a customer for a substantial portion of the transmission developer's capacity. Indeed, several participants at the February 2012 workshop noted that part of the reason developers need to be able to negotiate more freely with potential customers is that there are a number of details to coordinate between the generation and transmission projects, recognizing that once a transmission developer has secured customers, its business success depends on its customers' success. In this way, the relationship between transmission developer and transmission customer will inherently resemble that of a joint venture. We believe the policies described herein ensure that there is an open, transparent, and fair process to become a transmission customer, and in particular we believe that the Commission's review of the post-selection demonstration will help discipline the process. We further believe the flexibility allowed through bilateral negotiations is appropriate in light of the risk-sharing inherent in the relationship between the transmission developer and its customers.

21. The Commission similarly appreciates concerns with respect to transmission siting fatigue and right-of-way limitations. Under the policies

[34] TAPS at 6 (citing *Promoting Wholesale Competition Through Open Access Non-Discriminatory Transmission Services by Public Utilities; Recovery of Stranded Costs by Public Utilities and Transmitting Utilities,* Order No. 888, FERC Stats. & Regs. ¶ 31,036 at 31,643). NJ Rate Counsel additionally posits that, in private negotiations, an anchor tenant that expects to gain market power by excluding other generators from access to the new transmission project could seek an allocation of 100 percent of project capacity in return for an offer to split the anticompetitive gains with the merchant developer. NJ Rate Counsel at 7.

[35] Transmission siting fatigue is the idea that, after a transmission line is sited and permitted in an area, it will be significantly more difficult to get an additional transmission line sited and permitted in that same area.

[36] TAPS at 6; NRECA at 10–11.

[37] The remaining two Chinook factors, the justness and reasonableness of rates and regional reliability and operational efficiency requirements, remain elements of the Commission's analysis of merchant applications for negotiated rate authority.

[38] *See Chinook,* 126 FERC ¶ 61,134 at P 41.

adopted herein, the Commission will evaluate a developer's reasoning for the sizing of new transmission facilities to ensure that the sizing of such facilities was based on objective criteria, rather than the result of undue preference or undue discrimination. In doing so, the Commission will be cognizant of the potential for undersized transmission facilities that show an undue preference for one customer over another, involve undue discrimination against a potential customer, and/or that, as a result of the anticompetitive nature of the sizing, result in rates for transmission service that are not just and reasonable. If the Commission finds that a transmission project is undersized as the result of undue preference, undue discrimination or other anticompetitive behavior, the Commission has the authority to reject the proposed allocation of capacity on such project. Moreover, entities that believe that such biases resulted in a discriminatory allocation of capacity will have the opportunity to protest the transmission developer's post-selection demonstration.[39] The Commission can, and has demonstrated that it will, reject unacceptable proposals for transmission capacity allocation when appropriate.[40]

22. We reaffirm here that all merchant transmission developers and nonincumbent cost-based, participant-funded transmission projects become public utilities at the time their projects are energized (and, depending on the circumstances, may become public utilities even earlier). Public utility transmission providers are subject to the Commission's OATT requirements, including the obligation to expand their transmission systems, if necessary, to provide transmission service.[41] This should help to allay concerns about the potential for undue discrimination and preference with respect to the sizing of these types of projects.

B. Merchant Projects

1. Open Solicitation Process

23. Based on the Commission's experience with prior cases and information received from the technical conference, the workshop, and in responses to the proposed policy statement, the Commission believes that bilateral negotiations, if conducted in a transparent manner, may serve the same purpose as an open season process to ensure against undue discrimination or preference in the provision of transmission service. Hence, under this final policy statement, merchant transmission developers seeking negotiated rate authority may instead engage in an open solicitation of interest in their projects from potential transmission customers in lieu of the previous requirement of a formal open season. Such open solicitation should include a broad notice issued in a manner that ensures that all potential and interested customers are informed of the proposed project. For example, such notice may be placed in trade magazines or regional energy publications, may include communications with regional transmission planning groups such as through the Order No. 1000 regional planning process,[42] and may use email distribution lists addressing transmission-related matters. In response to commenters that asked that we clarify what constitutes broad notice,[43] we note that these examples of broad notice are not intended to be exhaustive or prescriptive. A developer should make reasonable efforts to ensure that all potential transmission customers would be made aware of the intention to develop the project.

24. Such notice should include transmission developer points of contact and pertinent project dates, as well as sufficient technical specifications and contract information to inform interested customers of the nature of the project, including:

- Project size/capacity: MW and/or kV rating (specific value or range of values)
- End points of line (as specific as possible such as points of interconnection to existing lines and substations, although it may be potentially broad, such as Montana to Nevada, if the project is very early in development)
- Projected construction and/or in-service dates
- Type of line—for example, AC, DC, bi-directional
- Precedent agreement (if developed)
- Other capacity allocation arrangements (including how it will address potential oversubscription of capacity)

25. The developer should also specify in the notice the criteria it plans to use to select transmission customers, such as credit rating; ''first mover'' status (i.e., customers who respond early and take on greater project risk); and customers' willingness to incorporate project risk-sharing into their contracts. This will contribute to the transparency of the process and will help interested entities know at the outset the features of the project and how the merchant transmission developer will consider bids. This list of criteria is not prescriptive or exhaustive.

26. Developers may also adopt a specific set of objective criteria that they will use to rank prospective customers, provided they can justify why such criteria are appropriate. Clean Line suggests the Commission should consider incorporating additional criteria as part of the capacity allocation process, including: Willingness to pay, length of term for transmission service, acceptance of proposed business terms, and the state of advancement in generation project development.[44] The Commission believes that, while the additional criteria suggested by Clean Line appear reasonable on their face, we would need additional information to ensure the criteria proposed are indeed uniformly appropriate and are not discriminatory. Thus, we decline to incorporate at this time the additional criteria proposed by Clean Line, though we could consider these types of criteria in a specific case before the Commission.

27. Finally, the Commission expects the merchant transmission developer to update its posting if there are any material changes to the nature of the project or the status of the capacity allocation process, in particular to ensure that interested entities are informed of remaining available capacity. As proposed by WITG,[45] time-stamped updates on a developer's Web site is one reasonable approach for alerting interested parties to periodic changes in project information, provided that the developer's initial broad notice had alerted entities to the developer's Web site, and to the possibility that changes might occur and would be posted there.

28. Under the final policy statement, once a subset of customers has been identified by the developer through the open solicitation process, the Commission will allow developers to engage in bilateral negotiations with each potential customer on the specific rates, terms, and conditions for

[39] Such entities remain entitled to exercise their statutory right to challenge such capacity allocations under section 206 of the FPA.

[40] *See, e.g., Mountain States Transmission Intertie, LLC and NorthWestern Corp.,* 127 FERC ¶ 61,270 (2009).

[41] *See Pro Forma* Open Access Transmission Tariff § 15.4(a). *See also Tres Amigas LLC,* 130 FERC ¶ 61,207, at PP 18, 76, 80 (2010); *SunZia Transmission LLC,* 131 FERC ¶ 61,162, at P 43 (2010); *SunZia Transmission LLC,* 135 FERC ¶ 61,169, at PP 10–11, 22 (2011); *Montana Alberta Tie, Ltd.,* 119 FERC ¶ 61,216, at P 7 (2007).

[42] We note that NJ Rate Counsel suggested that a group's participation in the Order No. 1000 process could bear on the open solicitation requirements. NJ Rate Counsel at 12–13.

[43] *See, e.g.,* Pattern Transmission, LP at 10; WITG at 4.

[44] Clean Line at 6.

[45] WITG at 2, 5.

procuring transmission capacity, as the Commission recognizes that developers and potential customers may need to negotiate individualized terms that meet their unique project-specific needs.[46] In these negotiations, the Commission will allow for distinctions among prospective customers based on transparent and not unduly discriminatory or preferential criteria—so long as the differences in negotiated terms recognize material differences and do not result in undue discrimination or preference—with the potential result that a single customer, including an affiliate, may be awarded up to 100 percent of capacity. For instance, developers might offer ''first mover'' customers more favorable rates, terms, and conditions than later customers. This represents a change from prior policy, under which the Commission required that a developer offer their ''anchor customer deal'' in the open season to any other customer willing to make the same commitment as the anchor customer, such that all customers had access to the same rates, terms, and conditions.[47] For reasons discussed above, including the need to negotiate individualized terms and incent early movers, we conclude that this policy change is appropriate.

2. Post-Selection Demonstration

29. In the past, the Commission required that developers file a report, shortly after the close of the open season, on the results of the open season and any anchor customer presubscription, including information on the notice of the open season, the method used for evaluating bids, the identity of the parties that purchased capacity, and the amount, term, and price of that capacity.[48] The Commission required this report to provide transparency to the allocation of initial transmission rights, and to enable unsuccessful bidders to determine if they were treated in an unduly discriminatory manner so that they may file a complaint if they believe they were.[49] These reports were not noticed, and did not receive Commission action.

30. The Commission will continue to require merchant transmission developers to disclose the results of their capacity allocation process, though this disclosure will be part of the Commission's approval of such capacity allocation process, and thus noticed and acted upon under section 205 of the FPA. Specifically, to provide transparency, and to prevent against undue discrimination and undue preference by merchant transmission developers, this final policy statement expects developers to demonstrate that the processes that led to the identification of transmission customers and the execution of the relevant contractual arrangements are consistent with the policies described herein, and consistent with our open access principles. The merchant transmission developer should describe the criteria used to select customers, any price terms, and any risk-sharing terms and conditions that served as the basis for identifying transmission customers selected versus those that were not. To this end, and in response to comments suggesting additional transparency measures,[50] the Commission will expect that the developer include, at a minimum, the following information in the demonstration to provide sufficient transparency to the Commission and interested parties:

(1) Steps the developer took to provide broad notice, including the project information and customer evaluation criteria that were relayed in the broad notice;

(2) Identity of the parties that expressed interest in the project, placed bids for project capacity, and/or purchased capacity; and the capacity amounts, terms, and prices involved in that interest, bid, or purchase;

(3) Basis for the developer's decision to prorate, or not to prorate, capacity, if a proposed project is oversubscribed;

(4) Basis for the developer's decision not to increase capacity for a proposed project if it is oversubscribed (including the details of the economic, technical, or financial infeasibility that is the basis for declining to increase capacity);

(5) Justification for offering more favorable rates, terms, and conditions to certain customers, such as ''first movers'' or those willing to take on greater project risk-sharing;

(6) Criteria used for distinguishing customers and the method used for evaluating bids. This should include the details of how each potential transmission customer (including both those who were and those who were not allocated capacity) was evaluated and compared to other potential transmission customers, both at the early stage when the developer chooses with whom to enter into bilateral negotiations and subsequently when the developer chooses in the negotiation phase to whom to award transmission capacity;

(7) Explanation of decisions used to select and reject specific customers. In particular, the report should identify the facts, including any rates, terms or conditions of agreements unique to individual customers that led to their selection, and relevant information about others that led to their rejection. If a selected customer is an affiliate, the Commission will look more carefully at the basis for reaching that determination.

31. In response to requests that the Commission clarify when a transmission developer needs to request approval of its capacity allocation process,[51] we will allow a developer discretion in timing its request that the Commission approve a capacity allocation process. For example, developers can seek approval of their capacity allocation approach after having completed the process of selecting customers in accordance with our policies. Alternatively, a developer can first seek approval of its capacity allocation approach, and then demonstrate in a compliance filing to the Commission order approving that approach that the developer's selection of customers was consistent with the approved selection process. Under either procedural framework, the Commission will notice the demonstration, allow protests, and reach a determination regarding whether the developer's selection of customers was consistent with our policies herein and our open access principles.[52] However, we agree with some commenters that protests filed in response to the post-selection demonstration should be focused on the

[46] While negotiations for the allocation of initial transmission rights may address terms and conditions of the transmission service to be ultimately taken once the facilities are in service, the Commission will adhere to its policy, regardless of any negotiated agreement, that any deviations from the Commission's *pro forma* OATT must be justified as consistent with or superior to the *pro forma* OATT when the transmission developer files its OATT with the Commission. The Commission will evaluate any deviations on that basis when they are submitted. *See Chinook,* 126 FERC ¶ 61,134 at PP 47, 63.

[47] *See Chinook,* 126 FERC ¶ 61,134 at P 61.

[48] *Chinook,* 126 FERC ¶ 61,134 at PP 41, 43.

[49] *See Chinook,* 126 FERC ¶ 61,134 at P 41; *Montana Alberta Tie, Ltd.,* 116 FERC ¶ 61,071, at P 37 (2006).

[50] AAI at 6–7; TAPS at 13–14.

[51] *See, e.g.,* Pattern Transmission, LP at 13.

[52] Under this policy statement, the Commission's policies for reviewing capacity allocation processes will apply equally to both new merchant transmission developers and new nonincumbent cost-based participant-funded transmission developers. With respect to new merchant transmission developers, the Commission's consideration of this capacity allocation process will be a part of the Commission's evaluation of the applicant's request for negotiated rate authority.

matters at issue in the Commission's review.[53]

32. We emphasize that the information in the post-selection demonstration is an essential part of a merchant developer's request for approval of a capacity allocation process, and that the developer will have the burden to demonstrate that its process was in fact not unduly discriminatory or preferential, and resulted in rates, terms, and conditions that are just and reasonable. Thus, interested parties will have the opportunity to submit protests on the demonstration to ensure there is sufficient transparency. The Commission expects that interested parties who believe that the process used to select customers and allocate capacity on merchant transmission projects was unjust or preferential would file comments or protests on the demonstration. Interested parties also remain entitled to exercise their statutory right to challenge the process under section 206 of the FPA.

33. In response to commenters that request that we recognize the commercially sensitive nature of the business arrangements associated with capacity allocation, we clarify that we will address whether to allow for protection of such information on a case-by-case basis.[54] We believe transparency is essential to our allowing capacity to be allocated through bilateral negotiations rather than a more formally structured open season process. Thus, we do not agree that certain types of commercial information should be generically protected. To the extent developers believe they cannot file certain information publicly, they may make their case for confidential treatment to the Commission when they file their post-selection demonstrations.

34. With respect to potential affiliate participation in the capacity allocation process, the Commission will continue to expect an affirmative showing that the affiliate is not afforded an undue preference.[55] The developer will bear a high burden to demonstrate that the assignment of capacity to its affiliate and the corresponding treatment of non-affiliated potential customers is just, reasonable, and not unduly preferential or discriminatory. While the Commission will not require non-affiliates to receive the same rates, terms and conditions as affiliates as suggested by some commenters,[56] the Commission will carefully scrutinize any differences in rates, terms and conditions for affiliates versus non-affiliates to ensure those differences are appropriately based on objective criteria.

35. Commenters are concerned that the reporting obligations described in the proposed policy statement provide inadequate protections for potential transmission customers. NRECA argues that discrimination can take place not only in the solicitation of a project, but also in the design of a project, and that the proposed reporting requirement would not remedy this flaw.[57] APPA asserts that this ''after-the-fact'' reporting requirement is of particular concern, because the Commission will be under substantial pressure to rubberstamp an after-the-fact filing because the applicants will have already completed their contract negotiations and selected successful customers.[58] APPA cautions that, if the Commission adopts this proposed policy despite commenters' concerns, it is critical that the associated reporting requirements not be eroded over time.[59]

36. The Commission believes that the reporting obligations set forth in this final policy statement offer sufficient protections to ensure that a capacity allocation process protects against undue preference or discrimination. In response to commenters that questioned if any consequences attach to the report or if it is just informational,[60] we reiterate that we will notice the demonstration and consider any protests submitted in reaching our determination on such demonstration.

37. Certain commenters argue that the section 206 complaint process is an insufficient deterrent to undue preference or discrimination in the capacity allocation process, and that few section 206 complaints are likely to be filed particularly due to inadequate resources or time to mount effective section 206 challenges.[61] In particular, NJ Rate Counsel is concerned that the filing of section 206 challenges will depend on the willingness of participants to assume a heavy burden without attendant discovery rights, and on the need for an expedited process with no assurance that the process will move quickly.[62] Similarly, NRECA argues that complainants are unlikely to have access to some or all of the required information, and NRECA notes that the Commission has at times dismissed complaints alleging wrong-doing for lack of specificity.[63] The NJ Rate Counsel asserts that reliance on the section 206 complaint process shifts the Commission's independent regulatory responsibility to third-party complainants, and argues that the Commission must exercise its independent responsibility to ensure that rates remain just and reasonable and not unduly discriminatory.[64]

38. In response to these comments, we clarify that, under the processes adopted in this final policy statement, entities will be able to protest a developer's proposed capacity allocation process (which we expect to be described in detail as part of the developer's post-selection demonstration pursuant to section 205 of the FPA). Under this final policy statement, the Commission will evaluate the capacity allocation process to ensure that the process was not unduly discriminatory or preferential, and resulted in rates, terms, and conditions that are just and reasonable. Entities also remain entitled to challenge such capacity allocation processes by filing a complaint under section 206 of the FPA.

C. Nonincumbent, Cost-Based, Participant-Funded Projects

39. The Commission will apply the policy clarifications and refinements in this final policy statement not only to new merchant transmission projects, but also to nonincumbent, cost-based, participant-funded transmission projects. The Commission has similar concerns regarding the capacity allocation process regardless of whether the project is a new merchant transmission project, or a nonincumbent, cost-based, participant-funded transmission project. That is, the Commission is concerned that access not be unduly discriminatory or preferential. We believe that the process outlined herein will address such concerns, however. Commenters and workshop participants, moreover, support the Commission's application of these policy clarifications and refinements to both new merchant transmission developers and

[53] *See* Pattern Transmission, LP at 14; WITG at 6.

[54] *See* AEP at 4; AAI at 10–11; Duke at 4; EEI at 5; Pattern Transmission, LP at 13; and WITG at 6.

[55] *See Chinook,* 126 FERC ¶ 61,134 at PP 49–50.

[56] *See, e.g.,* TAPS at 26.

[57] NRECA at 14.

[58] APPA at 9.

[59] APPA at 7.

[60] *See, e.g.,* TAPS at 17–20.

[61] APPA at 8; AAI at 6; NJ Rate Counsel at 3; NRECA at 14–15. NRECA adds that the proposed Policy Statement is inconsistent with the Commission's statement in Order No. 1000–A that, ''individual complaints under section 206 of the FPA would not suffice to overcome the free rider problem because litigating complaints burdens and unduly delays the transmission planning process'' (or in this case, unduly delay open access to transmission service). NRECA at 15 (citing *Transmission Planning and Cost Allocation by Transmission Owning and Operating Public Utilities* Order No. 1000–A, 139 FERC ¶ 61,132, at P 577 (2012)).

[62] NJ Rate Counsel at 3.

[63] NRECA at 14–15.

[64] NJ Rate Counsel at 10.

nonincumbent, cost-based, participant-funded transmission developers.[65] Petitions regarding capacity allocation on nonincumbent, cost-based, participant-funded transmission projects will be evaluated by the Commission in accordance with the Commission's responsibilities under the FPA.

40. However, use of this common process does not eliminate the distinction between these types of projects. In particular, although the negotiations between developers and potential customers could address a transmission rate, among other issues, the Commission's approach to reviewing such a rate would be different for a new merchant transmission project than for a new nonincumbent, cost-based, participant-funded transmission project. For a nonincumbent, cost-based, participant-funded transmission project, the Commission will review the transmission rate, terms and conditions, including any agreed upon return on equity, more closely to ensure that they satisfy Commission precedent regarding cost-based transmission service.

D. Incumbent, Cost-Based, Participant-Funded Projects

41. The Commission is not changing its case-by-case evaluation of requests for cost-based participant-funded transmission projects by incumbent transmission providers.[66] This final policy statement thus does not affect incumbent transmission development for the purpose of serving native load. Incumbents differ from nonincumbents in that the former have a clearly defined set of existing obligations under their OATTs with regard to new transmission development, including participation in regional planning processes and the processing of transmission service request queues. Nonincumbent transmission developers do not yet own or operate transmission facilities in the region that they propose to develop transmission; thus, they are not yet subject to an OATT in that region.[67] Thus, the Commission's final policy statement establishes the Commission's process for evaluating, going forward, the allocation of capacity only for merchant transmission developers and nonincumbent, cost-based, participant-funded projects for new transmission facilities.

42. In contrast, in most instances, we would expect that an incumbent transmission provider will be able to use existing processes set forth in its OATT to allocate capacity on a new transmission facility. These existing OATT processes do not prohibit incumbent transmission owners from identifying projects that could be constructed on a participant-funded basis in conjunction with processing of transmission service requests or in addition to meeting transmission needs through participation in a regional transmission planning process.[68] Furthermore, the Commission will continue to entertain on a case-by-case basis requests for waiver of any OATT requirements that may be needed for the incumbent transmission owner to pursue innovative transmission development that is just, reasonable, and not unduly discriminatory. For example, an incumbent may seek waiver of serial queue processing requirements so that it may cluster transmission service requests,[69] or it may seek to ''ring fence'' a transmission project in order to ensure that new transmission facilities developed for a particular customer or set of customers do not adversely affect existing customers, including native load.[70] Incumbent developers should address capacity allocation issues in a manner that does not constitute undue discrimination or preference and is consistent with applicable Commission-accepted tariffs.[71]

E. Miscellaneous

43. WITG requests that the Commission allow developers that have already been granted negotiated rate authority the ability to allocate any unsubscribed capacity according to the processes in this policy statement. We clarify here that such developers, if they want to utilize the capacity allocation process described in this final policy statement for any unsubscribed capacity, must seek Commission approval to deviate from their current capacity allocation process authority set forth in the Commission order granting them negotiated rate authority. This will ensure that all interested parties are fully aware of and have an opportunity to comment on the proposed capacity allocation.

44. Several commenters raise concerns regarding the role of the merchant transmission developer in the Order No. 1000 regional planning processes. The policies set forth herein are intended only to be a roadmap for the capacity allocation process for new merchant and nonincumbent, cost-based, participant-funded transmission facilities. Thus, we believe that comments addressing the Order No. 1000 regional planning processes are outside the scope of this final policy statement. However, we note that Order No. 1000 requires a merchant transmission developer to provide adequate information and data to allow public utility transmission providers in the transmission planning region to assess the potential reliability and operational impacts of the merchant transmission developer's proposed transmission facilities on other systems in the region.[72]

45. Clean Line requests that the Commission ensure that all RTOs/ISOs and transmission providers create interconnection queue processes that do not hinder high voltage direct current (HVDC) transmission development, and suggests that a standard interconnection procedure specifically for HVDC lines would solve this issue.[73] The Commission believes that the matter of HVDC-specific interconnection procedures is similarly outside the scope of this final policy statement.

IV. Document Availability

46. In addition to publishing the full text of this document in the **Federal Register**, the Commission provides all interested persons an opportunity to view and/or print the contents of this document via the Internet through the Commission's Home Page (*http://www.ferc.gov*) and in the Commission's

[65] TAPS March 29, 2012 Comments at 24; Pathfinder Renewable Wind Energy, LLC March 28, 2012 Comments at 3–4.

[66] *See, e.g., NU/NSTAR,* 127 FERC ¶ 61,179 (2009), *order denying reh'g and clarification,* 129 FERC ¶ 61,279 (2009); *National Grid,* 139 FERC ¶ 61,129 (2012).

[67] We clarify, in response to Clean Line, that, for purposes of this final policy statement, a nonincumbent transmission developer will not become an incumbent within a transmission planning region until such time as it energizes a transmission facility within that region. See Order No. 1000–A, 139 FERC ¶ 61,132 at P 421.

[68] *See, e.g.,* Subscription Process for Proposed PacifiCorp Transmission Expansion Projects, *available* at *http://www.oasis.pacificorp.com/oasis/ppw/SUBSCRIPTION_PROCESS.PDF* (noting incumbent's solicitation of interest from third parties in the development of a cost-based transmission project in advance of receipt of transmission service requests from third parties under the incumbent's OATT).

[69] *See, e.g., Portland General Electric Co.,* 139 FERC ¶ 61,133 (2012) (granting waiver of serial queue processing requirements, allowing a general facilities study for a cluster of transmission and interconnection service requests).

[70] *See, e.g., Mountain States Transmission Intertie, LLC and NorthWestern Corp.,* 127 FERC ¶ 61,270, at PP 2, 5 (2009) (incumbent developing an export-only transmission project through a separate stand-alone company so that their existing transmission customers will not be required to subsidize the cost of a new transmission facility to serve off-system markets; the Commission presented the option of this project proceeding on a cost-of-service basis).

[71] *See National Grid,* 139 FERC ¶ 61,129 at P 33.

[72] *See* Order No. 1000, FERC Stats. & Regs. ¶ 31,323 at PP 163–164; Order No. 1000–A, 139 FERC ¶ 61,132 at P 297.

[73] Clean Line at 8.

Public Reference Room during normal business hours (8:30 a.m. to 5:00 p.m. Eastern time) at 888 First Street NE., Room 2A, Washington, DC 20426.

47. From Commission's Home Page on the Internet, this information is available on eLibrary. The full text of this document is available on eLibrary in PDF and Microsoft Word format for viewing, printing, and/or downloading. To access this document in eLibrary, type the docket number excluding the last three digits of this document in the docket number field.

48. User assistance is available for eLibrary and the Commission's Web site during normal business hours from FERC Online Support at (202) 502–6652 (toll free at 1–866–208–3676) or email at *ferconlinesupport@ferc.gov,* or the Public Reference Room at (202) 502–8371, TTY (202) 502–8659. Email the Public Reference Room at *public.referenceroom@ferc.gov.*

By the Commission.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2013–01507 Filed 1–24–13; 8:45 am]

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DEPARTMENT OF THE INTERIOR

National Indian Gaming Commission

25 CFR Parts 556 and 558

RIN 3141–AA15

Tribal Background Investigations and Licensing

AGENCY: National Indian Gaming Commission, Interior.

ACTION: Final rule.

SUMMARY: The National Indian Gaming Commission (NIGC or Commission) is amending certain NIGC regulations concerning background investigations and licenses to streamline the submission of documents to the Commission; to ensure that two notifications are submitted to the Commission in compliance with the Indian Gaming Regulatory Act (IGRA); and to clarify the regulations regarding the issuance of temporary and permanent gaming licenses.

DATES: *Effective Date:* February 25, 2013.

FOR FURTHER INFORMATION CONTACT: John Hay, National Indian Gaming Commission, 1441 L Street NW., Suite 9100, Washington, DC 20005. Telephone: 202–632–7009.

SUPPLEMENTARY INFORMATION:

I. Background

The Indian Gaming Regulatory Act (IGRA or Act), Public Law 100–497, 25 U.S.C. 2701 *et seq.,* was signed into law on October 17, 1988. The Act establishes the NIGC and sets out a comprehensive framework for the regulation of gaming on Indian lands. On November 18, 2010, the Commission issued a Notice of Inquiry and Notice of Consultation (NOI) advising the public that the NIGC was conducting a comprehensive review of its regulations and requesting public comment on which of its regulations were most in need of revision, in what order the Commission should review its regulations, and the process NIGC should utilize to make revisions. 75 FR 70680 (Nov. 18, 2010). On April 4, 2011, after holding eight consultations and reviewing all comments, NIGC published a Notice of Regulatory Review Schedule (NRR) setting out a consultation schedule and process for review. 76 FR 18457. The Commission's regulatory review process established a tribal consultation schedule with a description of the regulation groups to be covered at each consultation. These parts 556 and 558 were included in this regulatory review.

II. Previous Rulemaking Activity

The Commission consulted with tribes as part of its review of parts 556 and 558. Tribal consultations were held in every region of the country and were attended by numerous tribes, tribal leaders or their representatives. After considering the comments received from the public and through tribal consultations, the Commission published a Notice of Proposed Rulemaking regarding background and investigation licensing procedures on December 22, 2011.

III. Review of Public Comments

In response to our Notice of Proposed Rulemaking, published December 22, 2011, 76 FR 79567, we received the following comments.

General Comments

Comment: Many commenters supported the formalization of the ''pilot program'' because it reduces the quantity of documents a tribe must submit to the NIGC, formalizes a streamlined process, and is a cost effective measure.

Response: The Commission agrees and has decided to amend parts 556 and 558 to implement the pilot program.

Comment: Many commenters generally support the changes to part 558.

Response: The Commission has decided to go forward with many of the amendments set forth in the proposed rule.

Comment: One commenter supported the agency's efforts to improve tribal access to background investigation materials but was puzzled by the suggestion that the Commission presently lacks ''sufficient resources and technology'' to make this information available in a secure format. The commenter believes that the necessary technology is available and the Commission resources would be minimal. Further, the commenter urges the Commission to develop a plan and a timeline for implementing such a system.

Response: The Commission will continue to review this issue closely to determine whether it is feasible to make background investigation information available in a secure format.

Comment: One commenter stated that there is potential for confusion and/or possible non-compliance when attempting to reconcile the requirements in 556.1, 556.6(b)(2), 558.1, and 558.3(b), because the perimeters of temporary versus permanent licenses are unclear in these sections. The commenter suggested that a revision to the regulations may not be necessary; however, additional guidance may be beneficial for applying the regulatory sections.

Response: The Commission reviewed this provision and believes it is sufficiently clear. The Commission will examine whether it is appropriate to issue additional guidance for those sections.

Comment: One commenter inquired whether a tribe would be out of compliance with 556.2(b)(2) and/or 558.3(b) if it allows for temporary employees to be used and/or issues temporary licenses for a period of 90 days or less and it hires such temporary employee or individual with a temporary license as a key employee or primary management official during that time period.

Response: Temporary licenses are used by tribes that choose to have individuals working in their gaming facilities while the individuals are undergoing the background investigation and licensing process. No key employee or primary management official can work at a gaming facility for longer than 90 days without a gaming license issued pursuant to parts 556 and 558. The tribe should implement the regulatory licensing process for a key employee or primary management official simultaneously with issuing a temporary license to ensure that a

permanent license is issued within 90 days of the individual beginning work.

556.4 Background Investigations

Comment: Two commenters supported the revision to 556.4(b) to clarify that a tribe may use investigative materials obtained from the NIGC that were submitted by another tribe. Specifically, one commenter noted that information regarding an applicant's prior gaming licenses and disciplinary actions in relation to previously held licenses can be of great benefit to tribal governments in determining the suitability of an applicant and, among other things, can help verify the information provided in a license application.

Response: The Commission agrees and has adopted the amendment in the proposed rule.

Comment: Several commenters contended that requesting that an applicant provide a list of ''associations to which they pay dues'' is overly broad and unnecessary, and the Commission should not add this to the regulation concerning background investigation applications. One commenter disagrees, because a requirement to list and disclose all such associations provides valuable information concerning an applicant's suitability.

Response: The Commission agrees with the majority of commenters that the addition of a requirement to provide a list of associations is unnecessary, because tribes may require any additional information they deem necessary through 556.4(a)(13). This broad provision should be sufficient for tribes to request a list of associations as well as any other information that they deem necessary for purposes of a background investigation.

Comment: One commenter requested that the NIGC consider deleting 556.4(c) mandating that tribal investigators ''shall keep confidential the identity of each person interviewed in the course of an investigation,'' because the rules of investigatory processes should be determined by each tribal jurisdiction. Further, the commenter is concerned that this provision may violate due process in certain tribal jurisdictions because an applicant would be denied the opportunity to confront an accuser.

Response: IGRA requires background investigations for primary management officials and key employees. Accordingly, such investigations are conducted pursuant to Federal and tribal law. Confidentiality is an existing requirement under the current regulations and pilot program. Section 556.4(c) requires tribal gaming commissions to keep individual identities confidential to promote candor in interviews to determine an applicant's eligibility for a license. Confidentiality facilitates an interviewee's willingness to provide information during the process. A lack of candor in interviews could needlessly prolong the background investigation process and impact both tribal and federal resources. The Commission feels that the need for candid information outweighs any due process concerns.

Comment: One commenter believed that the NIGC does not want to be notified every time a tribe does not license an individual because there are potentially thousands of applicants each year that a tribe does not license. The commenter explained that these applicants may have moved or found other employment before the background was completed or requested withdrawal for any number of reasons.

Response: The Commission appreciates the potential for a large number of key employee and primary management official applicants a tribe may receive. However, the NIGC often receives notice regarding an applicant long before a complete application is submitted. Once a person has been entered into the NIGC system for fingerprints, a record is automatically created. If the NIGC does not receive notification that licensing action was not taken as to such persons, it will not have accurate and up to date information. Accurate information regarding the results of individuals seeking employment as key employees or primary management officials enhances the NIGC's ability to provide current investigative information as to particular individuals. Consequently, notifying the Commission of the results of a license application serves to maintain the integrity of Indian gaming.

Comment: Two commenters recommended that the Commission eliminate the requirement that background investigations include personal references.

Response: Personal references help to implement IGRA's requirement that eligibility determinations include an evaluation of an individual's reputation, habits, and associations. See 25 U.S.C. 2710(b)(2)(F). Such an evaluation is furthered by interviews conducted beyond the context of documented business relationships.

Comment: One commenter supported a change to 556.4(b) that would allow tribes to rely on notice of results of an applicant already on file at NIGC and to simply update the investigation and investigation report, because this would save tribal resources.

Response: The Commission understands the need to conserve tribal resources and agrees with this comment. Section 556.4(b) provides for a tribe to rely on materials on file with NIGC or with a previous tribal investigative body and to update those materials.

556.5 Tribal Eligibility Determination

Comment: Two commenters stated that the NIGC should reconsider its decision against replacing the term ''eligibility'' with ''suitability'' in 556.5. The commenter proposed that the standard for issuing a gaming license is based on the suitability of the applicant and the standard for hiring is based on the eligibility of the applicant and that hiring and licensing are done by different tribal entities.

Response: The Commission disagrees in light of IGRA's language, which specifically requires that background investigation processes include an *eligibility* determination. *See* 25 U.S.C. 2710(b)(2)(F)(ii).

556.6 Report to the Commission

Comment: One commenter stated that the proposed regulation would require the tribe to send the notice of results before 60 days of employment and also requires a tribe to send a licensing decision notification prior to 90 days of employment. The commenter believes that the 60 day requirement should be eliminated, leaving only the 90 day requirement.

Response: IGRA requires two notifications: The first involves notifying the Commission of the results of the background check before the issuance of a license, and the second involves notifying the Commission of the issuance of the license. *See* 25 U.S.C. 2710(b)(2)(F)(ii)(I) and (III). The Commission requires tribes to submit the notice of results within 60 days of employment to provide the Commission an opportunity to object while the tribe is still considering issuing the license. IGRA dictates that the NIGC has 30 days to provide objections to a tribe regarding the issuance of a gaming license. *See* 25 U.S.C. 2710(c)(1). This 30 day time period, prior to the 90 day deadline for issuing a license, ensures that the NIGC's objections will be received prior to the issuance of a permanent license. *See* 25 U.S.C. 2710(c)(2).

Comment: One commenter recommended that the Commission adopt a single form to be used for the notice of results (NOR).

Response: After careful review of this issue, the Commission has determined not to adopt a single form to be used for the notice of results. This will allow tribes greater flexibility over how the

information is submitted to the Commission.

Comment: One commenter stated that submissions made pursuant to 558.3 for purposes of the Indian Gaming Individuals Record System (IGIRS) should be voluntary, not mandatory, because a mandatory requirement exceeds the Commission's authority. Another commenter believes that mandatory submissions are overly burdensome.

Response: The submissions to the IGIRS include the notice of results of the background check, the eligibility determination, and the notification of the licensing action. IGRA requires that tribes notify the Commission of background check results and subsequently notify the Commission of the issuance of a license. See 25 U.S.C. 2710(b)(2)(F)(ii)(I) and (III). Receipt of these submissions serves to maintain the integrity of Indian gaming and promotes the ability of tribal regulators to receive accurate information concerning key employees and primary management officials.

558.1 Scope of This Part

Comment: Many commenters stated that they were pleased that the Commission added language to 558.1 to clarify that the regulations ''do not apply to any license that is intended to expire within 90 days of issuance.''

Response: The Commission agrees and has decided to make this addition.

558.3 Notification to NIGC of License Issuance and Retention Obligations

Comment: Two commenters supported 558.3(c)(2), which requires a tribe that does not license an applicant to forward the eligibility determination and any investigative report ''to the Commission for inclusion in the Indian Gaming Individuals Records System.'' However, one commenter believes that this submission should be discretionary, because a mandatory requirement would exceed NIGC's authority. Another commenter believes that, although this is a useful resource, the regulation should be voluntary instead of mandatory.

Response: IGRA, 25 U.S.C. 2710(b)(2)(F)(ii)(I) and (III), requires tribes to submit results of background checks of key employees and primary management officials to the Commission, as well as to notify the Commission when licenses are issued to such employees. The Commission agrees with commenters' suggestion that submitting the full investigative report should be voluntary and, therefore, the submission is now limited to eligibility determinations, notice of background results, and licensing action notices.

Comment: One commenter suggested that the NIGC limit the notifications to NIGC in 558.3(c) to require notification to NIGC only if an applicant is unsuitable or has been denied a gaming license, by adding language to 558.3(c) that states, ''(c) if a tribe denies an applicant a license—'' or '' if a tribe finds an applicant unsuitable for licensing—,'' thereby eliminating the requirement that tribes notify the NIGC if an application is either incomplete or the investigative process is otherwise not completed. Other commenters stated that the requirement in 558.3(c) to notify NIGC if an applicant is not licensed is overly burdensome and fails to recognize benign reasons why a license is not issued.

Response: The Commission disagrees. The suggested limitation would limit the NIGC's ability to provide accurate information on an individual applicant. Often, an individual is identified in the NIGC system before an application is complete or before the eligibility determination is made because fingerprints are processed first. Without information on every applicant, NIGC is unable to provide accurate investigative information to gaming tribes. Thus, licensing information on each applicant is necessary to ensure that accurate information is disseminated.

Comment: A few commenters believed that determining the retention period for applications, investigation reports, and eligibility determinations should be a matter of tribal discretion and, therefore, 558.3(e) should be revised or removed.

Response: IGRA requires an adequate system to ensure that background investigations are conducted and that oversight of primary management officials and key employees is conducted on an ongoing basis. 25 U.S.C. 2710(b)(2)(F). A purpose of IGRA is to provide a statutory basis of gaming regulation by Indian tribes adequate to shield them from organized crime and other corrupting influences. The NIGC is tasked with creating regulations to implement IGRA. To implement IGRA's requirements consistent with that purpose of the legislation, the Commission believes that a three year minimum time period is appropriate. An alternative approach, as set forth in the current regulations, would be to provide the NIGC with all the necessary information, eliminating the three year time period. However, maintaining that approach would negate the positive aspects of the pilot program, including the reduction of the submission burden on tribes.

558.4 Notice of Information Impacting Eligibility and Licensee's Right to a Hearing

Comment: One commenter stated that the word ''immediately'' in 558.4(b) should be replaced with ''promptly'' to give the tribe more latitude, because the term ''promptly'' more closely conforms to the language contained in IGRA.

Response: The Commission disagrees. IGRA's requirement that a tribe ''shall suspend the license'' indicates that the tribe should act without delay. 25 U.S.C. 2710(c)(2). Therefore, IGRA provides no latitude in proceeding with the suspension of the license.

Comment: One commenter suggested the term ''employment'' in 558.4(a) be changed to ''licensure,'' because a gaming commission issues licenses and does not employ key employees or primary management officials.

Response: The Commission carefully considered this issue and disagrees with the comment because IGRA mandates that tribes have an adequate system for assessing the eligibility of primary management officials and key employees for ''employment.'' 25 U.S.C. 2710(b)(2)(F)(ii)(II).

Regulatory Matters

Regulatory Flexibility Act

The proposed rule will not have a significant impact on a substantial number of small entities as defined under the Regulatory Flexibility Act, 5 U.S.C. 601, *et seq.* Moreover, Indian Tribes are not considered to be small entities for the purposes of the Regulatory Flexibility Act.

Small Business Regulatory Enforcement Fairness Act

The proposed rule is not a major rule under 5 U.S.C. 804(2), the Small Business Regulatory Enforcement Fairness Act. The rule does not have an effect on the economy of $100 million or more. The rule will not cause a major increase in costs or prices for consumers, individual industries, Federal, State, local government agencies or geographic regions, nor will the proposed rule have a significant adverse effect on competition, employment, investment, productivity, innovation, or the ability of the enterprises, to compete with foreign based enterprises.

Unfunded Mandates Reform Act

The Commission, as an independent regulatory agency, is exempt from compliance with the Unfunded Mandates Reform Act, 2 U.S.C. 1502(1); 2 U.S.C. 658(1).

Takings

In accordance with Executive Order 12630, the Commission has determined that the proposed rule does not have significant takings implications. A takings implication assessment is not required.

Civil Justice Reform

In accordance with Executive Order 12988, the Commission has determined that the rule does not unduly burden the judicial system and meets the requirements of sections 3(a) and 3(b)(2) of the Order.

National Environmental Policy Act

The Commission has determined that the rule does not constitute a major federal action significantly affecting the quality of the human environment and that no detailed statement is required pursuant to the National Environmental Policy Act of 1969, 42 U.S.C. 4321, *et seq.*

Paperwork Reduction Act

The information collection requirements contained in this rule were previously approved by the Office of Management and Budget as required by the Paperwork Reduction Act, 44 U.S.C. 3501, *et seq.,* and assigned OMB Control Number 3141–0003. The OMB control number expires on October 31, 2013.

List of Subjects in 25 CFR Parts 556 and 558

Gaming, Indian lands.

For the reasons discussed in the Preamble, the Commission 25 CFR chapter III as follows:

■ 1. Revise part 556 to read as follows:

PART 556—BACKGROUND INVESTIGATIONS FOR PRIMARY MANAGEMENT OFFICIALS AND KEY EMPLOYEES

Sec.
556.1 Scope of this part.
556.2 Privacy notice.
556.3 Notice regarding false statements.
556.4 Background investigations.
556.5 Tribal eligibility determination.
556.6 Report to the Commission.
556.7 Notice.
556.8 Compliance with this part.

Authority: 25 U.S.C. 2706, 2710, 2712.

§ 556.1 Scope of this part.

Unless a tribal-state compact assigns sole jurisdiction to an entity other than a tribe with respect to background investigations, the requirements of this part apply to all class II and class III gaming. The procedures and standards of this part apply only to primary management officials and key employees. This part does not apply to any license that is intended to expire within 90 days of issuance.

§ 556.2 Privacy notice.

(a) A tribe shall place the following notice on the application form for a key employee or a primary management official before that form is filled out by an applicant:

In compliance with the Privacy Act of 1974, the following information is provided: Solicitation of the information on this form is authorized by 25 U.S.C. 2701 *et seq.* The purpose of the requested information is to determine the eligibility of individuals to be granted a gaming license. The information will be used by the Tribal gaming regulatory authorities and by the National Indian Gaming Commission (NIGC) members and staff who have need for the information in the performance of their official duties. The information may be disclosed by the Tribe or the NIGC to appropriate Federal, Tribal, State, local, or foreign law enforcement and regulatory agencies when relevant to civil, criminal or regulatory investigations or prosecutions or when pursuant to a requirement by a tribe or the NIGC in connection with the issuance, denial, or revocation of a gaming license, or investigations of activities while associated with a tribe or a gaming operation. Failure to consent to the disclosures indicated in this notice will result in a tribe's being unable to license you for a primary management official or key employee position.

The disclosure of your Social Security Number (SSN) is voluntary. However, failure to supply a SSN may result in errors in processing your application.

(b) A tribe shall notify in writing existing key employees and primary management officials that they shall either:

(1) Complete a new application form that contains a Privacy Act notice; or

(2) Sign a statement that contains the Privacy Act notice and consent to the routine uses described in that notice.

(c) All license application forms used one-hundred eighty (180) days after February 25, 2013 shall comply with this section.

§ 556.3 Notice regarding false statements.

(a) A tribe shall place the following notice on the application form for a key employee or a primary management official before that form is filled out by an applicant:

A false statement on any part of your license application may be grounds for denying a license or the suspension or revocation of a license. Also, you may be punished by fine or imprisonment (U.S. Code, title 18, section 1001).

(b) A tribe shall notify in writing existing key employees and primary management officials that they shall either:

(1) Complete a new application form that contains a notice regarding false statements; or

(2) Sign a statement that contains the notice regarding false statements.

(c) All license application forms used 180 days after February 25, 2013 shall comply with this section.

§ 556.4 Background investigations.

A tribe shall perform a background investigation for each primary management official and for each key employee of a gaming operation.

(a) A tribe shall request from each primary management official and from each key employee all of the following information:

(1) Full name, other names used (oral or written), social security number(s), birth date, place of birth, citizenship, gender, all languages (spoken or written);

(2) Currently and for the previous five years: Business and employment positions held, ownership interests in those businesses, business and residence addresses, and driver's license numbers;

(3) The names and current addresses of at least three personal references, including one personal reference who was acquainted with the applicant during each period of residence listed under paragraph (a)(2) of this section;

(4) Current business and residence telephone numbers;

(5) A description of any existing and previous business relationships with Indian tribes, including ownership interests in those businesses;

(6) A description of any existing and previous business relationships with the gaming industry generally, including ownership interests in those businesses;

(7) The name and address of any licensing or regulatory agency with which the person has filed an application for a license or permit related to gaming, whether or not such license or permit was granted;

(8) For each felony for which there is an ongoing prosecution or a conviction, the charge, the name and address of the court involved, and the date and disposition if any;

(9) For each misdemeanor conviction or ongoing misdemeanor prosecution (excluding minor traffic violations) within 10 years of the date of the application, the name and address of the court involved and the date and disposition;

(10) For each criminal charge (excluding minor traffic charges) whether or not there is a conviction, if such criminal charge is within 10 years of the date of the application and is not otherwise listed pursuant to paragraph

(a)(8) or (a)(9) of this section, the criminal charge, the name and address of the court involved and the date and disposition;

(11) The name and address of any licensing or regulatory agency with which the person has filed an application for an occupational license or permit, whether or not such license or permit was granted;

(12) A photograph;

(13) Any other information a tribe deems relevant; and

(14) Fingerprints consistent with procedures adopted by a tribe according to § 522.2(h) of this chapter.

(b) If, in the course of a background investigation, a tribe discovers that the applicant has a notice of results on file with the NIGC from a prior investigation and the tribe has access to the earlier investigative materials (either through the NIGC or the previous tribal investigative body), the tribe may rely on those materials and update the investigation and investigative report under § 556.6(b)(1).

(c) In conducting a background investigation, a tribe or its agents shall keep confidential the identity of each person interviewed in the course of the investigation.

§ 556.5 Tribal eligibility determination.

A tribe shall conduct an investigation sufficient to make an eligibility determination.

(a) To make a finding concerning the eligibility of a key employee or primary management official for granting of a gaming license, an authorized tribal official shall review a person's:

(1) Prior activities;

(2) Criminal record, if any; and

(3) Reputation, habits and associations.

(b) If the authorized tribal official, in applying the standards adopted in a tribal ordinance, determines that licensing of the person poses a threat to the public interest or to the effective regulation of gaming, or creates or enhances the dangers of unsuitable, unfair, or illegal practices and methods and activities in the conduct of gaming, an authorizing tribal official shall not license that person in a key employee or primary management official position.

§ 556.6 Report to the Commission.

(a) When a tribe employs a primary management official or a key employee, the tribe shall maintain a complete application file containing the information listed under § 556.4(a)(1) through (14).

(b) Before issuing a license to a primary management official or to a key employee, a tribe shall:

(1) Create and maintain an investigative report on each background investigation. An investigative report shall include all of the following:

(i) Steps taken in conducting a background investigation;

(ii) Results obtained;

(iii) Conclusions reached; and

(iv) The basis for those conclusions.

(2) Submit a notice of results of the applicant's background investigation to the Commission no later than sixty (60) days after the applicant begins work. The notice of results shall contain:

(i) Applicant's name, date of birth, and social security number;

(ii) Date on which applicant began or will begin work as key employee or primary management official;

(iii) A summary of the information presented in the investigative report, which shall at a minimum include a listing of:

(A) Licenses that have previously been denied;

(B) Gaming licenses that have been revoked, even if subsequently reinstated;

(C) Every known criminal charge brought against the applicant within the last 10 years of the date of application; and

(D) Every felony of which the applicant has been convicted or any ongoing prosecution.

(iv) A copy of the eligibility determination made under § 556.5.

§ 556.7 Notice.

(a) All notices under this part shall be provided to the Commission through the appropriate Regional office.

(b) Should a tribe wish to submit notices electronically, it should contact the appropriate Regional office for guidance on acceptable document formats and means of transmission.

§ 556.8 Compliance with this part.

All tribal gaming ordinances and ordinance amendments approved by the Chair prior to the February 25, 2013 and that reference this part, do not need to be amended to comply with this part. All future ordinance submissions, however, must comply.

■ 2. Revise part 558 to read as follows:

PART 558—GAMING LICENSES FOR KEY EMPLOYEES AND PRIMARY MANAGEMENT OFFICIALS

Sec.

558.1 Scope of this part.
558.2 Review of notice of results for a key employee or primary management official.
558.3 Notification to NIGC of license decisions and retention obligations
558.4 Notice of disqualifying information and licensee right to a hearing.
558.5 Submission of notices.
558.6 Compliance with this part.

Authority: 25 U.S.C. 2706, 2710, 2712.

§ 558.1 Scope of this part.

Unless a tribal-state compact assigns responsibility to an entity other than a tribe, the licensing authority for class II or class III gaming is a tribal authority. The procedures and standards of this part apply only to licenses for primary management officials and key employees. This part does not apply to any license that is intended to expire within 90 days of issuance.

§ 558.2 Review of notice of results for a key employee or primary management official.

(a) Upon receipt of a complete notice of results for a key employee or primary management official as required by § 556.6(b)(2) of this chapter, the Chair has 30 days to request additional information from a tribe concerning the applicant or licensee and to object.

(b) If the Commission has no objection to issuance of a license, it shall notify the tribe within thirty (30) days of receiving notice of results pursuant to § 556.6(b)(2) of this chapter.

(c) If, within the 30-day period described in § 558.3(a), the Commission provides the tribe with a statement itemizing objections to the issuance of a license to a key employee or to a primary management official applicant for whom the tribe has provided a notice of results, the tribe shall reconsider the application, taking into account the objections itemized by the Commission. The tribe shall make the final decision whether to issue a license to such applicant.

(d) If the tribe has issued the license before receiving the Commission's statement of objections, notice and hearing shall be provided to the licensee as provided by § 558.4.

§ 558.3 Notification to NIGC of license decisions and retention obligations.

(a) After a tribe has provided a notice of results of the background check to the Commission, a tribe may license a primary management official or key employee.

(b) Within 30 days after the issuance of the license, a tribe shall notify the Commission of its issuance.

(c) A gaming operation shall not employ a key employee or primary management official who does not have a license after ninety (90) days.

(d) If a tribe does not license an applicant—

(1) The tribe shall notify the Commission; and

(2) Shall forward copies of its eligibility determination and notice of

results, under § 556.6(b)(2) of this chapter, to the Commission for inclusion in the Indian Gaming Individuals Record System.

(e) A tribe shall retain the following for inspection by the Chair or his or her designee for no less than three years from the date of termination of employment:

(1) Applications for licensing;
(2) Investigative reports; and
(3) Eligibility determinations.

§ 558.4 Notice of information impacting eligibility and licensee's right to a hearing.

(a) If, after the issuance of a gaming license, the Commission receives reliable information indicating that a key employee or a primary management official is not eligible for employment under § 556.5 of this chapter, the Commission shall notify the issuing tribe of the information.

(b) Upon receipt of such notification under paragraph (a) of this section, a tribe shall immediately suspend the license and shall provide the licensee with written notice of suspension and proposed revocation.

(c) A tribe shall notify the licensee of a time and a place for a hearing on the proposed revocation of a license.

(d) A right to a hearing under this part shall vest only upon receipt of a license granted under an ordinance approved by the Chair.

(e) After a revocation hearing, a tribe shall decide to revoke or to reinstate a gaming license. A tribe shall notify the Commission of its decision within 45 days of receiving notification from the Commission pursuant to paragraph (a) of this section.

§ 558.5 Submission of notices.

(a) All notices under this part shall be provided to the Commission through the appropriate Regional office.

(b) Should a tribe wish to submit notices electronically, it should contact the appropriate Regional office for guidance on acceptable document formats and means of transmission.

§ 558.6 Compliance with this part.

All tribal gaming ordinances and ordinance amendments that have been approved by the Chair prior to February 25, 2013 and that reference this part do not need to be amended to comply with this section. All future ordinance submissions, however, must comply.

Dated: January 17, 2013, Washington, DC.

Tracie L. Stevens,

Chairwoman.

Daniel J. Little,

Associate Commissioner.

[FR Doc. 2013–01315 Filed 1–24–13; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

[FRL–9723–8]

40 CFR Parts 124 and 270

Revisions to Procedural Rules To Clarify Practices and Procedures Applicable in Permit Appeals Pending Before the Environmental Appeals Board

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This rule revises existing procedures for appeals from RCRA, UIC, NPDES, PSD or other final permit decisions that are filed with the Environmental Appeals Board in an effort to simplify and make more efficient the review process, particularly in appeals from permits issued under new source review provisions. Most significantly, the changes reconcile current provisions of the regulation governing appeals, which over time has proven to be somewhat confusing and redundant. The changes will bring the regulation more fully in line with current practice. Under the current rule, a Petitioner is required to file a substantive petition for review demonstrating that review is warranted. The Environmental Appeals Board considers that substantive petition, as well as any briefs filed in response to the petition, to determine whether to grant review. If review is granted, the current rule contemplates that a second substantive round of briefing is begun and another substantive review process occurs. In practice, however, the Board has determined that a second round of briefing generally is unnecessary because in nearly all cases, a decision on the merits can be made based on the substantive briefs already filed. The changes to the rule clarify to practitioners that substantive briefing must be submitted at the outset of the appeal and that one substantive review will occur. Additional briefing may be ordered when the Board determines it warranted. A number of additional provisions governing procedure are also added to the rule to reflect existing practices that are currently guided by standing orders of the Environmental Appeals Board and its Practice Manual. Revising the regulation to reflect current practice will provide clarity to practitioners before the Board, which will in turn make the appeals process more efficient by avoiding unnecessary filings and Board orders.

DATES: This final rule will become effective on March 26, 2013.

FOR FURTHER INFORMATION CONTACT: Eurika Durr, Clerk of the Board, U.S. Environmental Protection Agency, Environmental Appeals Board (EAB), 1200 Pennsylvania Avenue NW., Mail Code 1103M, Washington, DC 20460–0001; telephone (202) 233–0122; fax number: (202) 233–0121; email address: *durr.eurika@epa.gov.* For more information regarding this rule, please visit *http://www.epa.gov/eab.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

This action is directed to the public in general, and has particular applicability to anyone who seeks review of a RCRA, UIC, NPDES, PSD or other final permit decision under 40 CFR § 124.19 by the Environmental Appeals Board. Because this action may apply to everyone, the Agency has not attempted to describe all the specific entities that may be affected by this action. If you have any questions regarding the applicability of this action to the particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How can I get additional information?

Electronic copies of this document and certain other related documents are available at *http://www.epa.gov/eab/.*

C. When will this rule become effective?

This rule will become effective sixty days after the date of publication in the **Federal Register**. The sixty days between the date of publication and the effective date will allow the Board to notify current practitioners of the changes, modify its procedural guidance documents and take other measures to implement the rule as appropriate.

II. Background

A. What action is the agency taking?

The existing rule governing appeals of RCRA, UIC, NPDES, PSD and other applicable final permit decisions is potentially redundant and cumbersome, lacks detailed procedures that would help simplify the permit review process, and is not fully reflective of the Environmental Appeals Board's current practice. EPA is amending the language of the rule to more fully reflect current practice, which is bound by the current language but also guided in large part by Board precedent, Board standing orders, and the Board's Practice Manual.

The amendments to the rule clarify review procedures for practitioners before the Environmental Appeals Board, which will simplify and make

more efficient the review process in all permit appeals filed with the Board under this section, particularly in PSD and other new source appeals. As explained in more detail below, the changes:

■ Clarify that substantive briefing occurs at the outset of the appeal followed by one substantive review process and that a second round of substantive briefs will not occur as a matter of course, allowing the regulation to more fully reflect current Board practice; and

■ Add provisions to the rule governing procedures that are currently guided by standing orders of the Environmental Appeals Board and the Board's Practice Manual.

1. Full Briefing During Initial Review by the Environmental Appeals Board

In most permit appeals, the Environmental Appeals Board bases its final decision on the petition(s) filed, the response(s) to the petition, and on the administrative record of the permit decision. Although the current rule provides for a second substantive briefing and review period following a decision to ''grant review,'' a large majority of the time the Board concludes that additional briefing is unnecessary to determine whether to affirm a permit decision or remand a permit decision to the permitting agency for further consideration. Paragraph (a) of the current rule requires Petitioners to demonstrate that review is warranted in the petition for review. Board precedent, affirmed by the Federal Courts of Appeal, interprets this provision in the rule to require Petitioners to demonstrate substantively why the permit decision warrants review. *See, e.g., In re Teck Alaska, Inc.,* NPDES Appeal No. 10–04, at 7–11 (EAB Nov. 18, 2010) (Order Denying Review), *review denied, Native Vill. of Kivalina IRA Council* v. *EPA,* 687 F.3d 1216, 1221 (9th Cir. 2012); *In re City of Pittsfield,* NPDES Appeal No. 08–19, at 7, 11–12 (EAB Mar. 4, 2009) (Order Denying Review), review denied, 614 F.3d 7, 11–13 (1st Cir. 2010); *In re Wastewater Treatment Facility of Union Twp.,* NPDES Appeal Nos. 00–26 & 00–28, at 9–13 (EAB Jan. 23, 2001) (Order Denying Petitions for Review), *review denied, Mich. Dep't Envtl. Quality* v. *EPA,* 318 F.3d 705, 708 (6th Cir. 2003); *see also In re Peabody W. Coal Co.,* 12 E.A.D. 22, 33, 51–53 (EAB 2005).

In cases where the Board finds no error based on its review of the petition, the responses to the petition, and the administrative record, the Board will typically deny review. In cases where the Board finds error based on its initial review, the Board often determines that additional briefing on appeal would not shed further light on the issues and, therefore, determines that a direct remand without additional submissions would be more efficient and appropriate. *See In re DC Water and Sewer Auth.,* 13 E.A.D. 714, n.82 (EAB 2008) (remanding after initial review and explaining that ''[a]lthough 40 CFR § 124.19(c) contemplates that additional briefing typically will be submitted upon a grant of review, a direct remand without additional submissions is appropriate where, as here, it does not appear as though further briefs on appeal would shed light on the issues'' to be addressed on remand); *see also, e.g., In re Amerada Hess,* 12 E.A.D. 1, 21 n.39 (EAB 2005); *In re Rohm and Haas Co.,* 9 E.A.D. 499, 514 n.24 (EAB 2000); *In re Knauf Fiber Glass, GmbH,* 8 E.A.D. 121, 176 n.73 (EAB 1999); *In re Beckman Prod. Servs.,* 8 E.A.D. 302, 314 n.16 (EAB 1999); *In re Ash Grove Cement Co.,* 7 E.A.D. 387, 433 n. 40 (EAB 1997); *In re Chem. Waste Mgmt. of Ind.,* 6 E.A.D. 144, 173 n.28 (EAB 1995); *In re Reinkiewicz,* 4 E.A.D. 61, 67 n.5 (EAB 1992). The utilization of a direct remand, without further briefing, has been a practice of the Agency since before the Board was created. *See In re Chem. Waste Mgmt, Inc.,* 2 E.A.D. 575, 577 (Adm'r 1988).

The Environmental Appeals Board's long-standing practice of issuing a direct remand in matters based on errors found in its initial review of a petition stands in contrast to the provision in 40 CFR 124.19(c) that provides for a second round of briefing following a grant of review. Notwithstanding the requirement to provide a substantive demonstration that review is warranted in the petition for review, the existing regulation contemplates that following the Board's grant of review, public notice of the grant of review must be provided and a briefing schedule established for the appeal, including an invitation to any interested person to file an amicus brief.

Today's revision of § 124.19 simplifies the review process and promotes judicial economy by clarifying that one complete round of briefing will occur at the outset of the appeal and by removing the language that refers to a second round of briefing once review has been granted. As always, any person who filed comments on the draft permit or participated in a public hearing on the draft permit may file a petition for review. With today's revision of the rule, any interested person may file an amicus brief in any permit appeal pending before the Board under part 124 during the initial briefing period within the timeframe and in the manner prescribed by the rule. Notice of all docketed appeals pending before the Environmental Appeals Board is available to the public on the Board's Web site: *www.epa.gov/eab.* Nothing in this revision to the rule prevents the Board from ordering additional briefing after the first round in any matter where the Board determines that additional briefing may assist the Board in its deliberations.

Several provisions in parts 124 and 270 reference the granting of review by the Environmental Appeals Board and use the second round of briefing and permit review as a trigger or deadline for other agency action. As such, these provisions are being revised to reflect the clarification that all substantive briefing occurs at the outset of the appeal. Specifically, before today, § 124.19 authorized the Regional Administrator to unilaterally withdraw a permit and prepare a new draft permit at any time prior to the Board's grant of review under what was § 124.19(c). The provision served to prevent unilateral withdrawal of a permit by the Region after the Environmental Appeals Board had begun substantive consideration of an appeal. This rule revises § 124.19 to allow the Regional Administrator to unilaterally withdraw the permit at any time prior to 30 days after the Regional Administrator files its response to the petition under paragraph (b) of this section. This revision will continue to ensure that unilateral withdrawal of a permit will occur before the Board has devoted significant resources to the substantive consideration of an appeal. Nothing in this regulation prevents the Region from seeking to withdraw the permit by motion at any time.

Additionally § 270.42(b)(6)(iii) provides for the automatic authorization of certain hazardous waste permit modifications where the Director fails to make a determination on a modification request within the allotted time. That automatic authorization is appealable to the Environmental Appeals Board under § 124.19, as provided in § 270.42(f)(3). The provision authorizing the appeal also provides that ''the permittee may continue to conduct the activities pursuant to the automatic authorization until the appeal has been granted pursuant to § 124.19(c), notwithstanding the provisions of § 124.15(b).'' Because today's rule modifies the appeal procedures to eliminate a second round of substantive review after the grant of review, § 270.42((f)(3) must be modified as well. Accordingly, the provision is modified to allow the permittee to conduct activities pursuant to automatic authorization until a final

determination, if any, is made by the Environmental Appeals Board to grant review and remand the permit. The revision is consistent with the original provision in that it allows the permittee to continue to conduct activities described in the modification request pursuant to automatic authorization until the Board determines review is warranted.

Section 270.155(a) authorizes appeals to the Environmental Appeals Board from decisions to approve or deny a remedial action plan (RAP) permit under RCRA. That provision historically has required that specific notice be given to the public of the Environmental Appeals Board's grant of review of any RAP decision, and an opportunity provided for any interested person to participate in the second (substantive review) stage of the appeal. Because today's revision of § 124.19 clarifies that the substantive review of a petition is based on one complete round of briefing at the outset of the appeal, the rule also clarifies that all interested persons in any appeal under § 124.19, including those appeals authorized under § 270.155, may file an amicus brief during the initial briefing period within the timeframe and in the manner prescribed by the rule. Notice of a final decision to approve or deny a RAP is provided under § 270.150, and such notice includes the procedures for appealing the decision under § 270.155. Additionally, as provided above, notice of all docketed appeals pending before the Environmental Appeals Board is available to the public on the Board's Web site: *www.epa.gov/eab.* Thus, the provision in § 270.155(a), which provides for specific notice of the second stage of the appeal process that is being eliminated, is no longer necessary and is also being deleted.

2. Procedural Additions to the Rule

Practitioners before the Environmental Appeals Board in permit appeals currently are guided by Board precedent, standing orders of the Board, and the Board's Practice Manual. Current regulations do not provide the parameters for filing documents before the Board, such as where to file, how to file, when to file, as well as any content requirements or limits to what is filed. The revisions adopted today are intended to codify current procedural practices, clarify existing review procedures, and simplify the permit review process. Practitioners before the Board will benefit from the greater clarity and efficiency in these procedural rules, as will the Agency. Specific changes are summarized below.

In matters where the permit applicant is not the petitioner in an appeal, the petitioner must notify the permit applicant when a petition is filed, and the permit applicant's deadline for filing a response is specified in the regulation. This change eliminates the current practice that typically involves the permit applicant filing a motion to participate in the appeal, which the Board typically grants, followed by filing a substantive brief according to the Board's briefing schedule. Allowing participation of the permit applicant by rule and specifying a response brief deadline will streamline and make more efficient the briefing process for permit applicants.

When a petition is filed, the Environmental Appeals Board typically sends a letter to the permit issuer requesting a response to the petition and requiring the permit issuer to submit its response and a certified index to the administrative record by a date certain. This rule adds procedures that require a petitioner to serve notice of the petition on the permit issuer when the petition is filed. The rule also requires the permit issuer to submit a response to the petition, as well as a certified index of the administrative record and relevant portions of the record, by a date certain. This eliminates the need for the Board to notify the permit issuer and facilitates an earlier response deadline, making the process more efficient for the permit issuer and the Board.

The changes to the rule also impose briefing procedures and deadlines for interested state or tribal authorities that are located where the permitted facility or site is located or proposed to be located (if that authority is not the permit issuer), as well as for any person(s) interested in filing an amicus brief. Again, the briefing deadlines and explicit authorization to file are intended to streamline and make more efficient the appeal process, by removing the need to request permission from the Board to participate, and eliminating the corresponding additional time needed to grant participation and to impose briefing schedules later in the process.

Procedures for PSD and other new source review appeals are contained in the Environmental Appeals Board's April 19, 2011, standing order. *See* Order Governing Petitions for Review of Clean Air Act New Source Review Permits (EAB Apr. 19, 2011), *available at www.epa.gov/eab.* These procedures were adopted ''to facilitate [the] expeditious resolution of NSR appeals, while simultaneously giving fair consideration to the issues raised in any given matter[.]'' *Id.* at 2. In effect, the procedures simplify and make more efficient the review process in PSD and other new source appeals (including OCS appeals) by imposing certain presumptions, tighter deadlines, briefing limitations, and other measures. Today's rule incorporates many of these procedures into the regulation.

To date, practitioners before the Environmental Appeals Board have had little guidance on the form and content of submissions to the Board. The revised rule adds provisions imposing procedural rules governing the content and form of filings for briefs and motions practice. This will improve the quality and consistency of filings before the Board, which will also contribute to greater efficiency.

The revised rule clarifies existing filing requirements and procedures that are currently found in the Board's standing orders and in the Board's Practice Manual, all of which may be found on the Board's Web site. These include procedures for both filing paper documents and for electronic filing. The procedures also address the service of notice on participants of documents filed, including the availability of electronic service. This portion of the rule will also provide greater clarity and efficiency to the appeals process.

The revised rule also adds a provision clarifying the Board's inherent authority to manage its docket in the most meaningful and efficient manner possible, including the ability to impose procedural sanctions for failure to comply with Board orders and rules. The language clarifying this authority is consistent with the express language found in regulations pertaining to enforcement appeals before the Environmental Appeals Board. *See* 22 CFR § 22.4(a)(2). The language is also consistent with Board precedent. *See In re Peabody Western Coal Co.,* CAA Appeal No. 10–01 (EAB Aug. 13, 2010) (Order Granting Motion for Voluntary Remand) (articulating Board's inherent authority to rule on motions and fill other ''gaps'' in its procedural rules); *see also, e.g., In re MGP Ingredients of Illinois, Inc.,* PSD Appeal No. 09–03 (EAB Jan. 8, 2010) (Order Imposing Sanctions, Setting Final Deadline for Filing Response and Scheduling Status Conference) (imposing page-limit sanction against permit issuer and ordering appearance at a status conference in response to ''systematic failure to timely assemble the administrative record, provide representation and defend a permit issued''); *In re Desert Rock Energy Co.,* LLC, PSD Appeal Nos. 08–03 to 08–06 (EAB May 21, 2009) (Order Denying Motion to Participate) (initially denying

amici's motion to participate filed two months after the deadline for submission without explanation or justification). Further support for the Board's inherent authority to manage its docket may be found in general and well-established principles of administrative law. *See Vermont Yankee Nuclear Power Corp. v. Natural Resources Defense Council,* 435 U.S. 519, 543–44 (1978) (''Absent constitutional constraints or extremely compelling circumstances the administrative agencies should be free to fashion their own rules of procedure to pursue methods of inquiry capable of permitting them to discharge their multitudinous duties.''); *see also American Farm Lines v. Black Ball Freight Service,* 397 U.S. 532, 539 (1970) (explaining that it is ''always within the discretion of * * * an administrative agency to relax or modify its procedural rules adopted for the orderly transaction of business before it when in a given case the ends of justice require it.''). The Board's inherent authority to manage its docket includes the authority to relax or suspend, for good cause, the procedural requirements prescribed by these rules or Board order. *See In re Circle T Feedlot, Inc.,* NPDES Appeals Nos. 09–02 & 09–03, slip op at 11 (EAB Jun. 7, 2010).

Finally, current regulations allow a petitioner to challenge ''any condition of a permit decision.'' 40 CFR 124.19(a). The Environmental Appeals Board historically and consistently has construed ''any condition of the permit decision'' to include not only specific permit conditions, but also the permit decision in its entirety, whether based on alleged substantive or procedural defects. *See, e.g., In re Circle T Feedlot, Inc.,* NPDES Appeal Nos. 09–02 & 09–03, slip op. at 5 n.l (EAB June 7, 2010), 14 E.A.D. ___ (citations omitted) (challenging the permit in its entirety based on the permit issuer's alleged lack of authority to issue the permit); *In re Russell City Energy Ctr.,* PSD Appeal No. 08–01, slip op. at 21–25 (EAB July 29, 2008), 14 E.A.D. ___ (considering adequacy of public notice); *In re Weber, #4–8,* 11 E.A.D. 241, 245 (EAB 2003) (considering timeliness of response to comments); *In re Indeck-Elwood, LLC,* 13 E.A.D. 126, 189 (EAB 2006) (considering, among other things, the alleged failure to include an emission limit for fluoride). The Board's extension of review to include challenges broader than ones specific to a permit condition is consistent with the language in 40 CFR 124.15(a), which defines a permit decision as a ''final decision to issue, deny, modify, revoke and reissue, or terminate a permit.'' A petitioner challenging the decision to deny a permit, for example, could not identify specific permit ''conditions'' being challenged; rather, such petitioner would challenge the overall decision to deny the permit. Thus, the Board has reviewed permit decisions where the petitioner did not challenge a specific permit condition, but instead challenged the permit as a whole.

On the other hand, the Environmental Appeals Board has also denied review of permit decisions where the petition for review failed to identify any specific permit condition being challenged. Such denial of review has consistently been based on a petitioner's failure to identify—with any specificity—any error of fact or law warranting review. *See, e.g., In re LCP Chemicals—New York,* 4 EAD 661, 664–65 (EAB 1993) (denying review of certain issues for which petitioner had failed to identify specific permit conditions and stating that, ''[a]bsent any references to the specific permit conditions at issue, *and* a discussion as to why the Region's decision to impose those conditions warrants review, this Board has no basis for granting review.'') (emphasis added); *In re Envotech, L.P.,* 6 EAD 260, 269 (EAB 1996) (dismissing a petition that raised the issue of strict liability but did not explain what permit condition was implicated by the doctrine of strict liability or how the doctrine of strict liability established that the region erred in granting the permit); *see also, e.g., In re Peabody W. Coal Co.,* NPDES Appeal Nos. 10–15 & 10–16, slip op. at 32 n.36 (EAB Aug. 31, 2011) (dismissing several issues as ''vague'' and ''unsubstantiated'' where it was unclear how the issues raised related to any conditions of the permit that petitioner was attempting to challenge (citing *In re City of Attleboro,* NPDES Appeal No. 08–08, slip op. at 61 (EAB Dec. 15, 2009) (explaining that, because petitioner bears the burden of demonstrating that review is warranted, the Board ''will not entertain vague or unsubstantiated claims'')); *In re City of Moscow,* 10 E.A.D. 135, 172 (EAB 2001) (denying review where petitioner raised vague and unsubstantiated concerns and failed to point to any clearly erroneous findings of fact or conclusions of law in the Region's permitting decision or to identify any specific permit conditions that gave rise to those concerns)).

Today's revision to the rule therefore clarifies that, consistent with well-established precedent, petitioners must identify the contested permit condition or other specific challenge to the permit decision and clearly set forth, with legal and factual support, petitioner's contentions for why the permit decision should be reviewed. This revised language is intended to capture permit challenges that are within the Environmental Appeals Board's existing scope of review, but that are not necessarily tied to a specific permit condition; the revised language is not intended to expand the Board's existing scope of review. As always, such challenges must demonstrate that the permit decision is based on a finding of fact or conclusion of law that is clearly erroneous, or an exercise of discretion or an important policy consideration that the Environmental Appeals Board should, in its discretion, review. Additionally, the rule incorporates the precedential requirement that petitions not only demonstrate that any issue raised in the petition was raised previously during the public comment period (to the extent required), but also that the petition addresses any response by the permit issuer and explain why that response was clearly erroneous or otherwise warrants review. *See, e.g., In re Prairie State Generating Co., LLC,* 13 E.A.D. 1, 109 (EAB 2006); *see also, e.g. In re Pittsfield,* NPDES Appeal No. 08–19, slip op. at 6–9, 11 (EAB Mar. 4, 2009), *aff'd,* 614 F.3d 7 (1st Cir. 2010).

In addition, EPA is clarifying a provision in section 124.19 addressing when final agency action occurs following the disposition of an appeal by the Environmental Appeals Board. Sections 124.15(a) and 124.19(f) of EPA's existing regulations both use the term ''final permit decision.'' Some parties have interpreted the use of the term ''final permit decision'' in the first sentence of section 124.19(f)(1) to describe a ''final permit decision'' previously issued under section 124.15 rather than an additional final permit decision issued by the Regional Administrator after any administrative review proceedings under section 124.19 are exhausted. EPA generally has applied the latter reading based on the second sentence of section 124.19(f)(1), but some EPA offices and members of the public have occasionally misunderstood the meaning of this provision. In some instances, this has led to inconsistent actions within EPA and disputes over the reading of section 124.19(f) between EPA and parties seeking judicial review of permits issued under Part 124. Thus, in order to avoid further disputes and ensure consistency across EPA offices that issue permits under Part 124, we are revising the relevant language in section 124.19 to make more clear that final agency action does not occur under 124.19 until the Regional Administrator

issues a subsequent ''final permit decision'' under section 124.19 *after* administrative review proceedings are exhausted. This revised text now appears in section 124.19(l)(2).

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

EPA is issuing this document under its general rulemaking authority, Reorganization Plan No. 3 of 1970 (5 U.S.C. app.).

Section 553 of the Administrative Procedure Act (APA), 5 U.S.C. § 553(b)(3)(A), provides that ''rules of agency organization, procedure, or practice'' are exempt from notice and comment requirements. The action the Agency is taking today involves revisions to the Environmental Appeals Board's procedural rules to clarify existing practices and procedures that are applicable in permit appeals filed with the Environmental Appeals Board. These revisions fall under the exemption provided in APA § 553(b)(3)(A). Accordingly, EPA is not taking comment on this action.

III. Statutory and Executive Order Reviews

This action involves revisions to the Environmental Appeals Board's procedural rules to clarify existing practices and procedures that are applicable in permit appeals filed with the Environmental Appeals Board. This type of action is exempt from review under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011). Because this action is not subject to notice and comment requirements under the Administrative Procedures Act or any other statute, it is not subject to the Regulatory Flexibility Act (5 U.S.C. 601 *et. seq.*) or sections 202 and 205 of the Unfunded Mandates Reform Act of 1999 (UMRA) (Pub. L. 104–4). In addition, this action does not significantly or uniquely affect small governments. This action does not create new binding legal requirements that substantially and directly affect Tribes under Executive Order 13175 (63 FR 67249, November 9, 2000). This action does not have significant Federalism implications under Executive Order 13132 (64 FR 43255, August 10, 1999). This rule also is not subject to Executive Order 13045, ''Protection of Children from Environmental Health Risks and Safety Risks,'' (62 FR 19885, April 23, 1997), because it is not economically significant. This action is not subject to Executive Order 13211, ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355, May 22, 2001), because it is not a significant regulatory action under Executive Order 12866. This action does not involve technical standards; thus the requirements of § 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) do not apply. This action does not impose an information collection burden under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). The Congressional Review Act, 5 U.S.C 801 et seq., as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. Section 804 exempts from section 801 the following types of rules (1) rules of particular applicability; (2) rules relating to agency management or personnel; and (3) rules of agency organization, procedure, or practice that do not substantially affect the rights or obligations of non-agency parties. 5 U.S.C. 804(3). EPA is not required to submit a rule report regarding today's action under section 801 because this is a rule of agency organization, procedure, or practice that does not substantially affect the rights or obligations of non-agency parties.

List of Subjects

40 CFR Part 124

Administrative Practice and Procedures.

40 CFR Part 270

Environmental Protection, Hazardous Waste.

Dated: January 14, 2013.

Lisa P. Jackson,

Administrator.

For the reasons stated in the preamble, the Environmental Protection Agency amends title 40 parts 124 and 270 of the Code of Federal Regulations as follows:

PART 124—PROCEDURES FOR DECISIONMAKING

■ 1. The authority citation for part 124 continues to read as follows:

Authority: Resource Conservation and Recovery Act, 42 U.S.C. 6901 *et seq.;* Safe Drinking Water Act, 42 U.S.C. 300f *et seq.;* Clean Water Act, 33 U.S.C. 1251 *et seq.;* Clean Air Act, 42 U.S.C. 7401 *et seq.*

■ 2. Section 124.10 is amended by removing paragraph (a)(1)(iv) and redesignating paragraphs (a)(1)(v) through (a)(1)(vi) as paragraphs (a)(1)(iv) through paragraphs (a)(1)(v), respectively.

■ 3. Paragraph (b)(1) of § 124.16 is revised to read as follows:

§ 124.16 Stays of contested permit conditions.

* * * * *

(b) *Stays based on cross effects.* (1) A stay may be granted based on the grounds that an appeal to the Administrator under § 124.19 of one permit may result in changes to another EPA-issued permit only when each of the permits involved has been appealed to the Administrator.

* * * * *

■ 4. Section 124.19 is revised to read as follows:

§ 124.19 Appeal of RCRA, UIC, NPDES and PSD Permits.

(a) *Petitioning for review of a permit decision.* (1) *Initiating an appeal.* Appeal from a RCRA, UIC, NPDES, or PSD final permit decision issued under § 124.15 of this part, or a decision to deny a permit for the active life of a RCRA hazardous waste management facility or unit under § 270.29 of this chapter, is commenced by filing a petition for review with the Clerk of the Environmental Appeals Board within the time prescribed in paragraph (a)(3) of this section.

(2) *Who may file?* Any person who filed comments on the draft permit or participated in a public hearing on the draft permit may file a petition for review as provided in this section. Additionally, any person who failed to file comments or failed to participate in the public hearing on the draft permit may petition for administrative review of any permit conditions set forth in the final permit decision, but only to the extent that those final permit conditions reflect changes from the proposed draft permit.

(3) *Filing deadline.* A petition for review must be filed with the Clerk of the Environmental Appeals Board within 30 days after the Regional Administrator serves notice of the issuance of a RCRA, UIC, NPDES, or PSD final permit decision under § 124.15 or a decision to deny a permit for the active life of a RCRA hazardous waste management facility or unit under § 270.29 of this chapter. A petition is filed when it is received by the Clerk of the Environmental Appeals Board at the address specified for the appropriate method of delivery as provided in paragraph (i)(2) of this section.

(4) *Petition contents.* (i) In addition to meeting the requirements in paragraph (d), a petition for review must identify the contested permit condition or other

specific challenge to the permit decision and clearly set forth, with legal and factual support, petitioner's contentions for why the permit decision should be reviewed. The petition must demonstrate that each challenge to the permit decision is based on:

(A) A finding of fact or conclusion of law that is clearly erroneous, or

(B) An exercise of discretion or an important policy consideration that the Environmental Appeals Board should, in its discretion, review.

(ii) Petitioners must demonstrate, by providing specific citation to the administrative record, including the document name and page number, that each issue being raised in the petition was raised during the public comment period (including any public hearing) to the extent required by § 124.13. For each issue raised that was not raised previously, the petition must explain why such issues were not required to be raised during the public comment period as provided in § 124.13. Additionally, if the petition raises an issue that the Regional Administrator addressed in the response to comments document issued pursuant to § 124.17, then petitioner must provide a citation to the relevant comment and response and explain why the Regional Administrator's response to the comment was clearly erroneous or otherwise warrants review.

(b) *Response(s) to a petition for review.* (1) In a PSD or other new source permit appeal, the Regional Administrator must file a response to the petition for review, a certified index of the administrative record, and the relevant portions of the administrative record within 21 days after the filing of the petition.

(2) In all other permit appeals under this section, the Regional Administrator must file a response to the petition, a certified index of the administrative record, and the relevant portions of the administrative record within 30 days after the filing of a petition.

(3) A permit applicant who did not file a petition but who wishes to participate in the appeal process must file a notice of appearance and a response to the petition. Such documents must be filed by the deadlines provided in paragraph (b)(1) or (2) of this section, as appropriate.

(4) The State or Tribal authority where the permitted facility or site is or is proposed to be located (if that authority is not the permit issuer) must also file a notice of appearance and a response if it wishes to participate in the appeal. Such response must be filed by the deadlines provided in paragraph (b)(1) or (2) of this section, as appropriate.

(c) *Replies.* (1) In PSD and other new source permit appeals, the Environmental Appeals Board will apply a presumption against the filing of a reply brief. By motion, petitioner may seek leave of the Environmental Appeals Board to file a reply to the response, which the Environmental Appeals Board, in its discretion, may grant. The motion must be filed simultaneously with the proposed reply within 10 days after service of the response. In its motion, petitioner must specify those arguments in the response to which petitioner seeks to reply and the reasons petitioner believes it is necessary to file a reply to those arguments. Petitioner may not raise new issues or arguments in the motion or in the reply.

(2) In all other permit appeals under this section, petitioner may file a reply within 15 days after service of the response. Petitioner may not raise new issues or arguments in the reply.

(d) *Content and form of briefs.* (1) *Content requirements.* All briefs filed under this section must contain, under appropriate headings:

(i) A table of contents, with page references;

(ii) A table of authorities with references to the pages of the brief where they are cited;

(iii) A table of attachments, if required under paragraph (d)(2) of this section; and

(iv) A statement of compliance with the word limitation.

(2) *Attachments.* Parts of the record to which the parties wish to direct the Environmental Appeals Board's attention may be appended to the brief submitted. If the brief includes attachments, a table must be included that provides the title of each appended document and assigns a label identifying where it may be found (e.g., Excerpts from the Response to Comments Document * * * Attachment 1).

(3) *Length.* Unless otherwise ordered by the Environmental Appeals Board, petitions and response briefs may not exceed 14,000 words, and all other briefs may not exceed 7,000 words. Filers may rely on the word-processing system used to determine the word count. In lieu of a word limitation, filers may comply with a 30-page limit for petitions and response briefs, or a 15-page limit for replies. Headings, footnotes, and quotations count toward the word limitation. The table of contents, table of authorities, table of attachments (if any), statement requesting oral argument (if any), statement of compliance with the word limitation, and any attachments do not count toward the word limitation. The Environmental Appeals Board may exclude any petition, response, or other brief that does not meet word limitations. Where a party can demonstrate a compelling and documented need to exceed such limitations, such party must seek advance leave of the Environmental Appeals Board to file a longer brief. Such requests are discouraged and will be granted only in unusual circumstances.

(e) *Participation by amicus curiae.* Any interested person may file an amicus brief in any appeal pending before the Environmental Appeals Board under this section. The deadline for filing such brief is 15 days after the filing of the response brief, except that amicus briefs in PSD or other new source permit appeals must be filed within 21 days after the filing of the petition. Amicus briefs must comply with all procedural requirements of this section.

(f) *Motions.* (1) *In general.* A request for an order or other relief must be made by written motion unless these rules prescribe another form.

(2) *Contents of a motion.* A motion must state with particularity the grounds for the motion, the relief sought, and the legal argument necessary to support the motion. In advance of filing a motion, parties must attempt to ascertain whether the other party(ies) concur(s) or object(s) to the motion and must indicate in the motion the attempt made and the response obtained.

(3) *Response to motion.* Any party may file a response to a motion. Responses must state with particularity the grounds for opposition and the legal argument necessary to support the motion. The response must be filed within 15 days after service of the motion unless the Environmental Appeals Board shortens or extends the time for response.

(4) *Reply.* Any reply to a response filed under paragraph (f)(3) of this section must be filed within 10 days after service of the response. A reply must not introduce any new issues or arguments and may respond only to matters presented in the response.

(5) *Disposition of a motion for a procedural order.* The Environmental Appeals Board may act on a motion for a procedural order at any time without awaiting a response.

(g) Timing of motions for extension of time. Parties must file motions for extensions of time sufficiently in advance of the due date to allow other

parties to have a reasonable opportunity to respond to the request for more time and to provide the Environmental Appeals Board with a reasonable opportunity to issue an order.

(h) *Oral argument.* The Environmental Appeals Board may hold oral argument on its own initiative or at its discretion in response to a request by one or more of the parties. To request oral argument, a party must include in its substantive brief a statement explaining why oral argument should be permitted. The Environmental Appeals Board will apply a presumption against oral argument in PSD or other new source permit appeals. The Environmental Appeals Board may, by order, establish additional procedures governing any oral argument before the Environmental Appeals Board.

(i) *Filing and service requirements.* Documents filed under this section, including the petition for review, must be filed with the Clerk of the Environmental Appeals Board. A document is filed when it is received by the Clerk of the Environmental Appeals Board at the address specified for the appropriate method of delivery as provided in paragraph (i)(2) of this section.

(1) *Caption and other filing requirements.* Every document filed with the Environmental Appeals Board must specifically identify in the caption the permit applicant, the permitted facility, and the permit number. All documents that are filed must be signed by the person filing the documents or the representative of the person filing the documents. Each filing must also indicate the signer's name, address, and telephone number, as well as an email address, and facsimile number, if any.

(2) *Method of filing.* Unless otherwise permitted under these rules, documents must be filed either electronically, by mail, or by hand delivery. In addition, a motion or a response to a motion may be submitted by facsimile if the submission contains no attachments. Upon filing a motion or response to a motion by facsimile, the sender must, within one business day, submit the original copy to the Clerk of the Environmental Appeals Board either electronically, by mail, or by hand-delivery.

(i) *Electronic filing.* Documents that are filed electronically must be submitted using the Environmental Appeals Board's electronic filing system, subject to any appropriate conditions and limitations imposed by order of the Environmental Appeals Board. All documents filed electronically must include the full name of the person filing below the signature line. Compliance with Environmental Appeals Board electronic filing requirements constitutes compliance with applicable signature requirements.

(ii) *Filing by U.S. Mail.* Documents that are sent by U.S. Postal Service (except by U.S. Express Mail) must be sent to the official mailing address of the Clerk of the Environmental Appeals Board at: U.S. Environmental Protection Agency, Environmental Appeals Board, 1200 Pennsylvania Avenue NW., Mail Code 1103M, Washington, DC 20460–0001. The original and two copies of each document must be filed. The person filing the documents must include a cover letter to the Clerk of the Environmental Appeals Board clearly identifying the documents that are being submitted, the name of the party on whose behalf the documents are being submitted, as well as the name of the person filing the documents, his or her address, telephone number and, if available, fax number and email address.

(iii) *Filing by hand delivery.* Documents delivered by hand or courier (including deliveries by U.S. Express Mail) must be delivered to the Clerk of the Environmental Appeals Board at: U.S. Environmental Protection Agency, Environmental Appeals Board, EPA East Building, 1201 Constitution Avenue NW., Room 3334, Washington, DC 20004. The original and two copies of each document must be filed. The person filing the documents must include a cover letter to the Clerk of the Environmental Appeals Board clearly identifying the documents being submitted, the name of the party on whose behalf the documents are being submitted, as well as the name of the person filing the documents, his or her address, telephone number and, if available, fax number and email address.

(3) *Service requirements.* Petitioner must serve the petition for review on the Regional Administrator and the permit applicant (if the applicant is not the petitioner). Once an appeal is docketed, every document filed with the Environmental Appeals Board must be served on all other parties. Service must be by first class mail, or by any reliable commercial delivery service. Upon agreement by the parties, service may be made by facsimile or electronic means.

(4) *Proof of service.* A certificate of service must be appended to each document filed stating the names of persons served, the date and manner of service, as well as the electronic, mailing, or hand delivery address, or facsimile number, as appropriate.

(j) *Withdrawal of permit or portions of permit by Regional Administrator.* The Regional Administrator, at any time prior to 30 days after the Regional Administrator files its response to the petition for review under paragraph (b) of this section, may, upon notification to the Environmental Appeals Board and any interested parties, withdraw the permit and prepare a new draft permit under § 124.6 addressing the portions so withdrawn. The new draft permit must proceed through the same process of public comment and opportunity for a public hearing as would apply to any other draft permit subject to this part. Any portions of the permit that are not withdrawn and that are not stayed under § 124.16(a) continue to apply. If the Environmental Appeals Board has held oral argument, the Regional Administrator may not unilaterally withdraw the permit, but instead must request that the Environmental Appeals Board grant a voluntary remand of the permit or any portion thereof.

(k) *Petitioner request for dismissal of petition.* Petitioner, by motion, may request to have the Environmental Appeals Board dismiss its appeal. The motion must briefly state the reason for its request.

(l) *Final disposition and judicial review.* (1) A petition to the Environmental Appeals Board under paragraph (a) of this section is, under 5 U.S.C. 704, a prerequisite to seeking judicial review of the final agency action.

(2) For purposes of judicial review under the appropriate Act, final agency action on a RCRA, UIC, NPDES, or PSD permit occurs when agency review procedures under this section are exhausted and the Regional Administrator subsequently issues a final permit decision under this paragraph. A final permit decision must be issued by the Regional Administrator:

(i) When the Environmental Appeals Board issues notice to the parties that the petition for review has been denied;

(ii) When the Environmental Appeals Board issues a decision on the merits of the appeal and the decision does not include a remand of the proceedings; or

(iii) Upon the completion of remand proceedings if the proceedings are remanded, unless the Environmental Appeals Board's remand order specifically provides that appeal of the remand decision will be required to exhaust administrative remedies.

(3) The Regional Administrator must promptly publish notice of any final agency action regarding a PSD permit in the **Federal Register**.

(m) *Motions for reconsideration or clarification.* Motions to reconsider or clarify any final disposition of the Environmental Appeals Board must be filed within 10 days after service of that order. Motions for reconsideration must set forth the matters claimed to have been erroneously decided and the nature of the alleged errors. Motions for clarification must set forth with specificity the portion of the decision for which clarification is being sought and the reason clarification is necessary. Motions for reconsideration or clarification under this provision must be directed to, and decided by, the Environmental Appeals Board. Motions for reconsideration or clarification directed to the Administrator, rather than the Environmental Appeals Board, will not be considered, unless such motion relates to a matter that the Environmental Appeals Board has referred to the Administrator pursuant to § 124.2 and for which the Administrator has issued the final order. A motion for reconsideration or clarification does not stay the effective date of the final order unless the Environmental Appeals Board specifically so orders.

(n) *Board authority.* In exercising its duties and responsibilities under this part, the Environmental Appeals Board may do all acts and take all measures necessary for the efficient, fair, and impartial adjudication of issues arising in an appeal under this part including, but not limited to, imposing procedural sanctions against a party who, without adequate justification, fails or refuses to comply with this part or an order of the Environmental Appeals Board. Such sanctions may include drawing adverse inferences against a party, striking a party's pleadings or other submissions from the record, and denying any or all relief sought by the party in the proceeding. Additionally, for good cause, the Board may relax or suspend the filing requirements prescribed by these rules or Board order.

(o) *General NPDES permits.* (1) Persons affected by an NPDES general permit may not file a petition under this section or otherwise challenge the conditions of a general permit in further Agency proceedings. Instead, they may do either of the following:

(i) Challenge the general permit by filing an action in court; or

(ii) Apply for an individual NPDES permit under § 122.21 as authorized in § 122.28 of this chapter and may then petition the Environmental Appeals Board to review the individual permit as provided by this section.

(2) As provided in § 122.28(b)(3) of this chapter, any interested person may also petition the Director to require an individual NPDES permit for any discharger eligible for authorization to discharge under an NPDES general permit.

(p) The Environmental Appeals Board also may decide on its own initiative to review any condition of any RCRA, UIC, NPDES, or PSD permit decision issued under this part for which review is available under paragraph (a) of this section. The Environmental Appeals Board must act under this paragraph within 30 days of the service date of notice of the Regional Administrator's action.

■ 5. Paragraph (b)(1) of § 124.60 is amended by removing the reference to ''§ 124.19(f)'' in the first sentence and adding in its place ''§ 124.19(k)(2)''.

PART 270—EPA ADMINISTERED PERMIT PROGRAMS: THE HAZARDOUS WASTE PERMIT PROGRAM

■ 6. The authority citation for part 270 continues to read as follows:

Authority: 42 U.S.C. 6905, 6912, 6924, 6925, 6927, 6939, and 6974.

■ 7. Paragraph (f)(3) of § 270.42 is revised to read as follows:

§ 270.42 Permit modification at the request of permittee.

* * * * *

(f) * * *

(3) An automatic authorization that goes into effect under paragraph (b)(6)(iii) or (v) of this section may be appealed under the permit appeal procedures of 40 CFR 124.19; however, the permittee may continue to conduct the activities pursuant to the automatic authorization unless and until a final determination is made by the Environmental Appeals Board to grant review and remand the permit decision.

* * * * *

■ 8. Paragraph (a) of 270.155 is revised to read as follows:

§ 270.155 May the decision to approve or deny my RAP application be administratively appealed?

(a) Any commenter on the draft RAP or notice of intent to deny, or any participant in any public hearing(s) on the draft RAP, may appeal the Director's decision to approve or deny your RAP application to EPA's Environmental Appeals Board under § 124.19 of this chapter. Any person who did not file comments, or did not participate in any public hearing(s) on the draft RAP, may petition for administrative review only to the extent of the changes from the draft to the final RAP decision. Appeals of RAPs may be made to the same extent as for final permit decisions under § 124.15 of this chapter (or a decision under § 270.29 to deny a permit for the active life of a RCRA hazardous waste management facility or unit).

* * * * *

[FR Doc. 2013–01318 Filed 1–24–13; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 239 and 258

[EPA–R01–RCRA–2012–0944; FRL–9771–7]

Adequacy of Massachusetts Municipal Solid Waste Landfill Permit Program

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: This action approves a modification to Massachusetts's approved municipal solid waste landfill (MSWLF) program. The approved modification allows the State to issue Research, Development, and Demonstration (RD&D) Permits to owners and operators of MSWLF in accordance with its State law. On March 22, 2004, EPA issued final regulations allowing research, development, and demonstration (RD&D) permits to be issued to certain municipal solid waste landfills by approved states. On December 7, 2012 Massachusetts submitted an application to EPA Region 1 seeking Federal approval of its RD&D requirements. After thorough review EPA Region 1 is determining that Massachusetts's RD&D permit requirements are adequate through this direct final action.

DATES: This determination of RD&D program adequacy for Massachusetts will become effective April 25, 2013 without further notice unless EPA receives adverse comments on or before March 26, 2013. If adverse comments are received, EPA will review the comments and publish another **Federal Register** document responding to the comments and either affirming or revising the initial decision.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R01–RCRA–2012–0944, by one of the following methods:

- *www.regulations.gov:* Follow the on-line instructions for submitting comments.
- *Email: hsieh.juiyu@epa.gov.*
- *Fax:* (617) 918–0646, to the attention of Juiyu Hsieh.
- *Mail:* Juiyu Hsieh, RCRA Waste Management and UST Section, Office of

Site Remediation and Restoration (OSRR07–1), EPA New England—Region 1, 5 Post Office Square, Suite 100, Boston, MA 02109–3912.

• *Hand Delivery or Courier:* Deliver your comments to Juiyu Hsieh, RCRA Waste Management and UST Section, Office of Site Remediation and Restoration (OSRR07–1), EPA New England—Region 1, 5 Post Office Square, 7th floor, Boston, MA 02109–3912. Such deliveries are only accepted during the Office's normal hours of operation.

Instructions: Identify your comments as relating to Docket ID No. EPA–R01–RCRA–2012–0944. EPA's policy is that all comments received will be included in the public docket without change and may be made available online at *www.regulations.gov,* including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or claimed to be other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through *www.regulations.gov* or email. The *www.regulations.gov* Web site is an ''anonymous access'' system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an email comment directly to EPA without going through *www.regulations.gov,* your email address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD–ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses. For additional information about EPA's public docket visit the EPA Docket Center homepage at *http://www.epa.gov/epahome/dockets.htm.*

Docket: EPA has established a docket for this action under Docket ID No. EPA–R01–RCRA–2012–0944. All documents in the docket are listed on the *www.regulations.gov* Web site. Although it may be listed in the index, some information might not be publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically through *www.regulations.gov* or in hard copy at the EPA Region 1 Library, 5 Post Office Square, 1st floor, Boston, MA 02109–3912; by appointment only; tel: (617) 918–1990.

FOR FURTHER INFORMATION CONTACT: Juiyu Hsieh, Remediation and Restoration II Branch (Mail Code OSRR07–1), U.S. EPA Region 1, 5 Post Office Square, Suite 100, Boston, MA 02109, telephone: (617) 918–1646, *hsieh.juiyu@epa.gov.*

SUPPLEMENTARY INFORMATION:

A. Background

On March 22, 2004, EPA issued a final rule amending the municipal solid waste landfill criteria in 40 CFR part 258 to allow for research, development and demonstration (RD&D) permits (69 FR 13242). This rule allows for variances from specified criteria for a limited period of time, to be implemented through state-issued RD&D permits. RD&D permits are available only in states with approved MSWLF permit programs that have been modified to incorporate RD&D permit authority. While States are not required to seek approval to allow permits under this new provision, those States that are interested in providing RD&D permits to owners and operators of MSWLFs must seek approval from EPA before issuing such permits. Approval procedures for new provisions of 40 CFR part 258 are outlined in 40 CFR 239.12.

Massachusetts's MSWLF permit program was approved on July 5, 1995 (60 FR 34982). On December 7, 2012, Massachusetts submitted an application to EPA Region 1 seeking Federal approval of its RD&D project program in conformance with Federal Requirements at 40 CFR 258.4. The Massachusetts RD&D program utilizes existing State regulations at 310 C.M.R. 19.080 and 310 C.M.R. 19.062, which allow the State to issue variances, and demonstration project permits, respectively. The State has the authority under these regulations to ensure that all federal requirements are met, by limiting the variances issued to those that are federally allowed, and by attaching conditions and requirements to any variances and permits that are issued which ensure that all federal requirements will be met. The Massachusetts Department of Environmental Protection has entered into a Memorandum of Agreement with the EPA in which it has committed to always exercise its authority to ensure that all federal requirements are met.

B. Decision

After a thorough review, EPA is determining that the Massachusetts RD&D permit provisions are adequate to comply with the Federal criteria as set out in 40 CFR 258.4.

C. Statutory and Executive Order Reviews

This action approves State solid waste requirements pursuant to Resource Conversation and Recovery Act (RCRA) Section 4005 and imposes no Federal requirements. Therefore, this rule complies with applicable executive orders and statutory provisions as follows:

1. Executive Order 12866: Regulatory Planning Review—The Office of Management and Budget has exempted this action from its review under Executive Order 12866;
2. Paperwork Reduction Act: This action does not impose an information collection burden under the Paperwork Reduction Act;
3. Regulatory Flexibility Act: Since this action will not add any requirements not already imposed under State law, I certify that this action will not have a significant economic impact on a substantial number of small entities;
4. Unfunded Mandates Reform Act: Because this action approves pre-existing requirement under State law and does not impose any additional enforceable duty beyond that required by State law, it does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act;
5. Executive Order 13132: Federalism—Executive Order 13132 does not apply to this action because this action will not have federalism implications (i.e., there are no substantial direct effects on States, on the relationship between the national government and States, or on the distribution of power and responsibilities between Federal and State governments);
6. Executive Order 13175: Consultation and Coordination with Indian Tribal Governments—Executive Order 13175 does not apply to this action because it will not have Tribal implications (i.e., there are no substantial direct effects on one or more Indian Tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes);

7. Executive Order 13045: Protection of Children from Environmental Health and Safety Risks—This action is not subject to Executive Order 13045 because it is not economically significant and it is not based on health or safety risks;

8. Executive Order 13211: Actions That Significantly Affect Energy Supply, Distribution, or Use: This action is not subject to Executive Order 13211 because it is not a significant regulatory action as defined in Executive Order 12866;

9. National Technology Transfer Advancement Act: This provision directs EPA to use voluntary consensus standards in its regulatory activities unless to do so would be inconsistent with applicable law or otherwise impracticable. Voluntary consensus standards are technical standards (e.g., material specifications, test methods, sampling procedures, and business practices) that are developed or adopted by voluntary consensus standards and bodies. EPA approves State programs so long as the State programs adequately meet the criteria set out in 40 CFR part 258. It would be inconsistent with applicable law for EPA, in its review of a State program, to require the use of any particular voluntary consensus standard in place of another standard that meets the 40 CFR part 258 criteria. Thus, the National Technology Transfer Advancement Act does not apply to this action;

10. Congressional Review Act: EPA will submit a report containing this action and other information required by the Congressional Review Act (5 U.S.C. 801 et seq.) to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication in the **Federal Register**.

List of Subjects

40 CFR Part 239

Environmental protection, Administrative practice and procedure, Intergovernmental relations, Waste treatment and disposal.

40 CFR Part 258

Reporting and recordkeeping requirements, Waste treatment disposal, Water pollution control.

Authority: This action is issued under the authority of section 2002, 4005 and 4010(c) of the Solid Waste Disposal Act, as amended, 42 U.S.C. 6912, 6945 and 6949(a).

Dated: January 4, 2013.

Ira W. Leighton,

Acting Regional Administrator, EPA New England, Region 1.

[FR Doc. 2013–01435 Filed 1–24–13; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R03–OAR–2012–0610; FRL–9770–6]

Approval and Promulgation of Air Quality Implementation Plans; Maryland; Reasonably Available Control Technology Requirements for Volatile Organic Compounds

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: EPA is approving a State Implementation Plan (SIP) revision submitted by the State of Maryland. These revisions pertain to the adoption of various test methods, calculations methods, work practice standards and exemptions which make Maryland Department of the Environment (MDE) regulations more consistent with EPA's Control Techniques Guidelines (CTGs) for seven source categories. These categories are: Paper, film, and foil coatings; industrial cleaning solvents; miscellaneous metal and plastic parts coatings; large appliance coatings; offset lithographic printing and letterpress printing; flat wood paneling coatings; and flexible package printing. EPA is approving these revisions to reduce volatile organic compound (VOC) emissions from these seven categories which will help Maryland attain and maintain the National Ambient Air Quality Standards (NAAQS) for ozone in accordance with the requirements of the Clean Air Act (CAA).

DATES: This final rule is effective on February 25, 2013.

ADDRESSES: EPA has established a docket for this action under Docket ID Number EPA–EPA–R03–OAR–2012–0610. All documents in the docket are listed in the *www.regulations.gov* Web site. Although listed in the electronic docket, some information is not publicly available, i.e., confidential business information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically through *www.regulations.gov* or in hard copy for public inspection during normal business hours at the Air Protection Division, U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103. Copies of the State submittal are available at the Maryland Department of the Environment, 1800 Washington Boulevard, Suite 705, Baltimore, Maryland 21230.

FOR FURTHER INFORMATION CONTACT: Christopher Cripps, (215) 814–2179, or by email at *cripps.christoher@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

On October 23, 2012 (77 FR 64787), EPA published a notice of proposed rulemaking (NPR) for the State of Maryland. The NPR proposed approval of revisions to Maryland regulations for the control of emissions of VOC from seven categories of sources covered by a CTG. The State of Maryland submitted the formal SIP revision (Revision No. 12–03) on April 4, 2012.

II. Summary of SIP Revision

On April 5, 2012, EPA received a SIP revision submittal from the Maryland Department of the Environment (MDE) which addressed sources of VOC emissions covered by EPA's CTGs for the following seven source categories: (1) Paper, film, and foil coatings; (2) industrial cleaning solvents; (3) miscellaneous metal and plastic parts coatings; (4) large appliance coatings; (5) offset lithographic printing and letterpress printing; (6) flat wood paneling coatings; and (7) flexible package printing. This SIP revision submittal included amended Regulation .04 ''Testing and Monitoring'' under COMAR 26.11.01 ''General Administrative Provisions'' (COMAR 26.11.01.04) and Regulation .02 ''Applicability, Determining Compliance, Reporting and General Requirements'' under COMAR 26.11.19 ''Volatile Organic Compounds from Specific Processes'' (COMAR 26.11.19.02). These amendments pertain to the adoption of various test methods, calculations methods, work practice standards and exemptions which make MDE's regulations more consistent with EPA's CTGs for these seven source categories.

An explanation of the CAA's reasonably available control technology (RACT) requirements for the 1997 8-hour ozone NAAQS as they apply to Maryland, the specific details of the amendments to COMAR 26.11.01.04 and COMAR 26.11.19.02 and EPA's rationale for approving this SIP revision were provided in the NPR and will not be restated here.

Only one set of comments was received during the comment period established by EPA's October 23, 2012 NPR. A summary of the comment and EPA's response is provided in Section III of this document.

III. Summary of Public Comment and EPA Response

These comments supported approving into the SIP MDE amendments to COMAR 26.11.01.04 and COMAR 26.11.19.02.

Comment:

In sum, the comments stated that these revisions to the Maryland SIP controlling VOC emissions from these seven different industries should be approved. The commenter agrees with all the amendments and stated that the ''EPA should, without question, approve all of them. The amendments made to COMAR by the MDE only make the 7 industries safer and update their practices with VOC to be more in accordance with EPA's updated CTG for them under the CAA.''

Response:

EPA appreciates the support for this action.

IV. Final Action

EPA is approving as a revision to the Maryland SIP the amendments to COMAR 26.11.01.04 and COMAR 26.11.19.02 pertaining to the adoption of various test methods, calculations methods, work practice standards and exemptions for seven CTG source categories.

V. Statutory and Executive Order Reviews

A. General Requirements

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

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

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

B. Submission to Congress and the Comptroller General

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

C. Petitions for Judicial Review

Under section 307(b)(1) of the CAA, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by March 26, 2013. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action concerning Maryland's adoption of various test methods, calculations methods, work practice standards and exemptions in accordance with CTGs for VOC RACT may not be challenged later in proceedings to enforce its requirements. (*See* section 307(b)(2).)

List of Subjects in 40 CFR Part 52

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

Dated: December 19, 2012.

W.C. Early,

Acting Regional Administrator, Region III.

40 CFR part 52 is amended as follows:

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

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

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

Subpart V—Maryland

■ 2. In § 52.1070, the table in paragraph (c) is amended by revising the entries for COMAR 26.11.01.04 and 26.11.19.02 to read as follows:

§ 52.1070 Identification of plan.

* * * * *

(c) * * *

EPA-APPROVED REGULATIONS, TECHNICAL MEMORANDA, AND STATUTES IN THE MARYLAND SIP

Code of Maryland administrative regulations (COMAR) citation	Title/subject	State effective date	EPA approval date	Additional explanation/ citation at 40 CFR 52.1100
26.11.01 General Administrative Provisions				
*	*	*	*	*
26.11.01.04	Testing and Monitoring	3/5/12	1/25/13 [*Insert page number where the document begins*].	Amended section 04C.
*	*	*	*	*
26.11.19 Volatile Organic Compounds From Specific Processes				
*	*	*	*	*
26.11.19.02	Applicability, Determining Compliance, Reporting, and General Requirements.	3/5/12	1/25/13 [*Insert page number where the document begins*].	Amended sections .02D, .02E, .02G and .02I.
*	*	*	*	*

[FR Doc. 2013–00839 Filed 1–24–13; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R01–OAR–2009–0433; EPA–R01–OAR–2012–0149; A–1–FRL–9754–6]

Approval and Promulgation of Air Quality Implementation Plans; Massachusetts and New Hampshire; Enhanced Motor Vehicle Inspection and Maintenance Program

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: EPA is approving State Implementation Plan (SIP) revisions submitted by the Commonwealth of Massachusetts and the State of New Hampshire. These revisions include regulations to update the enhanced motor vehicle inspection and maintenance (I/M) programs in Massachusetts and New Hampshire. The revised programs in Massachusetts and New Hampshire include a test and repair network for an on-board diagnostic (OBD2) testing program for model year 1996 and newer vehicles. The intended effect of this action is to approve the revised programs into the Massachusetts and New Hampshire SIPs. This action is being taken in accordance with the Clean Air Act.

DATES: This direct final rule will be effective March 26, 2013, unless EPA receives adverse comments by February 25, 2013. If adverse comments are received, EPA will publish a timely withdrawal of the direct final rule in the **Federal Register** informing the public that the rule will not take effect.

ADDRESSES: Submit your comments, identified by Docket ID Number EPA–R01–OAR–2009–0433 for comments pertaining to our approval action for Massachusetts or EPA–R01–OAR–2012–0149 for comments pertaining to our approval action for New Hampshire by one of the following methods:

1. *www.regulations.gov:* Follow the on-line instructions for submitting comments.
2. *Email: arnold.anne@epa.gov.*
3. *Fax:* (617) 918–0047.
4. *Mail:* ''Docket Identification Number EPA–R01–OAR–2009–0433 or EPA–R01–OAR–2012–0149,'' Anne Arnold, U.S. Environmental Protection Agency, EPA New England Regional Office, Office of Ecosystem Protection, Air Quality Planning Unit, 5 Post Office Square—Suite 100, (Mail code OEP05–2), Boston, MA 02109–3912.
5. *Hand Delivery or Courier.* Deliver your comments to: Anne Arnold, Manager, Air Quality Planning Unit, Office of Ecosystem Protection, U.S. Environmental Protection Agency, EPA New England Regional Office, Office of Ecosystem Protection, Air Quality Planning Unit, 5 Post Office Square—Suite 100, (Mail code OEP05–2), Boston, MA 02109–3912. Such deliveries are only accepted during the Regional Office's normal hours of operation. The Regional Office's official hours of business are Monday through Friday, 8:30 to 4:30, excluding legal holidays.

Instructions: Direct your comments to Docket ID No. EPA–R01–OAR–2009–0433 for comments pertaining to our approval action for Massachusetts or EPA–R01–OAR–2012–0149 for comments pertaining to our approval action for New Hampshire. EPA's policy is that all comments received will be included in the public docket without change and may be made available online at *www.regulations.gov,* including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit through *www.regulations.gov,* or email, information that you consider to be CBI or otherwise protected. The *www.regulations.gov* Web site is an ''anonymous access'' system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an email comment directly to EPA without going through *www.regulations.gov* your email address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD–ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

Docket: All documents in the electronic docket are listed in the

www.regulations.gov index. Although listed in the index, some information is not publicly available, i.e., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically in *www.regulations.gov* or in hard copy at Office of Ecosystem Protection, U.S. Environmental Protection Agency, EPA New England Regional Office, 5 Post Office Square—Suite 100, Boston, MA. EPA requests that if at all possible, you contact the contact listed in the **FOR FURTHER INFORMATION CONTACT** section to schedule your inspection. The Regional Office's official hours of business are Monday through Friday, 8:30 to 4:30, excluding legal holidays.

In addition, copies of the state submittal and EPA's technical support document are also available for public inspection during normal business hours, by appointment at the respective State Air Agency: Division of Air Quality Control, Department of Environmental Protection, One Winter Street, 8th Floor, Boston, MA 02108; and Air Resources Division, Department of Environmental Services, 6 Hazen Drive, P.O. Box 95, Concord, NH 03302–0095.

FOR FURTHER INFORMATION CONTACT: Ariel Garcia, Air Quality Planning Unit, U.S. Environmental Protection Agency, EPA New England Regional Office, 5 Post Office Square, Suite 100 (mail code: OEP05–2), Boston, MA 02109–3912, telephone number (617) 918–1660, fax number (617) 918–0660, email *garcia.ariel@epa.gov.*

SUPPLEMENTARY INFORMATION: Throughout this document whenever ''we,'' ''us,'' or ''our'' is used, we mean EPA.

Organization of this document. The following outline is provided to aid in locating information in this preamble.

I. Background and Purpose
II. What are the Clean Air Act requirements for I/M programs?
III. What are the OBD2 requirements and how do Massachusetts' and New Hampshire's programs address these requirements?
IV. What are all the other I/M regulatory requirements and how do Massachusetts' and New Hampshire's I/M programs satisfy these requirements?
A. Applicability
B. Enhanced I/M Performance Standard
C. Network Type and Program Evaluation
D. Adequate Tools and Resources
E. Test Frequency and Convenience
F. Vehicle Coverage
G. Test Procedures and Standards
H. Test Equipment
I. Quality Control
J. Waivers and Compliance via Diagnostic Inspection
K. Motorist Compliance Enforcement
L. Motorist Compliance Enforcement Program Oversight
M. Quality Assurance
N. Enforcement Against Contractors, Stations, and Inspectors
O. Data Collection, Analysis, and Reporting
P. Inspector Training and Licensing or Certification
Q. Public Information and Consumer Protection
R. Improving Repair Effectiveness
S. Compliance With Recall Notices
T. On-Road Testing
U. Concluding Statement
V. What additional I/M program components are being submitted into the SIPs?
VI. Final Action
VII. Statutory and Executive Order Reviews

I. Background and Purpose

On June 1, 2009, the Commonwealth of Massachusetts submitted a formal revision to its State Implementation Plan (SIP); Massachusetts later made a minor revision to that submittal on November 30, 2009.[1] On November 17, 2011, the State of New Hampshire submitted a formal revision to its SIP. These SIP revisions include regulations to update the enhanced motor vehicle inspection and maintenance (I/M) programs in Massachusetts and New Hampshire. EPA is approving Massachusetts' and New Hampshire's revised I/M programs because they are consistent with the Clean Air Act (CAA) I/M requirements and EPA's I/M regulations, and will strengthen the SIP. Specifically, the Massachusetts June 1, 2009 SIP revision includes amendments to the Massachusetts regulations 310 CMR 60.02 and 540 CMR 4.00, and other administrative and technical documentation required in a SIP submittal to address the requirements for the implementation of the motor vehicle inspection and maintenance program in Massachusetts. The New Hampshire November 17, 2011 SIP revision includes amendments to the New Hampshire regulations Saf-C 3200 and Saf-C 5800, and other administrative and technical documentation required in a SIP submittal to address the requirements for the implementation of the motor vehicle inspection and maintenance program in New Hampshire.

[1] The November 30, 2009 revision replaced the copy of the Registry of Motor Vehicles regulation 540 CMR 4.00, included as Appendix 3 of the June 1, 2009 SIP submittal, with a copy stamped by the Secretary of State.

II. What are the Clean Air Act requirements for I/M programs?

The CAA, 42 U.S.C. 7401, et seq., requires certain states to implement an enhanced I/M program to detect gasoline-fueled motor vehicles which emit excessive amounts of certain air pollutants. The enhanced I/M program is intended to help states meet federal health-based national ambient air quality standards (NAAQS) for ozone and carbon monoxide by requiring vehicles with excess emissions to have their emissions control systems repaired. Section 182 of the CAA requires I/M programs in those areas of the nation that are most impacted by carbon monoxide and ozone pollution. 42 U.S.C. 7511c. Section 184 of the CAA also created an ''Ozone Transport Region'' (OTR) and includes I/M requirements for that region. The OTR geographically includes the states from Virginia to Maine (including all of Massachusetts and New Hampshire) and the District of Columbia Consolidated Metropolitan Statistical Area. In addition, EPA promulgated I/M regulations at 40 CFR part 51 Subpart S. Depending on the severity of an area's nonattainment classification and/or geographic location within the OTR, EPA's regulation under 40 CFR 51.350 outlines the appropriate motor vehicle I/M requirements.

As a result of having areas designated nonattainment for the 1997 8-hour ozone NAAQS (see 40 CFR 81.322 for Massachusetts and 40 CFR 81.330 for New Hampshire), and by virtue of their inclusion in the OTR, Massachusetts and New Hampshire have implemented statewide enhanced vehicle emissions testing programs. Both states have operated a vehicle testing program, in some fashion, since 1999.

In 1999, as part of its comprehensive plan to improve the state's air quality, Massachusetts implemented an enhanced I/M program. The Massachusetts I/M program was first approved into the SIP on November 15, 2000 (65 FR 68898) as a limited approval and SIP strengthening measure. EPA's November 15, 2000 rulemaking describes the limited approval and the supplemental information needed in order for Massachusetts' program to be fully approved and meet the I/M requirements of the CAA. The previously SIP-approved Massachusetts I/M program consisted of a decentralized test and repair network, with minimal test-only facilities, which utilized dynamometers to test tailpipe emissions on model year 1984 and newer vehicles. Under this program,

vehicles were due for emissions inspections biennially. Since that time, the program has been modified in a number of ways. In 2004, Massachusetts implemented OBD2 testing of model year 1996 and newer vehicles. Most notable amongst all of Massachusetts' I/M program changes was the shift to an ''OBD2-testing only'' I/M program, which occurred on October 1, 2008. As of October 1, 2008, tailpipe testing conducted on a dynamometer ceased, the frequency for emissions inspections on vehicles changed from biennial to annual, and vehicles 15 model years old and older are exempt from emissions testing.

The New Hampshire I/M program was first approved into the SIP on January 10, 2001 (66 FR 1868) as a SIP strengthening measure. The January 10, 2001 SIP approval discusses the flexibility granted to New Hampshire for implementing an I/M program based on New Hampshire meeting the 1-hour ozone NAAQS. This SIP-approved New Hampshire I/M program consisted of an ''anti-tampering'' program, a visual check for proper connection of emissions control components, and the commitment for a statewide implementation of OBD2 testing on vehicles required to be equipped with OBD2 vehicle monitoring systems. Since that time, the New Hampshire I/M program has evolved into a robust decentralized I/M program consisting of a test and repair network which includes OBD2 testing of model year 1996 and newer vehicles. New Hampshire continues to operate an anti-tampering program on vehicles up to 20 years old that are not subject to an OBD2 inspection.

III. What are the OBD2 requirements and how do Massachusetts' and New Hampshire's programs address these requirements?

On April 5, 2001, EPA published in the **Federal Register** ''Amendments to Vehicle Inspection and Maintenance Program Requirements Incorporating the On-Board Diagnostics Check'' (66 FR 18156). The revised I/M rule requires that electronic checks of the OBD2 system on model year 1996 and newer OBD2-equipped motor vehicles be conducted as part of states' motor vehicle I/M programs. OBD2 is part of the sophisticated vehicle powertrain management system and is designed to detect engine and transmission problems that might cause vehicle emissions to exceed allowable limits. OBD2 requirements are a key part of this rulemaking action.

The OBD2 system monitors the status of up to 11 emission control related subsystems by performing either continuous or periodic functional tests of specific components and vehicle conditions. The first three testing categories—misfire, fuel trim, and comprehensive components—are continuous, while the remaining eight only run after a certain set of conditions has been met. The algorithms for running these eight periodic monitors are unique to each manufacturer and involve such things as ambient temperature as well as driving conditions. Most vehicles will have at least five of the eight remaining monitors (catalyst, evaporative system, oxygen sensor, heated oxygen sensor, and exhaust gas recirculation or EGR system) while the remaining three (air conditioning, secondary air, and heated catalyst) are not necessarily applicable to all vehicles. When a vehicle is scanned at an OBD2–I/M test site, these monitors can appear as either ''Ready'' (meaning the monitor in question has been evaluated, also interchangeably appears as ''Complete'' on some vehicles), ''Not Ready'' (meaning the monitor has not yet been evaluated, also interchangeably appears as ''Not Complete'' on some vehicles), or ''Unsupported'' (meaning the vehicle is not equipped with the component monitor in question and the monitor is not applicable). The monitors that are available in a certain vehicle's emission control design are referred to as being ''Supported,'' and only supported monitors need to be evaluated by the vehicle's computer to ultimately receive a ''Ready'' or ''Not Ready'' designation.

The OBD2 system is also designed to fully evaluate the vehicle's emissions control system. If the OBD2 system detects a problem that may cause vehicle emissions to exceed 1.5 times the Federal Test Procedure (FTP) standards, then the Malfunction Indicator Light (MIL) is illuminated. By turning on the MIL, the OBD2 system notifies the vehicle operator that an emissions-related fault has been detected and the vehicle should be repaired as soon as possible, thus reducing the harmful emissions contributed by that vehicle.

EPA's revised OBD2 I/M rule applies to those areas that are required to implement I/M programs under the CAA, which includes Massachusetts and New Hampshire. The revised I/M programs submitted by Massachusetts, on June 1, 2009, and New Hampshire, on November 17, 2011, both include OBD2 testing for model year 1996 and newer vehicles.

EPA's OBD2 program requires scan tool equipment to read the vehicle's built-in computer sensors in model year 1996 and newer vehicles. The OBD2–I/M check consists of two types of examinations: A visual check of the dashboard display function and status; and an electronic examination of the OBD2 computer itself. The failure criteria for OBD2 testing is any Diagnostic Trouble Code (DTC) or combination of DTCs that result in the MIL to be commanded on. A DTC is a code that indicates a malfunction in an emission control system or component which may cause emissions to increase to 1.5 times the limit due to the malfunction. Both Massachusetts and New Hampshire have incorporated this OBD2 component into their programs.

If the OBD2 scan reveals DTCs that have not commanded the MIL on, the motorist should be advised of the issue, but the vehicle should not be failed unless other non-DTC based failure criteria have been met. Vehicles may fail an inspection if the vehicle connector is missing, tampered with or otherwise inoperable, if the MIL is commanded on and is not visually illuminated, and if the MIL is commanded on for one or more DTCs as defined in the Society of Automotive Engineering (SAE) J2012 guidance document, and EPA regulations.

Vehicles are rejected from testing if the scan of the OBD2 system reveals a ''Not Ready'' code for any OBD2 component. EPA's final implementation guidance (''Performing Onboard Diagnostic System Checks as Part of a Vehicle Inspection and Maintenance Program,'' EPA 420–R–01–015, June 2001) allows states the flexibility to permit model year 1996 to 2000 vehicles with two or fewer unset readiness codes, and model year 2001 and newer with one unset readiness code to complete an OBD2–I/M inspection without being rejected. Vehicles would still fail if the MIL was commanded on or if other failure criteria were met, or be rejected from inspection if three or more unset readiness codes were encountered. If the MIL is not commanded to be illuminated the vehicle would pass the OBD2 inspection even if DTCs are present. Massachusetts' and New Hampshire's testing programs are consistent with the EPA recommended readiness failure criteria. Massachusetts' program regulations, at 310 CMR 60.02(12)(b), and New Hampshire's program regulations, at Saf-C 3222.03, require that the programs meet the OBD2 testing requirements and procedures set forth in 40 CFR 85.2222.[2]

[2] Both the Massachusetts regulation at 310 CMR 60.02(12)(b) and the New Hampshire regulation at Saf-C 3222.03 directly cite, and therefore incorporate by reference, the federal regulation at

EPA believes that for an OBD2–I/M test program to be most effective, it should be designed to allow for: (1) Real-time data link connections to a centralized testing database; (2) quality-controlled input of vehicle and owner identification information; and (3) automated generation of test reports. Massachusetts and New Hampshire have incorporated these OBD2 program elements into their I/M programs.

IV. What are all the other I/M regulatory requirements and how do Massachusetts' and New Hampshire's I/M programs satisfy these requirements?

A. Applicability

The SIP describes in detail the areas subject to the enhanced I/M SIP revision and, consistent with 40 CFR 51.372, includes the legal authority necessary to establish program boundaries. The Massachusetts I/M regulations (''Massachusetts Motor Vehicle Emissions Inspection and Maintenance Program'' at 310 CMR 60.02 and ''Annual Safety and Combined Safety and Emissions Inspection of All Motor Vehicles, Trailers, Semi-trailers and Converter Dollies'' at 540 CMR 4.00) and authorizing legislation (Massachusetts Statutes at M.G.L. c.111, sec. 142M; M.G.L. c.21A, subsec. 2(28) and 16; M.G.L. c.90, sec. 2, 7A, 7V, 7W, and 31), as well as the New Hampshire I/M regulations (''Official Motor Vehicle Inspection Requirements'' at Saf-C 3200) and authorizing legislation (New Hampshire Statutes codified at RSA 125–C:6, 260:6–b, 263:56–a, 266:1, 266:1–a, 266:5. 266:59–b, and 266:59–c), ensure that the enhanced I/M program be implemented statewide.

B. Enhanced I/M Performance Standard

Today's rulemaking discusses the I/M programs designed, in part, to meet the enhanced I/M performance standard for ozone precursors causing air quality problems in Massachusetts and New Hampshire. EPA's performance standard establishes an emission reduction target that must be met by a program in order for the SIP to be approvable. The I/M programs, as documented in the Massachusetts and New Hampshire SIP, must meet the performance standard in actual operation, with provisions for appropriate adjustments if the standard is not met.

The emissions modeling conducted as part of the performance standard evaluation in the I/M SIP submittals illustrates that the new Massachusetts and New Hampshire I/M programs are more stringent than the federally required performance standard, and more stringent than the previous I/M programs approved into the SIP. Thus, both SIP submittals satisfy the anti-backsliding requirements of CAA section 110(l).

Both Massachusetts' and New Hampshire's I/M SIP submittals include the appropriate MOBILE6 vehicle emissions modeling demonstration [3] considering the required performance standard and the actual program being implemented statewide in each state. Massachusetts's submittal also includes a comparison to the previously SIP-approved program that Massachusetts is no longer implementing. The modeling runs for Massachusetts included evaluations of 2009 through 2012, and an out year of 2018 compliance dates and the modeling runs for New Hampshire considered evaluations with 2007, 2009, and an out year of 2015 compliance dates. Both Massachusetts and New Hampshire have demonstrated that reductions from the updated program are greater than those achieved by the pre-existing I/M program and the EPA performance standard. The MOBILE6 modeling performed by Massachusetts and New Hampshire reflects the fact that both states conduct OBD2 testing of all gasoline powered model year 1996 and newer vehicles. For Massachusetts, the MOBILE6 modeling appropriately reflects the fact that Massachusetts conducts annual emissions testing on vehicles up to 15 years old. The MOBILE6 modeling performed by New Hampshire also shows that the State operates an anti-tampering program on vehicles up to 20 years old that are not subject to OBD2 testing. However, in the first year of analysis (2009 for Massachusetts and 2007 for New Hampshire), both Massachusetts' and New Hampshire's MOBILE6 analyses of the updated I/M programs, show a minimal increase in emissions. The minimal emissions increase can be attributed to the limitations of the MOBILE6 model. Vehicle testing requirements are included in 310 CMR 60.02 for Massachusetts and Saf-C 3200 for New Hampshire, and details of meeting the performance standard are included in section 2 of the narrative of each state's SIP submittal.

C. Network Type and Program Evaluation

Under the CAA and EPA's I/M rule, the SIP must include a description of the network to be employed and the required legal authority. Also, for enhanced I/M areas, the SIP needs to include a description of the evaluation schedule and protocol, the sampling methodology, the data collection and analysis system, the resources and personnel for evaluation and related details of the evaluation program, as well as the legal authority establishing the evaluation program.

Massachusetts' and New Hampshire's revised programs consist of a test and repair I/M network program design utilizing contractors to manage and oversee the inspection portion of the program. Both states have implemented a continuous ongoing evaluation program consistent with the federal I/M rule. Both states commit to developing and submitting the annual and biennial reports described by 40 CFR 51.366 and the results of the evaluation programs are included in the annual and biennial reports. Both Massachusetts and New Hampshire have sufficient legal authority to implement this contractor managed program in concert with local inspection stations and conduct the program evaluation, as necessary to implement I/M consistent with federal requirements. Details of the network type and program evaluation are included in section 3 of each state's SIP narrative.

D. Adequate Tools and Resources

Under the CAA and EPA's I/M rule, the SIP must include a description of the resources that will be used for program operation and must discuss how the performance standard will be met, including: (1) A detailed budget plan describing the source of funds for personnel, program administration, program enforcement, purchase of necessary equipment (such as vehicles for undercover audits), and for other requirements discussed throughout the I/M rule; and (2) a description of personnel resources, the number of

40 CFR 85.2222. For purposes of the federal SIPs, EPA interprets both regulations as incorporating by reference the version of 40 CFR 85.2222 as most recently amended on April 5, 2001 (66 FR 18156), rather than prospectively incorporating any future changes to 40 CFR 85.2222.

[3] Since March 2, 2010, EPA's required model for on-road vehicle emissions modeling in SIPs is the MOtor Vehicles Emissions Simulator (MOVES) model. (See 75 FR 9411; March 2, 2010.) The Massachusetts SIP revision was submitted prior to the MOVES release date. Regarding the New Hampshire SIP revision, EPA's March 2, 2010 Notice (75 FR 9411), as well as EPA's guidance document, ''Policy Guidance on the Use of MOVES2010 and Subsequent Minor Revisions for State Implementation Plan Development, Transportation Conformity, and Other Purposes'' (EPA–420–B–12–010), allow for SIPs relying on MOBILE6.2 vehicle emissions modeling to continue to be approvable where significant work has already occurred using the MOBILE6.2 model. New Hampshire conducted the vehicle emissions modeling using MOBILE6.2 prior to the release of the MOVES model, and significant work had been conducted on the New Hampshire I/M SIP revision.

personnel dedicated to overt and covert auditing, data analysis, program administration, enforcement, and other necessary functions, and the training attendant to each function.

Massachusetts and New Hampshire operate self-funded I/M programs. Revenue from the inspection fees charged to motorists is used for all expenses associated with the administration, implementation, and enforcement of the I/M programs. Both Massachusetts and New Hampshire have adequate staff dedicated to overt and covert auditing, data analysis, program administration, enforcement, and other necessary program functions. Section 4 of each state's SIP narrative, and the attachments to the SIP narratives, describe the budget, staffing support, and equipment needed to implement the programs.

E. Test Frequency and Convenience

Under EPA's I/M rule, the SIP must include a detailed test schedule, including the test year selection scheme if testing is other than annual. The SIP must also include the legal authority necessary to implement and enforce the test frequency requirement and explain how the test frequency will be integrated with the enforcement process. In addition, in enhanced I/M programs, the SIP needs to demonstrate that the network of stations providing testing services is sufficient to ensure customer convenience by providing short waiting times for a test, and short driving distances to the test center.

The Massachusetts and New Hampshire SIP revisions require annual inspections for all subject motor vehicles. Massachusetts obtains a ''blueprint'' of the emissions-related component monitors that are available, or ''supported,'' on a particular vehicle by conducting an initial inspection after a new vehicle is registered. This ''blueprint'' snapshot is extremely helpful if the vehicle ever has any emissions-related issues in the future and concerns arise about which monitors of emissions-related components should be operating on a particular vehicle. New Hampshire's SIP revision requires the annual testing of vehicles based on the vehicle owner's month of birth. Section 5 of the SIP narratives and the contracts with the I/M program vendors include additional information for ensuring convenient testing wait times and convenient testing locations.

F. Vehicle Coverage

Under EPA's I/M rule, the SIP must include a detailed description of the number and types of vehicles to be covered by the program, and a plan for identifying subject vehicles, including vehicles that are routinely operated in the area but may not be registered in the area. Also, the SIP must include a description of any special exemptions which will be granted by the program, and an estimate of the percentage and number of vehicles granted such exemptions. Such exemptions need to be accounted for in the emission reduction analysis. In addition, the SIP needs to include legal authority necessary to implement and enforce the vehicle coverage requirement.

The Massachusetts and New Hampshire I/M programs cover all light-duty vehicles and light-duty trucks up to 8,500 pounds Gross Vehicle Weight Rating (GVWR), operating on all fuel types, as required by the federal I/M rule for enhanced programs. Massachusetts' I/M program also covers heavy-duty vehicles (heavy-duty being those vehicles with a GVWR greater than 8,500 pounds). New Hampshire's I/M program does not set requirements on any heavy-duty gas vehicles, although heavy-duty diesel vehicles with a GVWR greater than 10,000 pounds are subject to roadside testing requirements under Saf-C 5800. Additional information on the heavy-duty vehicle testing requirements in Massachusetts and New Hampshire can be found in Section V of this rulemaking notice.

In Massachusetts and in New Hampshire, light-duty vehicles and trucks that are model year 1996 and newer, operating on a fuel other than diesel fuel, are subject to an OBD2 inspection. Both states require light-duty diesel-fueled vehicles that are model year 1997 and newer, to undergo an OBD2 inspection. New Hampshire also requires vehicles up to 20 years old to be subject to New Hampshire's anti-tampering program if such vehicles are not subject to an OBD2 inspection.

Both Massachusetts and New Hampshire exempt special classes of vehicles from the emission testing programs, including: Vehicles older than 15 model years old in Massachusetts and vehicles older than 20 model years old in New Hampshire; motorcycles; assembled vehicles, reconstructed vehicles, grey market vehicles,[4] and specialty import vehicles, as appropriate; and vehicles that have been issued exemptions by EPA. Based on information provided in the SIP submittals, Massachusetts and New Hampshire have shown that such exemptions will not prevent the programs from achieving the EPA-required performance standard. Additional detail supporting this conclusion was included in section 6 of each state's SIP narrative. Legal authority for the vehicle coverage requirements in Massachusetts are contained in the Massachusetts I/M regulations (''Massachusetts Motor Vehicle Emissions Inspection and Maintenance Program'' at 310 CMR 60.02 and ''Annual Safety and Combined Safety and Emissions Inspection of All Motor Vehicles, Trailers, Semi-trailers and Converter Dollies'' at 540 CMR 4.00) and the authorizing legislation (Massachusetts Statutes at M.G.L. c.111, sec. 142M; M.G.L. c.21A, subsec. 2(28) and 16; M.G.L. c.90, sec. 2, 7A, 7V, 7W, and 31). Legal authority for the vehicle coverage requirements in New Hampshire are contained in the New Hampshire I/M regulations (''Official Motor Vehicle Inspection Requirements'' at Saf-C 3200) and the authorizing legislation (New Hampshire Statutes codified at RSA 125–C:6, 260:6–b, 263:56–a, 266:1, 266:1–a, 266:5. 266:59–b, and 266:59–c).

G. Test Procedures and Standards

Under EPA's I/M rule, the SIP must include a description of each test procedure used. The SIP also must include the rule, ordinance, or law describing and establishing the test procedures. The Massachusetts and New Hampshire I/M SIP revisions and associated regulations obligate each state to perform OBD2 testing on all 1996 and newer vehicles, in accordance with EPA procedures. A vehicle which cannot be tested using OBD2, due to known issues with readiness monitors or lack of electronic communication, will be subject to alternative test procedures, consisting primarily of a visual bulb check to ensure the MIL is not illuminated. Both Massachusetts' and New Hampshire's OBD2 testing procedures are based on the testing procedures established by EPA for light duty vehicles in 40 CFR 85.2222. Details of the test procedures and standards are included each state's I/M regulations and in Section 7 of each state's SIP narrative.

H. Test Equipment

Under EPA's I/M rule, the SIP must include written technical specifications for all test equipment used in the program and address each of the requirements set forth at 40 CFR 51.358. The specifications must describe the emission analysis process, the necessary test equipment, the required features, and written acceptance testing criteria and procedures.

[4] Grey Market Vehicles being vehicles manufactured for use in a foreign country.

In Massachusetts' June 1, 2009 submittal and New Hampshire's November 17, 2011 submittal, both states provide written equipment specifications as contained in EPA's final implementation guidance and the appendices of EPA's I/M rule. Both SIP submittals and their appendices address the requirements in 40 CFR 51.358 and include descriptions of performance features and functional characteristics of the computerized test systems. The submittals reference 40 CFR Part 51 and 85, and are consistent with the procedures outlined in 40 CFR 85.2222 and EPA's final implementation guidance. The necessary test equipment, required features, and acceptance testing criteria are discussed in section 8 of each state's SIP narrative.

I. Quality Control

Under EPA's I/M rule, the SIP must include a description of quality control and recordkeeping procedures. The SIP also must include the procedures manual, rule, and ordinance or law describing and establishing quality control procedures and requirements.

Both the Massachusetts and New Hampshire I/M SIP narratives, as well as each state's program contract, contain descriptions and requirements establishing the quality control procedures in accordance with the federal I/M rule and EPA's final implementation guidance. These requirements will help ensure that equipment calibrations are properly performed and recorded and that the necessary compliance document security is maintained. As described in section 9 of each state's SIP narrative, the Massachusetts and New Hampshire SIPs comply with all specifications for quality control set forth in Section 51.359 and Appendix A of the federal I/M rule, and EPA's final implementation guidance.

J. Waivers and Compliance via Diagnostic Inspection

Under EPA's I/M rule, the SIP must include a maximum waiver rate expressed as a percentage of initially failed vehicles. This waiver rate is used for estimating emission reduction benefits in the modeling analysis. Corrective action must be taken if the waiver rate exceeds that estimated in the SIP, or a state must revise its SIP and claim emission reductions accordingly. The SIP also must describe the waiver criteria and procedures, including cost limits, quality assurance methods and measures, and administration. Lastly, the SIP must include the necessary legal authority, ordinance(s), or rules to issue waivers, set and adjust cost limits as required, and carry out any other functions necessary to administer the waiver system, including enforcement of the waiver provisions.

Cost limits for the minimum expenditure waivers must be in accordance with the CAA and the federal I/M rule. According to federal requirements, expenditures of at least $450 for actual, non-tampering related repairs, must be spent in order to qualify for a waiver in an enhanced I/M program; this amount shall be adjusted annually according to changes in the Consumer Price Index as specified in 40 CFR 51.360(a)(7). Massachusetts regulations at 310 CMR 60.02(17)(c)(8) allow for waivers to be issued which meet minimum repair expenditures ranging from $550 to $750 depending on the vehicle model year. Massachusetts intends to annually update the cost to receive a waiver from the emissions testing program in accordance with federal requirements. New Hampshire does not issue conventional repair waivers. However, an economic hardship time extension as allowed under EPA's rule, is also allowed in the Massachusetts and New Hampshire programs. Massachusetts and New Hampshire have demonstrated that they can meet the enhanced I/M performance standard testing with the current program design in each state.

The Massachusetts and New Hampshire programs include waiver rates of 1.0% and 0.5%, respectively, of initially failed vehicles. These waiver rates are used in the modeling demonstration. Massachusetts' and New Hampshire's SIP submittals essentially commit that, if the waiver rates determined by each state's I/M program reports are higher than the aforementioned waiver rates (1.0% for Massachusetts and 0.5% for New Hampshire), the state will take corrective action to address the deficiency. Both states' SIPs describe the types of waivers that will be allowed, minimum expenditure waivers and/or economic hardship time extensions. These issues are dealt with in a manner consistent with the federal I/M rule. The proper criteria, procedures, quality assurance and administration regarding the issuance of waivers, consistent with EPA's I/M rule, will be ensured by each state and their I/M program contractor and are detailed in section 10 of each state's SIP narrative and the state's regulations: Massachusetts at 310 CMR 60.02(16) through 60.02(19) and New Hampshire at Saf-C 3222.08.

K. Motorist Compliance Enforcement

Under EPA's I/M rule, the SIP must provide information concerning motorist enforcement, including: (1) A description of the existing compliance mechanism if it will continue to be used for the program, and the demonstration that it is as effective, or more effective, than registration denial enforcement; (2) an identification of the agencies responsible for performing each of the applicable activities in this section; (3) a description of, and accounting for, all classes of exempt vehicles; and (4) a description of the plan for testing fleet vehicles, and any other special classes of subject vehicles, such as those operated (but not necessarily registered) in the program area. Also, a SIP must include a determination of the current compliance rate based on a study of the system including an estimate of compliance losses due to loopholes, counterfeiting, and unregistered vehicles. Estimates of the effect of closing such loopholes and otherwise improving the enforcement mechanism must be supported with detailed analyses. In addition, the SIP needs to include the legal authority to implement and enforce the program. Lastly, the SIP must include a commitment to an enforcement level and minimum compliance level used for modeling purposes and to be maintained, at a minimum, in practice.

Massachusetts and New Hampshire both have chosen to use a registration suspension program which suspends the vehicle registration of a vehicle that fails to meet emission testing requirements. The motorist compliance enforcement program will be implemented primarily by the state agencies charged with implementing the I/M program in their respective states. However, state police and local law enforcement can provide citations for vehicles not complying with the I/M program. The enforcement strategy is described in each state's submittal. The enforcement strategy is designed to ensure a high rate of compliance. Those not receiving the emissions test as scheduled will be subject to fines and late penalties, and also will have their vehicle registrations suspended. Both Massachusetts and New Hampshire have over a 96 percent program compliance rate with the emissions inspection program. The legal authority to implement and enforce the program is included in each state's law and in the state agency regulations as submitted in the respective SIP submittals. (Massachusetts regulations at 540 CMR 4.07(4), authority at MGL c.90, sec. 2 and sec. 22; New Hampshire

authority at RSA 266:1, RSA 266:5, and RSA 263:56–a). Additional detail of the motorist compliance enforcement program is included in section 11 of each state's SIP narrative.

L. Motorist Compliance Enforcement Program Oversight

Under EPA's I/M rule, the SIP must include a description of enforcement program oversight and information management activities.

The Massachusetts and New Hampshire I/M SIP revisions provide for regular auditing of each state's enforcement program and adherence to effective management practices, including adjustments to improve the programs when necessary. These program oversight and information management activities are described in each state's SIP narrative, and include a description of the emissions testing databases of each state's programs (the Automated Licensing and Registration System, ALARS, in Massachusetts and the New Hampshire OBD and Safety Testing, NHOST, program testing and reporting system in New Hampshire). If a vehicle is out of compliance with the emissions testing requirement, registration is suspended. Each state's SIP describes the procedures to be followed in identifying noncomplying vehicles, along with appropriate follow-up and program documentation audits in sections 11 and 12 of their SIP narratives.

M. Quality Assurance

Under EPA's I/M rule, the SIP must include a description of the quality assurance program, and written procedure manuals covering both overt and covert performance audits, record audits, and equipment audits.

The June 1, 2009 Massachusetts submittal and the November 17, 2011 New Hampshire submittal include a description of each respective state's quality assurance program. The quality assurance programs will include overt and covert performance audits, digital audits on station and inspector performance, and equipment audits. New Hampshire does not currently have an official covert audit program that utilizes vehicles pre-set to pass or fail an emissions test. However, New Hampshire places emphasis on sophisticated electronic analyses to evaluate station and inspector performance by identifying anomalies and irregularities; law enforcement officers auditing a station and/or inspector that has been identified by the digital audit, begin by essentially conducting covert visual audits and then proceed to audit that stations and certified inspectors are following the inspection requirements. Both Massachusetts and New Hampshire cover all of their respective program's inspection stations with the implemented quality assurance plans and conduct overt and/or covert audits, both in response to customer complaints and as targeted follow-up. Detailed quality assurance/quality control (QA/QC) procedures are included in each state's SIP submittal at section 13 of the SIP narratives and in the inspection program contract agreements.

N. Enforcement Against Contractors, Stations, and Inspectors

Under EPA's I/M rule, the SIP must include a penalty schedule and legal authority for establishing and imposing penalties, civil fines, station and inspector license suspension, and revocations. In the case of state constitutional impediments precluding immediate authority to suspend licenses, each state's Attorney General shall furnish an official opinion within the state's SIP explaining the constitutional impediment as well as relevant case law. Each state's SIP also must describe the administrative and judicial procedures and responsibilities relevant to the enforcement process, including the agencies, courts, and jurisdictions involved; personnel to prosecute and adjudicate cases; and other aspects of the enforcement of the programs requirements, the resources to be allocated to the enforcement function, and the source of those funds. In states that are without immediate suspension authority, the SIP must demonstrate that sufficient resources, personnel, and systems are in place to meet the three-day case management requirement for violations that directly affect emission reductions.

The Massachusetts and New Hampshire I/M SIP revisions include specific penalties in its enforcement against contractors, stations, and inspectors in accordance with the federal I/M rule. Based on their SIP submittals dated June 1, 2009 for Massachusetts and dated November 17, 2011 for New Hampshire, each state's enforcement procedures can be pursued through contractual or regulatory action. Each state, through the contract that it has been authorized to enter into directly, under MGL c.111, sec. 142M and c.21A, sec. 16 for Massachusetts and under RSA 260:6–b for New Hampshire, has the authority to immediately suspend a station inspector for violations that directly affect emission reduction benefits and a variety of other violations of procedures. Details on enforcement against contractors, stations, and inspectors are found in section 14 of each state's SIP submittal narrative.

O. Data Collection, Analysis, and Reporting

Under EPA's I/M rule, the SIP must describe the types of data to be collected. EPA's I/M rule also requires that the SIP describe the procedures for data analysis and reporting to allow for monitoring and evaluation of the program.

The Massachusetts and New Hampshire I/M SIP revisions provide for collecting test data to link specific test results to specific vehicles, I/M program registrants, test sites, and inspectors. The test data and quality control data which will be collected are described in section 15 of each state's SIP narrative and I/M program vendor contract. The data will be used to generate reports concerning test data, quality assurance, quality control, enforcement, as well as necessary changes and identified weaknesses in the programs. Both Massachusetts and New Hampshire have also committed to collecting all data necessary for quality assurance and enforcement reports, as required by section 51.366 of the federal I/M rule. Details on data analysis and reporting are found in section 16 of each state's SIP narrative.

P. Inspector Training and Licensing or Certification

Under EPA's I/M rule, the SIP must include a description of the training program, the written and hands-on tests, and the licensing or certification process.

The I/M SIP submittals from Massachusetts and New Hampshire provide details on each state's respective inspector training program. Both Massachusetts' and New Hampshire's I/M SIP provides for implementation of training, licensing, and refresher programs for emission inspectors. The states' SIP and their respective inspection program contract describe the inspector training program and curriculum including written and hands-on testing. All inspectors will be required to be certified to inspect vehicles in their state's I/M program. Further details of the Inspector Training Program are included in section 17 of each state's SIP narrative.

Q. Public Information and Consumer Protection

Under EPA's I/M rule, the SIP must include a plan for consumer protection and informing the public, on an ongoing basis, of the air quality problems, the need for and benefits of a motor vehicle

inspection program, and how to find a qualified repair technician, amongst other information related to the requirements of the I/M program.

Both Massachusetts and New Hampshire have implemented a web site for their respective I/M program. Each state's Web site is designed to provide information to motorists, the general public, inspectors, and repair technicians regarding the respective state's I/M program. Both Massachusetts and New Hampshire have the ability to take in general questions and concerns, both via a telephone hotline and electronically via the Web site, and have established a mechanism by which a vehicle owner can contest the results of an inspection. Further details of the public information and consumer protection plans are included in section 18 of each state's SIP narrative and the program contract.

R. Improving Repair Effectiveness

Under EPA's I/M rule, the SIP must include a description of the technical assistance program to be implemented, a description of the procedures and criteria to be used in meeting the performance monitoring requirements of this section for enhanced I/M programs, and a description of the repair technician training resources available in the community.

In Massachusetts' June 1, 2009 and New Hampshire's November 17, 2011 submittals, each state provided additional detail and description of the technical assistance, performance monitoring, and repair technician training programs to be implemented. The SIP revisions, as detailed in section 19 of each state's SIP narrative, provide for regularly informing repair facilities about changes to the inspection program, training course schedules, common problems, and potential solutions for particular engine families, diagnostic tips, repairs, and other assistance issues. As described in the states' submittals, Massachusetts and New Hampshire have also ensured that repair technicians may utilize the telephone hotline, or the electronic inquiry system on the program Web site, with any repair questions or concerns. Performance monitoring statistics of repair facilities will be provided to motorists whose vehicles fail the I/M test, as required in enhanced I/M areas. The states have committed to ensure that adequate repair technician training exists by establishing training courses at technical schools in the area.

S. Compliance With Recall Notices

Under EPA's I/M rule, the SIP must describe, for enhanced I/M programs, the procedures used to incorporate the vehicle recall lists provided into the inspection or registration database, the quality control methods used to insure that recall repairs are properly documented and tracked, and the method (inspection failure or registration denial) used to enforce the recall requirements. EPA has not yet established a computerized database listing all recalled vehicles.

The revised Massachusetts and New Hampshire I/M SIPs will ensure that vehicles subject to enhanced I/M programs, that are included in either a voluntary emission recall or a remedial plan determination pursuant to the CAA, have had the appropriate repairs made prior to the inspection. As described in section 20 of each state's SIP narrative, the states and their contractors will implement this approach when EPA databases exist which identify vehicles that have not completed recall repairs. At that time, motorists with unresolved recall notices will be required to show proof of compliance or will be denied the opportunity for inspection.

T. On-Road Testing

Under the CAA and EPA's I/M rule, the SIP must include a detailed description of the on-road testing program required in enhanced I/M areas, including the types of testing, test limits and criteria, the number of vehicles (the percentage of the fleet) to be tested, the number of employees to be dedicated to the on-road testing effort, the methods for collecting, analyzing, utilizing, and reporting the results of on-road testing, and the portion of the program budget to be dedicated to on-road testing. Also, the SIP must include the legal authority necessary to implement the on-road testing program, including the authority to enforce off-cycle inspection and repair requirements. In addition, emission reduction credit for on-road testing programs can only be granted for a program designed to obtain significant emission reductions over and above those predicted to be achieved by other aspects of the I/M program. The SIP needs to include technical support for the claimed additional emission reductions.

The I/M SIPs submitted on June 1, 2009 by Massachusetts and on November 17, 2011 by New Hampshire, include a description of the status of an on-road testing program in section 21 of each state's SIP narrative. Massachusetts' and New Hampshire's SIPs highlight the ability for each state to implement pilot testing of remote emissions testing technologies, and will implement a full on-road testing program when the testing technology is demonstrated to be reliable. Neither Massachusetts nor New Hampshire included additional modeling credit for the on-road portion of their state inspection programs when demonstrating that EPA's performance standard was met.

U. Concluding Statement

A more detailed analysis of the Massachusetts and New Hampshire submittals and how they meet the federal requirements is contained in EPA's technical support document (TSD) prepared for this action. The TSD is available from the EPA Regional Office listed above and in the docket for this action. The criteria used to review the submitted SIP revisions are based on the requirements set forth in section 182 of the CAA and in the federal I/M regulations, 40 CFR Part 51 Subpart S. Based on these requirements, EPA developed a detailed I/M approvability checklist to be used nationally to determine if I/M programs meet the requirements of the CAA and the federal I/M rule. The checklist states the federal requirements, referenced by section of the rule, and whether the Massachusetts and New Hampshire programs meet such requirements. This checklist, the CAA, and the federal I/M regulation formed the basis for EPA's technical review. EPA has reviewed the Massachusetts and New Hampshire I/M SIP revisions submitted to EPA using the criteria stated above. The Massachusetts and New Hampshire regulations and accompanying materials contained in the SIP submittals from each state represent an acceptable plan to comply with the I/M requirements and meet all the criteria required for EPA to approve the SIP submittals. EPA's review of the materials submitted indicates that Massachusetts and New Hampshire have revised their I/M programs in accordance with the requirements of the CAA, 40 CFR Part 51, and all of EPA's technical requirements for an approvable vehicle inspection and maintenance program, including OBD2.

V. What additional I/M program components are being submitted into the SIPs?

The I/M SIPs submitted on June 1, 2009 by Massachusetts and on November 17, 2011 by New Hampshire, include a description of certain vehicle testing components that have been incorporated into each state's emissions testing program, which are not currently covered by the federal I/M rule. In this rulemaking, EPA is approving these

components into each state's respective SIP. The emissions testing requirements, vehicle coverage, testing frequency, and test procedures and standards discussed in Section V. of this rulemaking can be found at 310 CMR 60.02 and 540 CMR 4.00 for Massachusetts and Saf-C 3200 and Saf-C 5800 for New Hampshire.

Massachusetts requires non-diesel vehicles that are model year 2008 and newer, with a GVWR greater than 8,500 pounds and less than or equal to 14,000 pounds, to be subject to an OBD2 inspection. Diesel vehicles that are model year 2007 and newer, with a GVWR greater than 8,500 pounds and less than or equal to 14,000 pounds, are subject to an OBD2 inspection. All (diesel and non-diesel) heavy-duty vehicles with a GVWR greater than 14,000 pounds, are subject to an OBD2 inspection starting with model year 2010 vehicles as OBD systems are phased-in and required to be installed on the vehicles.

Diesel vehicles over 10,000 pounds GVWR that are model year 1984 and newer, are subject to Massachusetts' annual snap acceleration smoke test, the ''opacity'' test, based on the test specified by SAE J1667. In addition, Massachusetts also conducts roadside pullovers of diesel vehicles, over 10,000 pounds GVWR, registered in any state or country, and conducts opacity testing on all vehicles irrespective of age.

Massachusetts is also submitting revised testing standards, for the opacity testing conducted on those heavy-duty diesel vehicles subject to the Massachusetts opacity test, which are more stringent than those previously approved into the Massachusetts SIP. The revised opacity testing standards for Massachusetts are included at 310 CMR 60.02(12). Diesel trucks greater than 10,000 pounds GVWR: that are model year 1984 to 1990 must meet an opacity standard of 40% opacity (previous standard was 55% opacity); that are model year 1991 to 1996 must meet an opacity standard of 30% opacity (previous standard was 40%); and that are model year 1997 and newer must meet an opacity standard of 20% (previous standard was 40%). Diesel buses greater than 10,000 pounds GVWR: that are model year 1984 to 1987 must meet an opacity standard of 40% opacity (the same as previous standard); that are model year 1988 to 1993 must meet an opacity standard of 30% opacity (previous standard was 40%); and that are model year 1994 and newer must meet an opacity standard of 20% (previous standard was 30%). As stated earlier, all diesel vehicles under 14,000 pounds GVWR, are now subject to OBD2 testing; thus the opacity standards previously approved into the Massachusetts SIP for diesel vehicles under 10,000 pounds GVWR are no longer applicable. Diesel vehicles over 10,000 pounds GVWR receive an opacity test if OBD2 has not been phased-in on a particular vehicle.

New Hampshire operates a roadside pullover opacity inspection program. New Hampshire conducts opacity testing on all vehicles over 10,000 pounds GVWR, and all diesel-powered buses manufactured to carry 25 or more passengers, irrespective of age. New Hampshire's opacity testing standards are included at Saf-C 5804.08. New Hampshire exempts federal and military vehicles from opacity testing, as well as vehicles that can pass a ''quick screen'' process upon being pulled over and selected for testing. Upon being pulled over, any vehicle that can present proof of having passed an opacity test in New Hampshire, or any other state, within the previous 12 months or can present proof of having repairs to address emission violations, are exempted from testing. These non-federal exemptions do not apply if any subject vehicle appears to be emitting visible black smoke.

VI. Final Action

EPA is approving the SIP revisions submitted by the Commonwealth of Massachusetts on June 1, 2009 and November 30, 2009, as well as the SIP revision submitted by the State of New Hampshire on November 17, 2011. Each state's SIP revision contains the respective state's revised motor vehicle inspection and maintenance program regulations and associated SIP narrative. Specifically, EPA is approving the Massachusetts Department of Environmental Protection Regulation at 310 CMR 60.02 and the Massachusetts Registry of Motor Vehicles Regulation at 540 CMR 4.00. EPA is also approving the New Hampshire Department of Safety Regulations at Saf-C 3201, Saf-C 3202, Saf-C 3203, Saf-C 3204, Saf-C 3205, Saf-C 3206.04, Saf-C 3207, Saf-C 3209, Saf-C 3210, Saf-C 3218, Saf-C 3220, Saf-C 3222, Saf-C 3248, and Saf-C 5800. EPA is approving Massachusetts' and New Hampshire's revised I/M programs because they are consistent with the CAA I/M requirements and EPA's I/M regulations and they will strengthen the Massachusetts and New Hampshire SIPs.

EPA is incorporating the aforementioned rules by reference into the Massachusetts and New Hampshire SIPs, respectively, except as set forth below. Specifically, both the Massachusetts and New Hampshire programs contain enforcement provisions that detail state enforcement procedures, including administrative, civil, and criminal penalties, and administrative and judicial procedures. See 310 CMR 60.02(24)(f); NH Saf-C 3222.04(d), NH Saf-C Part 3248, NH Saf-C Part 5805. Such enforcement-related provisions are required elements of an I/M SIP under 40 CFR 51.364, and EPA is approving the provisions as meeting those requirements. However, EPA is not incorporating those provisions by reference into the EPA-approved federal regulations at 40 CFR part 52. In any federal action to enforce violations of the substantive requirements of the Massachusetts or New Hampshire I/M programs, the relevant provisions of Section 113 or 304 of the CAA, rather than state enforcement provisions, would govern. Similarly, the applicable procedures in any federal action would be the applicable federal court rules or EPA's rules for administrative proceedings at 40 CFR part 22, rather than state administrative procedures. Since the state enforcement provisions would not be applicable in a federal action, incorporating these state-only enforcement provisions into the federal regulations would have no effect. To avoid confusion to the public and regulated parties, EPA is not incorporating these provisions by reference into the EPA-approved federal regulations in the states' respective plan identifications in 40 CFR part 52. Specifically, EPA is not incorporating Massachusetts' regulation 310 CMR 60.02(24)(f) into the federal regulations at 40 CFR 52.1120(c) or 52.1167, and EPA is not incorporating New Hampshire's regulations Saf-C 3222.04(d), Saf-C Part 3248, or Saf-C Part 5805 into the federal regulations at 40 CFR 52.1520(c) or 52.1525.

The EPA is publishing this action without prior proposal because the Agency views this as a noncontroversial amendment and anticipates no adverse comments. However, in the proposed rules section of this **Federal Register** publication, EPA is publishing a separate document that will serve as the proposal to approve the SIP revision should relevant adverse comments be filed. This rule will be effective March 26, 2013 without further notice unless the Agency receives relevant adverse comments by February 25, 2013.

If the EPA receives such comments, then EPA will publish a notice withdrawing the final rule and informing the public that the rule will not take effect. All public comments received will then be addressed in a subsequent final rule based on the proposed rule. The EPA will not

institute a second comment period on the proposed rule. All parties interested in commenting on the proposed rule should do so at this time. If no such comments are received, the public is advised that this rule will be effective on March 26, 2013 and no further action will be taken on the proposed rule. Please note that if EPA receives adverse comment on an amendment, paragraph, or section of this rule and if that provision may be severed from the remainder of the rule, EPA may adopt as final those provisions of the rule that are not the subject of an adverse comment.

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

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

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

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

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by March 26, 2013. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. Parties with objections to this direct final rule are encouraged to file a comment in response to the parallel notice of proposed rulemaking for this action published in the proposed rules section of today's **Federal Register,** rather than file an immediate petition for judicial review of this direct final rule, so that EPA can withdraw this direct final rule and address the comment in the proposed rulemaking. This action may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Carbon monoxide, Incorporation by reference, Intergovernmental relations, Lead, Nitrogen dioxide, Ozone, Particulate matter, Reporting and recordkeeping requirements, Sulfur oxides, Volatile organic compounds.

Dated: November 14, 2012.

H. Curtis Spalding,

Regional Administrator, EPA New England.

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

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

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

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

Subpart W—Massachusetts

■ 2. Section 52.1120 is amended by adding paragraph (c)(137) to read as follows:

§ 52.1120 Identification of plan.

* * * * *

(c) * * *

(137) Revisions to the State Implementation Plan submitted by the Massachusetts Department of Environmental Protection on June 1, 2009 and November 30, 2009.

(i) Incorporation by reference.

(A) Regulation 310 CMR 60.02 entitled ''Massachusetts Motor Vehicle Emissions Inspection and Maintenance Program,'' effective in the Commonwealth of Massachusetts on September 5, 2008, with the exception of subsection 310 CMR 60.02(24)(f).

(B) Regulation 540 CMR 4.00 entitled ''Annual Safety and Combined Safety and Emissions Inspection of All Motor Vehicles, Trailers, Semi-trailers and Converter Dollies,'' effective in the Commonwealth of Massachusetts on September 5, 2008.

(ii) Additional materials.

(A) Letter from the Massachusetts Department of Environmental Protection, dated June 1, 2009, submitting a revision to the Massachusetts State Implementation Plan.

(B) Letter from the Massachusetts Department of Environmental Protection, dated November 30, 2009, amending the June 1, 2009 State Implementation Plan submittal.

(C) Massachusetts June 1, 2009 SIP Revision Table of Contents Item 7, ''Documentation of IM SIP Revision consistent with 42 USC Section 7511a and Section 182(c)(3)(A) of the Clean Air Act.''

■ 3. In § 52.1167, Table 52.1167 is amended by revising the entries for Regulations 310 CMR 60.02 and 540 CMR 4.00 to read as follows:

§ 52.1167 EPA-approved Massachusetts State regulations.

* * * * *

TABLE 52.1167—EPA-APPROVED MASSACHUSETTS REGULATIONS

[See notes at end of table]

State citation	Title/subject	Date submitted by State	Date approved by EPA	**Federal Register** citation	52.1120(c)	Comments/unapproved sections
*	*	*	*	*	*	*
310 CMR 60.02	Massachusetts Motor Vehicle Emissions Inspection and Maintenance Program.	6/1/09	1/25/13	[Insert **Federal Register** page number where the document begins].	137	Revises enhanced I/M test requirements to consist of "OBD2-only" testing program. Approving submitted regulation with the exception of subsection 310 CMR 60.02(24)(f).
540 CMR 4.00	Annual Safety and Combined Safety and Emissions Inspection of All Motor Vehicles, Trailers, Semi-trailers and Converter Dollies.	6/1/09	1/25/13	[Insert **Federal Register** page number where the document begins].	137	Revises requirements for inspections and enforcement of I/M program.

Notes:

1. This table lists regulations adopted as of 1972. It does not depict regulatory requirements which may have been part of the Federal SIP before this date.
2. The regulations are effective statewide unless otherwise stated in comments or title section.

Subpart EE—New Hampshire

■ 5. In § 52.1520:

■ a. The table in paragraph (c) is amended by removing the entry NHCAR, Part Saf-C 3221A and adding a new entry for Saf-C 3200 in its place, and by removing the entry for NHCAR, Part Saf-C 5800 and adding a new entry for Saf-C 5800 in its place; and

■ b. The table in paragraph (e) is amended by adding a new entry at the end of the table to read as follows:

§ 52.1520 Identification of plan.

* * * * *

(c) *EPA-approved regulations.*

EPA-APPROVED NEW HAMPSHIRE REGULATIONS

State citation	Title/subject	State effective date	EPA approval date [1]	Explanations
*	*	*	*	*
Saf-C 3200	Official Motor Vehicle Inspection Requirements.	6/22/07 and 6/20/08	1/25/13 [Insert **Federal Register** page number where the document begins].	EPA is approving submitted subsections Saf-C 3201, 3202, 3203, 3204, 3205, 3206.04, 3207.01, 3209, 3210, 3218, 3220, and 3222 (except for subsection 3222.04).
Saf-C 5800	Roadside Diesel Opacity Inspection.	1/1/99	1/25/13 [Insert **Federal Register** page number where the document begins].	Approving submitted regulation with the exception of subsection Saf-C 5805.
*	*	*	*	*

[1] In order to determine the EPA effective date for a specific provision listed in this table, consult the **Federal Register** notice cited in this column for the particular provision.

(e) *Nonregulatory.*

NEW HAMPSHIRE NON-REGULATORY

Name of non-regulatory SIP provision	Applicable geographic or non-attainment area	State submittal date/effective date	EPA-approved date [3]	Explanations

NEW HAMPSHIRE NON-REGULATORY—Continued

Name of non-regulatory SIP provision	Applicable geographic or non-attainment area	State submittal date/effective date	EPA-approved date [3]	Explanations
*	* *		* *	* *
SIP Narrative associated with New Hampshire Vehicle Inspection and Maintenance Program SIP Revision.	Statewide	11/17/2011	1/25/13 [Insert **Federal Register** page number where the document begins].	

[3] In order to determine the EPA effective date for a specific provision listed in this table, consult the **Federal Register** notice cited in this column for the particular provision.

[FR Doc. 2013–00929 Filed 1–24–13; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R07–OAR–2012–0763; FRL–9772–6]

Approval and Promulgation of Implementation Plans; State of Missouri; Control of Sulfur Emissions From Stationary Boilers

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: EPA is taking direct final action to approve revisions to the Missouri State Implementation Plan (SIP) submitted October 27, 2009. This revision adds a new rule to reduce the concentration of fine particles ($PM_{2.5}$) in the St. Louis nonattainment area by limiting sulfur dioxide (SO_2) emissions (a precursor pollutant to $PM_{2.5}$), from industrial boilers. EPA is approving this revision because it strengthens the Missouri SIP. EPA's approval of this SIP revision is being done in accordance with the requirements of the Clean Air Act (CAA).

DATES: This direct final rule will be effective March 26, 2013, without further notice, unless EPA receives adverse comment by February 25, 2013. If EPA receives adverse comment, we will publish a timely withdrawal of the direct final rule in the **Federal Register** informing the public that the rule will not take effect.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R07–OAR–2012–0763, by one of the following methods:

1. *www.regulations.gov.* Follow the on-line instructions for submitting comments.
2. *Email: bhesania.amy@epa.gov.*
3. *Mail or Hand Delivery:* Amy Bhesania, Environmental Protection Agency, Air Planning and Development Branch, 11201 Renner Boulevard, Lenexa, Kansas 66219.

Instructions: Direct your comments to Docket ID No. EPA–R07–OAR–2012–0763. EPA's policy is that all comments received will be included in the public docket without change and may be made available online at *www.regulations.gov,* including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit through *www.regulations.gov* or email information that you consider to be CBI or otherwise protected. The *www.regulations.gov* Web site is an ''anonymous access'' system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an email comment directly to EPA without going through *www.regulations.gov,* your email address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD–ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

Docket: All documents in the docket are listed in the *www.regulations.gov* index. Although listed in the index, some information is not publicly available, i.e., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy form. Publicly available docket materials are available either electronically in *www.regulations.gov* or in hard copy at the Environmental Protection Agency, Air Planning and Development Branch, 11201 Renner Boulevard, Lenexa, Kansas 66219. The Regional Office's official hours of business are Monday through Friday, 8:00 to 4:30 excluding Federal holidays. The interested persons wanting to examine these documents should make an appointment with the office at least 24 hours in advance.

FOR FURTHER INFORMATION CONTACT: Amy Bhesania, Environmental Protection Agency, Air Planning and Development Branch, 11201 Renner Boulevard, Lenexa, Kansas 66219 at (913) 551–7147, or by email at *bhesania.amy@epa.gov.*

SUPPLEMENTARY INFORMATION: Throughout this document ''we,'' ''us,'' or ''our'' refer to EPA. This section provides additional information by addressing the following questions:

Outline

I. What is being addressed in this document?
II. Have the requirements for approval of a SIP revision been met?
III. What action is EPA taking?

I. What is being addressed in this document?

EPA is approving revisions to the Missouri SIP submitted to EPA on October 27, 2009. EPA has conducted an analysis of the State's amendment, as detailed in the technical support document which is part of this docket, and has concluded that this new rule does not adversely affect the stringency of the SIP. Missouri's revision adds 10 CSR 10–5.570 *Control of Sulfur Emissions from Stationary Boilers* to the SIP. This rule reduces the concentrations of fine particles ($PM_{2.5}$) in the St. Louis nonattainment area by limiting sulfur dioxide (SO_2) emissions (a precursor pollutant to $PM_{2.5}$), from industrial boilers.

II. Have the requirements for approval of a SIP revision been met?

The state submittal has met the public notice requirements for SIP submissions in accordance with 40 CFR 51.102. The submittal also satisfied the completeness criteria of 40 CFR part 51, appendix V. In addition, as explained above and in more detail in the technical support document which is part of this docket, the revision meets the substantive SIP requirements of the CAA, including section 110 and implementing regulations.

III. What action is EPA taking?

EPA is approving the request to amend the Missouri SIP by approving the State's request to add 10 CSR 10–5.570 *Control of Sulfur Emissions from Stationary Boilers* to the SIP. EPA has determined that these changes strengthen the SIP and will not adversely impact air emissions.

We are processing this action as a direct final action because the revisions do not adversely impact air emissions, and we do not anticipate any adverse comments. Please note that if EPA receives adverse comment on part of this rule and if that part can be severed from the remainder of the rule, EPA may adopt as final those parts of the rule that are not the subject of an adverse comment.

Statutory and Executive Order Reviews

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

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

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

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

Under section 307(b)(1) of the CAA, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by March 26, 2013. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. Parties with objections to this direct final rule are encouraged to file a comment in response to the parallel notice of proposed rulemaking for this action published in the proposed rules section of today's **Federal Register**, rather than file an immediate petition for judicial review of this direct final rule, so that EPA can withdraw this direct final rule and address the comment in the proposed rulemaking. This action may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Particulate matter, Reporting and recordkeeping requirements, Sulfur oxides.

Dated: January 9, 2013.

Karl Brooks,

Regional Administrator, Region 7.

Chapter I, title 40 of the Code of Federal Regulations is amended as follows:

PART 52—[APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS]

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

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

Subpart AA—Missouri

■ 2. In § 52.1320 the table in paragraph (c) is amended by adding new entry 10–5.570 to read as follows:

§ 52.1320 Identification of plan.

* * * * *

(c) * * *

EPA-APPROVED MISSOURI REGULATIONS

Missouri citation	Title	State effective date	EPA approval date	Explanation
Missouri Department of Natural Resources				
* * *	*	*	*	*
Chapter 5—Air Pollution Control Regulations for the St. Louis Metropolitan Area				
* * *	*	*	*	*
10–5.570	*Control of Sulfur Emissions from Stationary Boilers.*	09/30/09	01/25/13 [*insert* **Federal Register** *page number where the document begins*].	
* * *	*	*	*	*

* * * * *

[FR Doc. 2013–01459 Filed 1–24–13; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R09–OAR–2012–0611; FRL–9755–9]

Revisions to the California State Implementation Plan, South Coast Air Quality Management District

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: EPA is finalizing approval of revisions to the South Coast Air Quality Management District (SCAQMD) portion of the California State Implementation Plan (SIP). These revisions were proposed in the **Federal Register** on September 19, 2012 and concern lead emissions from large lead-acid battery recycling facilities. We are approving a local rule that regulates these emission sources under the Clean Air Act as amended in 1990 (CAA or the Act).

DATES: This rule is effective on February 25, 2013.

ADDRESSES: EPA has established docket number EPA–R09–OAR–2011–0611 for this action. Generally, documents in the docket for this action are available electronically at *http://www.regulations.gov* or in hard copy at EPA Region IX, 75 Hawthorne Street, San Francisco, California. While all documents in the docket are listed at *http://www.regulations.gov,* some information may be publicly available only at the hard copy location (e.g., copyrighted material, large maps, multi-volume reports), and some may not be available in either location (e.g., confidential business information (CBI)). To inspect the hard copy materials, please schedule an appointment during normal business hours with the contact listed in the **FOR FURTHER INFORMATION CONTACT** section.

FOR FURTHER INFORMATION CONTACT: Adrianne Borgia, EPA Region IX, (415) 972–3576, *borgia.adrianne@epa.gov.*

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

Table of Contents

I. Proposed Action
II. Public Comments and EPA Responses
III. EPA Action
IV. Statutory and Executive Order Reviews

I. Proposed Action

On September 19, 2012 (77 FR 58076), EPA proposed to approve the following rule into the California SIP.

Local agency	Rule No.	Rule Title	Adopted	Submitted
SCAQMD	1420.1	Emissions Standard For Lead From Large Lead-Acid Battery Recycling Facilities.	11/5/10	9/27/11

We proposed to approve this rule because we determined that it complies with the relevant CAA requirements. Our proposed action contains more information on the rules and our evaluation.

II. Public Comments and EPA Responses

EPA's proposed action provided a 30-day public comment period. During this period, we received no relevant comments.

III. EPA Action

No comments were submitted that change our assessment that the submitted rule complies with the relevant CAA requirements. Therefore, as authorized in section 110(k)(3) of the Act, EPA is fully approving this rule into the California SIP.

IV. Statutory and Executive Order Reviews

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

- Is not a ''significant regulatory action'' subject to review by the Office of Management and Budget under Executive Order 12866 (58 FR 51735, October 4, 1993);
- Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- Is certified as not having a significant economic impact on a

substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);

• Does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);

• Does not have Federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);

• Is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);

• Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);

• Is not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the Clean Air Act; and

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

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

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

List of Subjects in 40 CFR Part 52

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

Dated: November 6, 2012.

Jared Blumenfeld,

Regional Administrator, Region IX.

Part 52, Chapter I, Title 40 of the Code of Federal Regulations is amended as follows:

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

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

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

Subpart F—California

■ 2. Section 52.220 is amended by adding paragraph (c)(404)(i)(A)(*2*) to read as follows:

§ 52.220 Identification of plan.

* * * * *

(c) * * *

(404) * * *

(i) * * *

(A) * * *

(*2*) Rule 1420.1, ''Emissions Standard For Lead From Large Lead-Acid Battery Recycling Facilities,'' adopted on November 5, 2010.

* * * * *

[FR Doc. 2013–01449 Filed 1–24–13; 8:45 am]

BILLING CODE P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 52 and 81

[EPA–R04–OAR–2011–0043; FRL–9771–2]

Approval and Promulgation of Implementation Plans and Designation of Areas for Air Quality Planning Purposes; Alabama; Redesignation of the Birmingham 2006 24-Hour Fine Particulate Matter Nonattainment Area to Attainment

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: EPA is taking final action to approve a request submitted on June 17, 2010, from the State of Alabama, through the Alabama Department of Environmental Management (ADEM), Air Division, to redesignate the Birmingham fine particulate matter ($PM_{2.5}$) nonattainment area (hereafter referred to as the ''Birmingham Area'' or ''Area'') to attainment for the 2006 24-hour $PM_{2.5}$ national ambient air quality standards (NAAQS). The Birmingham 2006 24-hour $PM_{2.5}$ nonattainment area is comprised of Jefferson and Shelby Counties in their entireties and a portion of Walker County. EPA's approval of the redesignation request is based on the determination that the State of Alabama has met the criteria for redesignation to attainment set forth in the Clean Air Act (CAA or Act), including the determination that the Birmingham Area has attained the 2006 24-hour $PM_{2.5}$ NAAQS. Additionally, EPA is approving a revision to the Alabama state implementation plan (SIP) to include the 2006 24-hour $PM_{2.5}$ maintenance plan for the Birmingham Area that contains the new 2024 motor vehicle emission budgets (MVEBs) for nitrogen oxides (NO_X) and $PM_{2.5}$. This action also approves the 2009 emissions inventory submitted with the maintenance plan.

DATES: *Effective Date:* This rule will be effective February 25, 2013.

ADDRESSES: EPA has established a docket for this action under Docket Identification No. EPA–R04–OAR–2011–0043. All documents in the docket are listed on the *www.regulations.gov* Web site. Although listed in the index, some information is not publicly available, i.e., Confidential Business Information or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically through *www.regulations.gov* or in hard copy at the Regulatory Development Section, Air Planning Branch, Air, Pesticides and Toxics Management Division, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street SW., Atlanta, Georgia 30303–8960. EPA requests that if at all possible, you contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section to schedule your inspection. The Regional Office's official hours of business are Monday through Friday, 8:30 to 4:30, excluding Federal holidays.

FOR FURTHER INFORMATION CONTACT: Joel Huey, Regulatory Development Section, Air Planning Branch, Air, Pesticides and Toxics Management Division, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street SW., Atlanta, Georgia 30303–8960. Joel Huey may be reached by phone at (404) 562–9104 or via electronic mail at *huey.joel@epa.gov.*

SUPPLEMENTARY INFORMATION:

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I. What is the background for the actions?
II. What are the actions EPA is taking?
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IV. What are the effects of these actions?

V. Final Action
VI. Statutory and Executive Order Reviews

I. What is the background for the actions?

As stated in our proposed approval notice published on November 10, 2011 (76 FR 70091), this redesignation action addresses the Birmingham Area's status solely with respect to the 2006 24-hour $PM_{2.5}$ NAAQS, for which designations were finalized on November 13, 2009 (74 FR 58688). On June 17, 2010, the State of Alabama, through ADEM, submitted a request to redesignate the Birmingham Area to attainment for the 2006 24-hour $PM_{2.5}$ NAAQS and for EPA approval of the Alabama SIP revisions containing a maintenance plan for the Area. In the November 10, 2011, notice, EPA proposed to take the following three separate but related actions, some of which involve multiple elements: (1) To redesignate the Birmingham Area to attainment for the 2006 24-hour $PM_{2.5}$ NAAQS, provided EPA approves the emissions inventory submitted with the maintenance plan; (2) to approve into the Alabama SIP, under section 175A of the CAA, Alabama's 2006 24-hour $PM_{2.5}$ NAAQS maintenance plan, including the associated MVEBs; and (3) to approve, under CAA section 172(c)(3), the emissions inventory submitted with the maintenance plan. No comments were received on the proposed action. EPA is now taking final action on the three actions identified above. Additional background for today's action, and other details regarding the proposed redesignation, is set forth in EPA's November 10, 2011, proposal and is summarized below. The following information also: (1) Affirms that the most recent available ambient monitoring data continue to support this redesignation action, (2) summarizes the NO_X and $PM_{2.5}$ MVEBs for the year 2024 for the Birmingham Area, and (3) provides additional information on events that have occurred since the November 10, 2011, proposal.

With regard to the data, EPA has reviewed the most recent ambient monitoring data, which indicate that the Birmingham Area continues to attain the 2006 24-hour $PM_{2.5}$ NAAQS beyond the 3-year attainment period of 2007–2009, which was provided with Alabama's June 17, 2010, submittal and request for redesignation. As stated in EPA's November 10, 2011, proposal notice, the 3-year design values of 34 $\mu g/m^3$ for 2007–2009 and 29 $\mu g/m^3$ for 2008–2010 meet the NAAQS of 35 $\mu g/m^3$. Quality assured and certified data now in EPA's Air Quality System (AQS) for 2011 provide a 3-year design value of 27 $\mu g/m^3$ for 2009–2011. Furthermore, preliminary monitoring data for 2012 indicate that the Area is continuing to attain the 2006 24-hour $PM_{2.5}$ NAAQS. The 2012 preliminary data are available in AQS although are not yet quality assured and certified.

The MVEBs, specified in tons per day (tpd), included in the maintenance plan are as shown in Table 1 below. In the November 10, 2011, proposed action, EPA noted that the period for public comment on the adequacy of these MVEBs (as contained in Alabama's submittal) began on March 24, 2011, and closed on April 25, 2011. No comments were received during the public comment period. Through this final action, EPA is finding the 2024 NO_X and $PM_{2.5}$ MVEBs adequate for transportation conformity purposes and finalizing the approval of the budgets.

TABLE 1—BIRMINGHAM AREA $PM_{2.5}$ NO_X MVEBS

(tpd)

	$PM_{2.5}$	NO_X
2024 On-road Mobile Emissions	0.96	25.20
Safety Margin Allocated to MVEBs	0.245	23.21
2024 Conformity MVEBs	1.21	48.41

In the November 10, 2011, proposed redesignation of the Birmingham Area, EPA proposed to determine that the emission reduction requirements that contributed to attainment of the 2006 24-hour $PM_{2.5}$ standard in the nonattainment area could be considered permanent and enforceable. *See* 76 FR at 70092, 70097–70099. At the time of proposal, EPA noted that the requirements of the Clean Air Interstate Rule (CAIR),[1] which had been in place since 2005, were to be replaced, starting in 2012, by the requirements in the then recently promulgated Cross-State Air Pollution Rule (CSAPR), 76 FR 48208 (August 8, 2011). CSAPR included regulatory changes to sunset (i.e., discontinue) the CAIR requirements for control periods in 2012 and beyond. *See* 76 FR at 48322. Although Alabama's redesignation request and maintenance plan included reductions associated with CAIR, EPA proposed to approve the request based in part on the fact that CSAPR achieved similar or greater reductions in the relevant areas in 2012 and beyond. *See* 76 FR at 70092, 70097–70099. Because CSAPR requirements were expected to replace the CAIR requirements starting in 2012, EPA considered the impact of CSAPR related reductions on the Birmingham Area. On this basis, EPA proposed to determine that, pursuant to CAA section 107(d)(3)(E)(iii), the pollutant transport part of the reductions that led to attainment in the Birmingham Area could be considered permanent and enforceable. *See* 76 FR at 70092, 70097–70099.

On December 30, 2011, shortly after EPA's proposed approval of the Birmingham redesignation, the D.C. Circuit issued an order addressing the status of CSAPR and CAIR in response to motions filed by numerous parties seeking a stay of CSAPR pending judicial review. In that order, the court stayed CSAPR pending resolution of the petitions for review of that rule in *EME Homer City Generation, L.P.* v. *EPA* (No. 11–1302 and consolidated cases), also referred to as *EME Homer City.* The court also indicated that EPA was expected to continue to administer CAIR in the interim until judicial review of CSAPR was completed. Subsequently, on August 21, 2012, the D.C. Circuit issued a decision in *EME Homer City* to vacate and remand CSAPR and to keep CAIR in place. Specifically, the court ordered EPA to continue administering CAIR pending the promulgation of a valid replacement. *EME Homer City Generation, L.P.* v. *EPA,* 696 F.3d 7, 38 (D.C. Cir. 2012). The D.C. Circuit has not yet issued the final mandate in *EME Homer City* as EPA (as well as several intervenors) petitioned for rehearing *en banc,* asking the full court to review the decision. While rehearing proceedings are pending, EPA intends to act in accordance with the panel opinion in the *EME Homer City* opinion.

Subsequent to the *EME Homer City* opinion, EPA published several proposals to redesignate both particulate matter and ozone nonattainment areas to attainment. These proposals explained the legal status of CAIR and CSAPR, and provided a basis on which EPA would consider emissions reductions associated with CAIR to be permanent and enforceable for redesignation purposes, pursuant to CAA section 107(d)(3)(D)(iii). In those actions, EPA explained that in light of the August 21, 2012, order by the D.C. Circuit, CAIR remains in place and enforceable until substituted by a

[1] On May 12, 2005, EPA published CAIR, which requires significant reductions in emissions of sulfur dioxide (SO_2) and NO_X from electric generating units to limit the interstate transport of these pollutants and the ozone and fine particulate matter they form in the atmosphere. *See* 70 FR 75163. The U.S. Court of Appeals for the District of Columbia Circuit (D.C. Circuit) initially vacated CAIR, *North Carolina* v. *EPA,* 531 F.3d 896 (D.C. Cir. 2008), but ultimately remanded the rule to EPA without vacatur to preserve the environmental benefits provided by CAIR, *North Carolina* v. *EPA,* 550 F.3d 1176, 1178 (D.C. Cir. 2008).

''valid'' replacement rule. *See, e.g.,* 77 FR 69409 (November 19, 2012); 77 FR 68087 (November 15, 2012).

Alabama's June 17, 2010, SIP submittal supporting its redesignation request includes CAIR as a control measure, which became state-effective on April 3, 2007, and was approved by EPA on October 1, 2007, for the purpose of reducing SO_2 and NO_X emissions. *See* 72 FR 55659. Due to the legal status of CSAPR at the time that EPA proposed approval of Alabama's June 17, 2010, redesignation submittal, EPA was able to rely on CSAPR related reductions. EPA also recognized that the monitoring data used to demonstrate the Birmingham Area's attainment of the 2006 24-hour $PM_{2.5}$ NAAQS included reductions associated with CAIR. Due to the uncertainty regarding the legal status of CAIR when Alabama provided its submittal on June 17, 2010, the State's analysis assumed that no additional reductions in SO_2 or NO_X emissions from utilities would occur above and beyond those achieved through 2012 as a result of CAIR. To the extent that the Alabama submittal relies on CAIR reductions that occurred through 2012, the recent directive from the D.C. Circuit in *EME Homer City* ensures that the reductions associated with CAIR will be permanent and enforceable for the necessary time period for purposes of CAA section 107(d)(3)(E)(iii). EPA has been ordered by the court to develop a new rule, and the opinion makes clear that after promulgating that new rule EPA must provide states an opportunity to draft and submit SIPs to implement that rule. CAIR thus cannot be replaced until EPA has promulgated a final rule through a notice-and-comment rulemaking process; states have had an opportunity to draft and submit SIPs; EPA has reviewed the SIPs to determine if they can be approved; and EPA has taken action on the SIPs, including promulgating a Federal Implementation Plan, if appropriate. The court's clear instruction to EPA is that it must continue to administer CAIR until a ''valid replacement'' exists, and thus CAIR reductions may be relied upon until the necessary actions are taken by EPA and states to administer CAIR's replacement. Furthermore, the court's instruction provides an additional backstop; by definition, any rule that replaces CAIR and meets the court's direction would require upwind states to have SIPs that eliminate significant contributions to downwind nonattainment and prevent interference with maintenance in downwind areas.

Further, in deciding to vacate CSAPR and to require EPA to continue administering CAIR, the D.C. Circuit emphasized that the consequences of vacating CAIR ''might be more severe now in light of the reliance interests accumulated over the intervening four years.'' *EME Homer City,* 696 F.3d at 38. The accumulated reliance interests include the interests of states who reasonably assumed they could rely on reductions associated with CAIR, which brought certain nonattainment areas into attainment with the NAAQS. If EPA were prevented from relying on reductions associated with CAIR in redesignation actions, states would be forced to impose additional, redundant reductions on top of those achieved by CAIR. EPA believes this is precisely the type of irrational result the court sought to avoid by ordering EPA to continue administering CAIR. For these reasons also, EPA believes it is appropriate to allow states to rely on CAIR, and the existing emissions reductions achieved by CAIR, as sufficiently permanent and enforceable for purposes such as redesignation. Following promulgation of the replacement rule, EPA will review SIPs as appropriate to identify whether there are any issues that need to be addressed.

In light of these unique circumstances and for the reasons explained above, EPA is approving the redesignation request and the related SIP revision for Jefferson and Shelby Counties in their entireties and a portion of Walker County in Alabama, including Alabama's plan for maintaining attainment of the 2006 24-hour $PM_{2.5}$ NAAQS in the Birmingham Area. EPA continues to implement CAIR in accordance with current direction from the court, and thus CAIR is in place and enforceable and will remain so until substituted by a valid replacement rule. Alabama's SIP revision lists CAIR as a control measure, which became state-effective on April 3, 2007, and was approved by EPA on October 1, 2007, for the purpose of reducing SO_2 and NO_X emissions. The monitoring data used to demonstrate the Area's attainment of the 2006 24-hour $PM_{2.5}$ NAAQS by the April 2010 attainment deadline was impacted by CAIR.

II. What are the actions EPA is taking?

In today's rulemaking, EPA is approving: (1) A change to the legal designation of the Birmingham Area from nonattainment to attainment for the 2006 24-hour $PM_{2.5}$ NAAQS; (2) under CAA section 175A, Alabama's 2006 24-hour $PM_{2.5}$ NAAQS maintenance plan, including the associated MVEBs; and (3) under CAA section 172(c)(3), the emissions inventory submitted with the maintenance plan for the Area. The maintenance plan is designed to demonstrate that the Birmingham Area will continue to attain the 2006 24-hour $PM_{2.5}$ NAAQS through 2024. EPA's approval of the redesignation request is based on EPA's determination that the Birmingham Area meets the criteria for redesignation set forth in CAA, sections 107(d)(3)(E) and 175A, including EPA's determination that the Birmingham Area has attained the 2006 24-hour $PM_{2.5}$ NAAQS. EPA's analyses of Alabama's redesignation request, emissions inventory, and maintenance plan are described in detail in the November 10, 2011, proposed rule (76 FR 70091).

Consistent with the CAA, the maintenance plan that EPA is approving also includes 2024 NO_X and $PM_{2.5}$ MVEBs for the Birmingham Area. In this action, EPA is approving these NOx and $PM_{2.5}$ MVEBs for the Birmingham Area for the purposes of transportation conformity. For required regional emissions analysis years that involve 2024 or beyond, the applicable budgets will be the new 2024 NO_X and $PM_{2.5}$ MVEBs.

III. Why is EPA taking these actions?

EPA has determined that the Birmingham Area has attained the 2006 24-hour $PM_{2.5}$ NAAQS and has also determined that all other criteria for the redesignation of the Birmingham Area from nonattainment to attainment of the 2006 24-hour $PM_{2.5}$ NAAQS have been met. *See* CAA section 107(d)(3)(E). One of those requirements is that the Birmingham Area has an approved plan demonstrating maintenance of the 2006 24-hour $PM_{2.5}$ NAAQS. EPA is also taking final action to approve the maintenance plan for the Birmingham Area as meeting the requirements of sections 175A and 107(d)(3)(E) of the CAA. In addition, EPA is approving the new NO_X and $PM_{2.5}$ MVEBs for the year 2024 for the Birmingham Area as contained in Alabama's maintenance plan because these MVEBs are consistent with maintenance of the 2006 24-hour $PM_{2.5}$ standard in the Birmingham Area. Finally, EPA is approving the emissions inventory as meeting the requirements of section 172(c)(3) of the CAA. The detailed rationale for EPA's determinations and actions are set forth in the proposed rulemaking and in other discussion in this final rulemaking.

IV. What are the effects of these actions?

Approval of the redesignation request changes the legal designation of the Birmingham Area from nonattainment

to attainment for the 2006 24-hour $PM_{2.5}$ NAAQS. EPA is modifying the regulatory table in 40 CFR 81.301 to reflect a designation of attainment for these full and partial counties. EPA is also approving, as a revision to the Alabama SIP, Alabama's plan for maintaining the 2006 24-hour $PM_{2.5}$ NAAQS in the Birmingham Area through 2024. The maintenance plan includes contingency measures to remedy possible future violations of the 2006 24-hour $PM_{2.5}$ NAAQS and establishes NO_X and $PM_{2.5}$ MVEBs for the year 2024 for the Birmingham Area. Additionally, this action approves the emissions inventory for the Birmingham Area pursuant to section 172(c)(3) of the CAA.

V. Final Action

EPA is taking final action to approve three separate but related actions, some of which involve multiple elements: (1) The redesignation of the Birmingham Area to attainment for the 2006 24-hour $PM_{2.5}$ NAAQS; (2) under CAA section 175A, Alabama's 2006 24-hour $PM_{2.5}$ NAAQS maintenance plan, including the associated MVEBs; and (3) under CAA section 172(c)(3), the emissions inventory submitted with the maintenance plan for the Area. The 2006 24-hour $PM_{2.5}$ maintenance plan for the Birmingham Area includes the new 2024 NO_X and $PM_{2.5}$ MVEBs of 48.41 tpd and 1.21 tpd, respectively. Within 24 months from the effective date of EPA's adequacy determination, the transportation partners will need to demonstrate conformity to the new NO_X and $PM_{2.5}$ MVEBs pursuant to 40 CFR 93.104(e).[2]

VI. Statutory and Executive Order Reviews

Under the CAA, redesignation of an area to attainment and the accompanying approval of the maintenance plan under CAA section 107(d)(3)(E) are actions that affect the status of a geographical area and do not impose any additional regulatory requirements on sources beyond those required by state law. A redesignation to attainment does not in and of itself impose any new requirements, but rather results in the application of requirements contained in the CAA for areas that have been redesignated to attainment. Moreover, the Administrator is required to approve a SIP submission that complies with the provisions of the Act and applicable federal regulations. 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, EPA's role is to approve state choices, provided that they meet the criteria of the CAA. Accordingly, this action merely approves state law as meeting federal requirements and does not impose additional requirements beyond those imposed by state law. For these reasons, these actions:

- Are 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);
- Do not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- Are 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.*);
- Do 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);
- Do not have Federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- Are not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- Are not significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- Are not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the CAA; and,
- Do 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 final rule does not have tribal implications as specified by Executive Order 13175 (65 FR 67249, November 9, 2000), because the SIP is not approved to apply in Indian country located in the State, and EPA notes that it will not impose substantial direct costs on tribal governments or preempt tribal law.

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

Under section 307(b)(1) of the CAA, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by March 26, 2013. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. *See* section 307(b)(2).

List of Subjects

40 CFR Part 52

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

40 CFR Part 81

Environmental protection, Air pollution control, National parks.

Dated: January 9, 2013.

Gwendolyn Keyes Fleming,

Regional Administrator, Region 4.

40 CFR parts 52 and 81 are 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 B—Alabama

■ 2. Section 52.50(e) is amended by adding a new entry for ''2006 24-hour $PM_{2.5}$ Maintenance Plan for the Birmingham Area'' at the end of the table to read as follows:

[2] The adequacy finding becomes effective upon the date of publication of this notice in the **Federal Register**. 40 CFR 93.118(f)(2)(iii).

§ 52.50 Identification of plan.

* * * * *

(e) * * *

EPA-APPROVED ALABAMA NON-REGULATORY PROVISIONS

Name of non-regulatory SIP provision	Applicable geographic or non-attainment area	State submittal date/effective date	EPA approval date	Explanation
*	*	*	*	*
2006 24-hour $PM_{2.5}$ Maintenance Plan for the Birmingham Area.	Birmingham $PM_{2.5}$ Nonattainment Area.	6/17/10	1/25/13 [Insert citation of publication].	

PART 81—[AMENDED]

■ 3. The authority citation for part 81 continues to read as follows:

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

■ 4. In § 81.301, the table entitled ''Alabama—$PM_{2.5}$ (24-hour NAAQS)'' is amended under ''Birmingham, AL'' by revising the entries for ''Jefferson County'', ''Shelby County'', and ''Walker County (part)'' to read as follows:

§ 81.301 Alabama.

* * * * *

ALABAMA—$PM_{2.5}$ (24-HOUR NAAQS)

Designation area	Designation for the 1997 NAAQS [a]		Designation for the 2006 NAAQS [a]	
	Date [1]	Type	Date [2]	Type
Birmingham, AL:				
Jefferson County		Unclassifiable/Attainment	This action is effective 1/25/13	Attainment.
Shelby County		Unclassifiable/Attainment	This action is effective 1/25/13	Attainment.
Walker County (part). The area described by U.S. Census 2000 block group identifiers 01–127–0214–5, 01–127–0215–4, and 01–127–0216–2.		Unclassifiable/Attainment	This action is effective 1/25/13	Attainment.
*	*	*	*	*

[a] Includes Indian Country located in each county or area, except as otherwise specified.
[1] This date is 90 days after January 5, 2005, unless otherwise noted.
[2] This date is 30 days after November 13, 2009, unless otherwise noted.

* * * * *

[FR Doc. 2013–01209 Filed 1–24–13; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF COMMERCE

National Telecommunications and Information Administration

47 CFR Part 301

[Docket No. 120620177–2445–02]

RIN 0660–AA26

Relocation of and Spectrum Sharing by Federal Government Stations—Technical Panel and Dispute Resolution Boards

AGENCY: National Telecommunications and Information Administration, Commerce.

ACTION: Final rule.

SUMMARY: The National Telecommunications and Information Administration (NTIA) adopts regulations governing the Technical Panel and dispute resolution process established by Congress to facilitate the relocation of, and spectrum sharing with, U.S. Government stations in spectrum bands reallocated from Federal use to non-Federal use or to shared use. This action is necessary to ensure the timely relocation of Federal entities' spectrum-related operations and, where applicable, the timely implementation of arrangements for the sharing of radio frequencies. Specifically, this action implements certain additions and modifications to the NTIA Organization Act as amended by the Middle Class Tax Relief and Job Creation Act of 2012 (the Tax Relief Act). As required by the Tax Relief Act, this rule has been reviewed and approved by the Director of the Office of Management and Budget (OMB).

DATES: These regulations become effective February 25, 2013.

ADDRESSES: A complete set of public comments filed in response to the *Notice of Proposed Rulemaking* is available for public inspection at the Office of the Chief Counsel, National Telecommunications and Information Administration, Room 4713, U.S. Department of Commerce, 1401 Constitution Avenue NW., Washington, DC.[1] The public comments can also be viewed electronically at *http://www.ntia.doc.gov/federal-register-notice/2012/comments-technical-panel-and-dispute-resolution-board-nprm.*

FOR FURTHER INFORMATION CONTACT: Milton Brown, NTIA, (202) 482–1816.

SUPPLEMENTARY INFORMATION:

Authority: National Telecommunications and Information Administration Organization Act, 47 U.S.C. 901 *et seq.,* as amended by the Middle Class Tax Relief and Job Creation Act of 2012, Pub. L. 112–96, Title VI, Subtitle G, 126 Stat. 245 (Feb. 22, 2012) (47 U.S.C. 923(g)–(i), 928).

[1] *See* Relocation of and Spectrum Sharing by Federal Government Stations—Technical Panel and Dispute Resolution Board, *Notice of Proposed Rulemaking,* Docket No. 110627357–2209–03, 77 FR 41956 (July 17, 2012) (*NPRM*).

I. Background

The Tax Relief Act amended the NTIA Organization Act to expand the types of costs for which Federal agencies can be reimbursed from the Spectrum Relocation Fund (Fund), which the Commercial Spectrum Enhancement Act (CSEA) originally established in 2004.[2] The changes made by the Tax Relief Act permit Federal agencies to receive funds for costs associated with, among other activities, the planning for Federal Communications Commission (FCC or Commission) spectrum auctions and relocations, spectrum sharing, the use of alternative technologies, the replacement of existing equipment with state-of-the-art systems, and the research, engineering studies and economic analyses conducted in connection with spectrum sharing arrangements, including coordination with auction winners.[3] Other improvements in the statute facilitate better transparency, coordination, and predictability for bidders in FCC spectrum auctions and the ultimate winners of those auctions through, for example, a new requirement that NTIA publish the agencies' transition plans on NTIA's Web site at least 120 days before the commencement of the corresponding FCC auction, with the exception of classified and other sensitive information.[4]

In addition, the Tax Relief Act: (1) Specified the content of transition plans, following a ''common format,'' for Federal agencies; (2) established a mechanism to review the sufficiency of such plans by an expert Technical Panel; and (3) created a dispute resolution process through which disagreement that may arise over the execution, timing, or cost of transition plans can be resolved by dispute resolution boards.[5]

On July 17, 2012, NTIA published an *NPRM* in the **Federal Register**, proposing regulations to govern the operation of the Technical Panel and the workings of any dispute resolution boards that would adjudicate disputes, should any arise, between non-Federal users and Federal entities during the transition period. NTIA sought comment from the public on the proposed regulations and several issues related to implementation, and received six public comments.[6]

II. Discussion

A. Overview

NTIA adopts these regulations pursuant to paragraphs (h)(3)(D) and (i)(8) of section 113 of the NTIA Organization Act.[7] Specifically, NTIA codifies part 301 of its regulations in Title 47 of the Code of Federal Regulations. Subpart A sets forth the overall purpose for the new regulations, includes the proposed cross-reference for informational purposes, and defines certain terminology used throughout the regulations. None of the public comments addressed the proposed rule in Subpart A, which is adopted as proposed, except for non-substantive or minor changes consistent with the statutory language.

Subpart B contains regulations governing the operations of the Technical Panel established by the Tax Relief Act. Subpart C of the final regulations provides a basic framework under which fair and rapid resolution of any disputes over the execution, timing, or cost of transition plans may take place.

B. Technical Panel

Sections 301.100 through 301.130 of the final regulations cover matters related to the membership, organization, and basic operations of the Technical Panel. Most of the commenters addressed the proposals related to the qualifications of the members of the Technical Panel and potential measures to prevent delays in the commencement of FCC spectrum auctions. In response to the comments, NTIA clarifies the text of the rule to ensure that the three appointing agencies have the flexibility, consistent with the statute, to appoint members with appropriate and relevant expertise and qualifications. NTIA rejects the recommendations by some commenters to curtail the statutory deadlines for the submission or resubmission of the Federal entities' transition plans. These issues are discussed in more detail below.

Membership Qualifications. Pursuant to the statute, the Technical Panel shall be composed of three members, to be appointed as follows: (1) One member to be appointed by the Director of OMB; (2) one member to be appointed by the Assistant Secretary of Commerce for Communications and Information (Assistant Secretary); and (3) one member to be appointed by the Chairman of the FCC.[8] Each member ''shall be a radio engineer or a technical expert,'' the term of each member shall be 18 months, and no individual may serve more than one consecutive term.[9] The statute also provides that the ''members of the Technical Panel shall not receive any compensation for service on the Technical Panel.'' [10] However, if any member is also an ''employee of the agency of the official that appointed such member to the Technical Panel, compensation in the member's capacity as such an employee shall not be considered compensation under [this provision].'' [11]

NTIA also proposed that the Assistant Secretary, in consultation with OMB and the Commission, would have the discretion to require additional qualifications for one or more members of the Technical Panel to ensure their timely appointment, committed service, and efficient dispatch of business.[12] For example, depending on the nature of the Federal systems likely to be the subject of agency transition plans, NTIA proposed that the Assistant Secretary could require that the members have appropriate and up-to-date security clearances to enable access to any classified or other sensitive information. Commenters addressing the potential security clearance requirement generally supported it.[13]

NTIA proposed that the Assistant Secretary could require that one or more Technical Panel members be Federal employees as defined in 5 U.S.C. 2105(a). Several commenters argued that the regulations should not restrict membership of the Technical Panel to only Federal employees.[14] Some parties asserted that imposing such a restriction would be inconsistent with the statute

[2] *See* Middle Class Tax Relief and Jobs Creation Act of 2012, Public Law 112–96, sections 6701–6703, 126 Stat. 245 (Feb. 22, 2012) (amending, among other provisions, sections 113(g)–(i) and 118 of the NTIA Organization Act, codified at 47 U.S.C. 923 and 928). Through the CSEA, enacted in December 2004, Congress amended the NTIA Organization Act to provide, among other things, for the costs associated with relocation of Federal entities' spectrum-dependent operations to be reimbursed from the proceeds of spectrum auctions.

[3] *See* 47 U.S.C. 923(g)(3) (relocation or sharing costs defined).

[4] 47 U.S.C. 923(h)(5)–(7).

[5] 47 U.S.C. 923(h)(2), (h)(3), (i). NTIA is implementing separately other provisions regarding the consideration and protection of classified and other sensitive information contained in agency transition plans. *See* 47 U.S.C. 923(h)(7) and 929.

[6] *See* Comments of AT&T Services, Inc. (AT&T); Comments of CTIA—The Wireless Association (CTIA); Comments of Ericsson, Inc. (Ericsson); Comments of Squire Sanders (US) LLP (Squire Sanders); Comments of The Telecommunications Industry Association (TIA); Comments of T-Mobile USA, Inc. (T-Mobile).

[7] 47 U.S.C. 923(h)(3)(D), (i)(8).

[8] *See* 47 U.S.C. 923(h)(3)(B)(i).

[9] 47 U.S.C. 923(h)(3)(B)(ii), (iv).

[10] 47 U.S.C. 923(h)(3)(B)(vi).

[11] *Id.*

[12] *See NPRM* at 41958–59, 41963.

[13] *See* TIA Comments at 5 (''Additional minimal requirements not contained in the law, such as having a security clearance, seems a highly advantageous characteristic.''); T-Mobile Comments at 7 (''[T]he proposed rules appropriately allow NTIA to require members of the Technical Panel to have appropriate and current security clearances.'').

[14] *See* AT&T Comments at 6; CTIA Comments at 5; Ericsson Comments at 3; TIA Comments at 5; T-Mobile Comments at 6–8.

and that the purposes of the statute would be better served by not preemptively excluding all available expertise outside the U.S. Government.[15] AT&T and TIA argue, for example, that by excluding those outside of government, the appointing agencies would have fewer qualified candidates with relevant experience to consider.[16] T-Mobile states that ''[r]epresentatives from the private sector in general, and from potential bidders in particular, will be in the best position to determine if the information in the transition plans is sufficient for prospective spectrum holders.'' [17] Two parties suggest that the regulations should specify that at least one member of each Technical Panel be from the commercial sector and have experience with commercial networks.[18] T-Mobile notes that experts in the private sector ''regularly obtain security clearances to, for example, work as government contractors.'' [19]

NTIA disagrees with the commenting parties' characterizations regarding the proposed additional qualifications beyond the ''radio engineer or technical expert'' and security clearance requirement. It appears that the commenters misinterpreted or misunderstood the language and purpose of the proposed rule, which was prefaced with the following language: ''The Assistant Secretary, in consultation with [the Director of] OMB and the Chairman of the Commission, *may* impose additional qualifications for one or more members of the Technical Panel *as are necessary pursuant to section 113(g)(6) of the NTIA Organization Act.''* [20] The cross-referenced provision states that ''NTIA shall take such actions as necessary to ensure the timely relocation of Federal entities' spectrum-related operations from [eligible] frequencies * * * to frequencies or facilities of comparable capability and to ensure the timely implementation of arrangements for the sharing of [eligible] frequencies.'' [21] As noted above, the purpose of these additional qualifications for the panel members is to ''ensure their timely appointment, committed service, and efficient dispatch of business.'' [22] Thus, the proposed rule is consistent with the statutory scheme.

Although NTIA disagrees with the parties' statutory arguments, NTIA did not intend to preemptively exclude all qualified and available experts outside the U.S. Government to serve on the Technical Panel. Therefore, NTIA clarifies the text of the rule to ensure that the three appointing agencies have the flexibility, consistent with the statute, to appoint members with appropriate and relevant expertise and qualifications. Such expertise may relate to commercial systems and networks, but it may also include experience in national security, law enforcement, or public safety matters or Federal systems. To the extent that a panel member is from the private sector, the final rule provides that such member would have to be a ''Special Government Employee'' as defined in 18 U.S.C. 202(a), which, according to the Office of Government Ethics, is a category of Federal employees created by Congress as a way to apply certain conflict of interest requirements to certain experts, consultants, and other advisers who serve the government on a temporary basis.[23]

As required by the statute, the respective agency heads of NTIA, the FCC, and OMB appointed the initial three members of the Technical Panel.[24] For members appointed in the future to fill expired or vacant seats on the panel, NTIA plans to exercise its discretion under section 301.100(b)(2) of the rule to consider whether to add requirements based on the characteristics of the Federal and non-Federal systems that are likely to be the subject of agency transition plans for the forthcoming term.

NTIA also modified the regulations to reflect that the Assistant Secretary's appointment will be accompanied by the Secretary of Commerce's approval. This change is consistent with the Appointments Clause of the United States Constitution.[25]

Review of Transition Plans. The primary role of the Technical Panel is to review each Federal entity's transition plan and report on its sufficiency. The panel has 30 days to conduct its review and issue a report to NTIA and the submitting agency after that agency submits its plan. As NTIA observed in the *NPRM,* a potential procedural dilemma would be presented if the Technical Panel concludes that an initial plan is not sufficient.[26] The *NPRM* suggested a number of options that NTIA and the FCC could consider under these circumstances, including the possible delay of the auction start date until the agency can submit, and the Technical Panel can review, a revised transition plan.[27]

Several commenters observed that the statutory time frames provide a relatively short period for the panel to conduct its assessment of transition plans.[28] Most of the commenters urged that NTIA, to the extent possible, ensure that consideration of transition plans not delay scheduled FCC auctions, especially when a statutory deadline applies to particular auctions. The parties suggested alternative options such as requiring: (1) Direct communications or meetings between the Technical Panel and an agency during the 90-day resubmission period; (2) notification to the FCC if no resolution is possible during the resubmission period; or (3) submission

[15] *See* CTIA Comments at 5 (stating there is no requirement in the Tax Relief Act that members of the Technical Panel be Federal employees and such an outcome would result in the Panel not having any expertise outside of the Federal entities' perspective); AT&T Comments at 6 (''The statute requires only that a member be 'a radio engineer or a technical expert,' not that she be a [F]ederal employee''); Ericsson Comments at 3 (arguing the statute does not empower NTIA to add new qualification requirements, but it does allow each appointing official to determine whether to appoint a Federal employee, a state employee, or an expert from the private sector). Ericsson notes that a prior draft of the bill would have required that the appointee not be ''employed by, or a paid consultant to, any Federal or State governmental agency'' and argues that by omitting that limitation in the final version Congress removed a strict limitation on eligibility and instead gave the appointing officials the flexibility to appoint the most qualified persons, regardless of their employers. *See id.* at 3 n.8 (citing H.R. 3019, 111th Cong., 1st Sess., Sec. 2(b) (June 24, 2009)).

[16] *See* AT&T Comments at 6; TIA Comments at 4–5 (''NTIA should encourage participation from representatives with both the necessary expertise to perform their duties, but also who can remain impartial when resolving disputes between Federal and non-Federal parties.'').

[17] T-Mobile Comments at 6–7.

[18] *See* CTIA Comments at 5; T-Mobile Comments at 6.

[19] T-Mobile Comments at 7.

[20] *See NPRM* at 41963 (emphasis added).

[21] 47 U.S.C. 923(g)(6). NTIA also notes that section 6003(b)(2) of the Tax Relief Act provides the Assistant Secretary explicit authority to ''promulgate such regulations as are necessary to implement and enforce any provision of this title that is expressly required to be carried out by the Assistant Secretary.'' Public Law 112–96, Title VI, section 6003(b)(2) (47 U.S.C. 1403(b)(2)).

[22] *NPRM* at 41958.

[23] *See http://www.oge.gov/Topics/Selected-Employee-Categories/Special-Government-Employees/.*

[24] *See* 47 U.S.C. 923(h)(3)(B)(i). Although NTIA proposed in the *NPRM* that the appointing agencies could consider additional qualifications for one or more members of the Technical Panel, the Assistant Secretary did not suggest any for the initial slate of members. However, he recommended that, in light of the short timeframe under which the initial panel members had to be in place along with the exemption to the no-compensation provision contained in 47 U.S.C. 923(h)(3)(B)(vi), each agency head appoint a current Federal employee that is employed by the agency. *See* Letters from the Hon. Lawrence E. Strickling, Assistant Secretary for Communications and Information to the Hon. Jeffrey Zients, Acting OMB Director and the Hon. Julius Genachowski, FCC Chairman (Aug. 6, 2012).

[25] U.S. CONST. art. II, sec. 2, cl. 2.

[26] *See NPRM* at 41959.

[27] *Id.*

[28] *See* AT&T Comments at 5; CTIA Comments at 6–7; Ericsson Comments at 4; TIA Comments at 7; T-Mobile Comments at 3–5.

or resubmission of agency transition plans earlier than the statute's deadlines.[29]

NTIA rejects the commenters' recommendations for shortening the statutory deadlines for the submission of Federal entities' transition plans. While NTIA may employ under certain circumstances and at its discretion other suggestions to improve interactions between the Technical Panel and the agencies, no modification to the proposed rule is necessary to implement the statute's provisions on the preparation of transition plans. In order to ensure timely and focused review of transition plans by the Technical Panel, the regulations proposed in the *NPRM* and adopted herein confine the scope and content of the panel's initial and, if necessary, subsequent reports to those assessments and findings specifically required under the statute. In addition, in the event the Technical Panel's initial report concludes that the Federal entity's transition plan is insufficient, the report shall also include a description of the specific information or modifications that are necessary for the Federal entity to include in a revised transition plan. To avoid a continuous loop of back and forth between the agencies and the Technical Panel, the proposed and final regulations provide that the panel's supplemental report shall be limited to the issues identified in its initial report.

As noted in the *NPRM,* NTIA will also provide guidance to the Federal entities in the revised Annex O of the NTIA Manual and other assistance to help ensure that each initial transition plan contains the information required by the statute.[30] While it is not necessary to impose shorter deadlines on the agencies, Annex O may, for example, request that Federal entities preparing transition plans submit draft or informal versions of their plans to NTIA and the Technical Panel as early as possible to allow for a more adequate, speedy, and informal review of such plans, and to allow the Technical Panel to assess potential issues in transition plans as early as possible. NTIA, in consultation with OMB, the FCC and the Federal agencies, may implement other mechanisms to ensure the timely review of each plan. Moreover, as noted in some comments, Congress provided incentives to ensure that Federal entities promptly develop such plans, because OMB is not authorized to make any transfers from the Fund unless the eligible Federal entity's transition plan is found to be sufficient and published on NTIA's Web site.[31]

C. Dispute Resolution Boards

Subpart C of the regulations govern the workings of any dispute resolution boards upon which parties would call to facilitate the resolution of disputes, should any arise, between non-Federal users and Federal entities during the transition period regarding the ''execution, timing, or cost'' of the Federal entity's transition plan. These regulations cover matters related to the workings of a board, including the content of any request to establish a board, the associated procedures for convening it, and the dispute resolution process itself.

In light of the tight statutory deadline for resolving any disputes, as well as NTIA's general obligation to ensure timely implementation of transition plans, NTIA proposed a streamlined, practical approach to process legitimate dispute resolution requests, to set up dispute resolution boards, and to facilitate the resolution of any dispute as quickly as possible. Four commenters specifically opposed the proposal in the *NPRM* to require that a dispute resolution board issue only nonbinding recommendations.[32] Another commenter offered observations and suggestions based on its experience managing the alternative dispute resolution process as a part of the reconfiguration of the 800 MHz band by the FCC.[33] As discussed below, NTIA modifies its proposal to acknowledge that dispute resolution boards will issue binding decisions with respect to the execution, timing, and cost of transition plans submitted by Federal entities.

Dispute Resolution Board Decisions. The *NPRM* noted that the scope of a dispute resolution request and, consequently, a board's decision, is limited by the statute to matters ''regarding the execution, timing, or cost of the transition plan submitted by the Federal entity.''[34] Because the statute does not confer independent authority on a dispute resolution board to bind the parties, NTIA proposed that a board's decision take the form of specific written recommendations to NTIA, OMB, the Commission, or the parties, as applicable, to take the suitable steps or remedial actions related to the execution, timing, or cost of the Federal entity's transition plan.[35] The *NPRM,* however, noted that the statute provides that decisions of a dispute resolution board may be appealed to the United States Court of Appeals for the District of Columbia Circuit.[36]

AT&T, CTIA, Ericsson, and T-Mobile argue that the proposed rule limiting a dispute resolution board's authority to issuing non-binding recommendations is contrary to the plain language and purpose of the statute.[37] They point out that the statutory language provides that a dispute resolution board would be established to ''resolve the dispute'' and that a board must ''rule'' on any such dispute within 30 days.[38] These parties assert that because ''a decision of the dispute resolution board may be appealed to the United States Court of

[29] *See* AT&T Comments at 5 (''NTIA should either require that agencies submit their initial transition plans earlier than 240 days prior to the auction, or that they submit a revised transition plan no later than 60 days after the Technical Panel finds its initial plan insufficient.''); CTIA Comments at 6 (suggesting NTIA require agencies to submit transition plans no later than 270 days, instead of 240 days, before commencement of any auction); Ericsson Comments at 4 (arguing that NTIA should require an agency to re-file plan with an urgency so as not to delay the auction); T-Mobile Comments at 5–6.

[30] Two commenters urge NTIA to require a greater level of detail be included in agency transition plans. *See* CTIA Comments at 7 (''Technical information such as transmitter power, receiver performance, antennas used, beamwidth of antenna and other technical parameters will allow the wireless industry to determine the effect that Federal operations may have on commercial operations and will help for determination of potential interim sharing between services.''); T-Mobile Comments at 8–9 (stating that rules should specify that transition plans include the realistic costs of achieving comparable capability and an agency's assessment of how it would achieve comparable capability). Not only are these suggestions beyond the scope of what the statute requires in transition plans, these issues are beyond the scope of this rulemaking proceeding, which only addresses regulations to govern the operation of the Technical Panel and the workings of any dispute resolution boards.

[31] *See* AT&T Comments at 5; TIA Comments at 7; *see also* 47 U.S.C. 928(d)(2)(A).

[32] *See* AT&T Comments at 6; CTIA Comments at 8; Ericsson Comments at 2; T-Mobile Comments at 10–11.

[33] *See* Squire Sanders Comments at 1–3.

[34] *NPRM* at 41961 (quoting NTIA Organization Act, section 113(i)(1), 47 U.S.C. 923(i)(1)).

[35] *Id.* at 41961, 41966 (proposed sec. 301.220(e)(4)–(5)).

[36] *Id.* at 41961 (citing NTIA Organization Act, section 113(i)(7), 47 U.S.C. 923(i)(7)).

[37] *See* AT&T Comments at 6 (arguing a mere non-binding recommendation does not meet Congress' express directives that the dispute resolution board ''rule on the dispute within 30 days'' and that this ruling be appealable in Federal court); CTIA Comments at 8 (noting treatment of a board's decisions as non-binding appears inconsistent with the intent of the statute, as the U.S. Court of Appeals typically does not review non-binding recommendations); Ericsson Comments at 2 (finding the proposal to make decisions of Dispute Resolution Boards non-binding is inconsistent with the plain language of the statute); T-Mobile Comments at 10–11 (arguing the *NPRM*'s assertion that Congress did not provide the Dispute Resolution Board with ''independent authority * * * to bind the parties'' to the dispute is incorrect).

[38] *See, e.g.,* AT&T Comments at 6; Ericsson Comments at 2; T-Mobile Comments at 10 (quoting NTIA Organization Act section 113(i)(1), (i)(4), 47 U.S.C. 923(i)(1), (i)(4)).

Appeals for the District of Columbia Circuit,'' no further process at NTIA, OMB, or the FCC is required prior to a party's exercise of that appeal right and non-final recommendations would not be ripe for judicial review.[39]

After further consideration, NTIA agrees with commenters that the statute requires a board to make decisions which can be appealed to the United States Court of Appeals for the District of Columbia Circuit.[40] Accordingly, NTIA now interprets the statute as authorizing a dispute resolution board to make binding decisions with respect to disputes regarding the execution, timing, or cost of the transition plan submitted by the Federal entity. Such decisions could thus be appealed to the court.

NTIA recognizes that a binding decision may have a detrimental impact on the Federal entity's operations or services that have national security, law enforcement or public safety functions. Accordingly, NTIA will permit the board, as necessary, to request additional written submissions from an agency regarding the impact of a binding decision on the agency's operations or services that have national security, law enforcement, or public safety functions. The dispute resolution board will also ensure that any decision it reaches does not have a detrimental impact on the Federal entity's operations or services that have national security, law enforcement, or public safety functions.[41]

NTIA, however, continues to interpret the Tax Relief Act so as not to authorize a board to exercise remedial authority statutorily granted to other Federal agencies. For example, NTIA does not interpret the Tax Relief Act as allowing boards to exercise NTIA's authority to ''assign frequencies to radio stations or classes of radio stations belonging to and operated by the United States.''[42] The statute also does not authorize a board to assess damages against the U.S. Government or non-Federal users arising out of the execution, timing, or cost of a Federal entity's transition plan.

As noted in the *NPRM,* the Federal agencies that comprise a board's membership (*i.e.,* the FCC, NTIA or OMB) do, however, possess statutory authority to take actions in support of a board's decision.[43] Therefore, as NTIA proposed, a board may make recommendations as to remedies or other corrective actions to the appropriate Federal agency that has the statutory authority to take such actions based on the board's findings. The Final Rule reflects these changes.

As noted in the *NPRM,* the statute's 30-day deadline for responding to formal dispute resolution requests will likely impact a board's ability to convene, meet with the parties, and adequately address complex cases. At the same time, however, the statute encourages cooperation to assure timely transitions between Federal and non-Federal use of the spectrum. Given the incentives created by the statute, NTIA expects only a minimal number, if any, of serious conflicts to arise. If such differences do surface, however, NTIA also expects the parties to make good faith efforts to solve these problems on an informal basis before submitting a request to establish a dispute resolution board. Therefore, as proposed, the final rule provides that any formal dispute resolution request must include a summary of the parties' prior efforts and attempts to resolve the dispute through negotiation, mediation, or non-binding arbitration.

NTIA also proposed that parties requesting dispute resolution provide sufficient information, including a concise and specific statement of the factual allegations sufficient to support the relief or action requested by the party. In its comments, Squire Sanders suggests that requiring early briefing of arguments may not generate productive written materials because the parties will not have clearly defined the issues in dispute ''at the start of the mediation process,'' or will focus on collateral matters not central to the issue to be resolved.[44] Furthermore, Squire Sanders notes that where recourse to independent alternative dispute resolution mechanisms is voluntary and at the parties' own expense, most parties will not likely embrace them.[45] NTIA expects that any informal negotiation, mediation, or non-binding arbitration efforts between the parties will help clearly define and narrow the issues that are necessary to bring into the formal dispute resolution process. In addition, in light of the limited scope of disputes and the short time to resolve them, the written material addressing such issues must concern deviations from the federal entity's transition plan or factors hindering or affecting the plan's execution, timing, or cost. The Final Rule reflects these expectations and pleading requirements.

III. Procedural Matters

Executive Order 12866

This rule has been determined to be not significant under section 3(f) of Executive Order 12866. Pursuant to the Tax Relief Act, this rule has been approved by the Director of the Office of Management and Budget.

Executive Order 12372

No intergovernmental consultation with State and local officials is required because this rule is not subject to the provisions of Executive Order 12372, Intergovernmental Consultation.

Executive Order 12988

This rule has been reviewed under Executive Order 12988, Civil Justice Reform, as amended by Executive Order 13175. NTIA has determined that the rule meets the applicable standards provided in section 3 of the Executive

[39] *See, e.g.,* Ericsson Comments at 2 (citing *CTIA—The Wireless Ass'n* v. *FCC,* 530 F.3d 984 (DC Cir. 2008)); T-Mobile Comments at 10 (quoting NTIA Organization Act section 113(i)(7), 47 U.S.C. 923(i)(7)).

[40] As pointed out by two commenting parties, the right of appeal to the DC Circuit does not necessarily mean that the court will address the merits of a board's decision if, for example, the case fails to meet finality, exhaustion, ripeness and other requirements under the Administrative Procedure Act (APA). *See* Ericsson Comments at 2; T-Mobile Comments at 10–12 (and cases cited therein); *see also* Circuit Rules of the United States Court of Appeals for the District of Columbia Circuit, Title IV, ''Review or Enforcement of an Order of an Administrative Agency, Board, Commission, or Officer'' (Dec. 2011).

[41] *See* 47 U.S.C. 923(h)(2)(H). Under this provision, each transition plan must identify any factors that could ''hinder fulfillment of the transition plan by the Federal entity,'' including the extent to which any classified information will affect ''the implementation of the relocation or sharing arrangement.'' 47 U.S.C. 923(h)(7)(A)(ii). Thus, another factor that could be included in a plan would be any impact on national security, law enforcement, or public safety functions that will affect the implementation of the relocation or sharing arrangement. A board must consider this factor and any additional information that it would request from the agency.

[42] 47 U.S.C. 902(b)(2)(A).

[43] For example, OMB is authorized to transfer funds to Federal entities from the Fund subject to conditions outlined in the statute. *See, e.g.,* 47 U.S.C. 928 (authorizing OMB Director, in consultation with the NTIA and subject to four specific conditions, to make additional payments to eligible Federal entities that are implementing a transition plan in order to encourage such entities to complete the implementation more quickly). NTIA has the authority to ''assign frequencies to radio stations or classes of radio stations belonging to and operated by the United States, including the authority to amend, modify, or revoke such assignments.'' 47 U.S.C. 902(b)(2)(A); *see also* 47 U.S.C. 923(g)(6) (authorizing NTIA to terminate or limit a Federal entity's authorization upon the completion of the entity's relocation, the implementation of its sharing arrangement or its unreasonable failure to comply with the timeline for relocation or sharing). Likewise, the FCC can make decisions regarding a licensee's operating rights and determine whether it is in compliance with FCC rules or its license conditions. *See* 47 U.S.C. 312; *see also* 47 U.S.C. 309(j)(16)(C) (authorizing the FCC to grant commercial licenses in eligible frequencies prior to relocation of Federal operations and the termination of a federal entity's authorization subject to a license condition requiring that the licensee cannot cause harmful interference to Federal operations).

[44] Squire Sanders Comments at 2.

[45] *Id.* at 3.

Order, to minimize litigation, eliminate ambiguity, and reduce burden.

Executive Order 13132

This rule does not contain policies having federalism implications requiring preparations of a Federalism Summary Impact Statement.

Executive Order 12630

This rule does not contain policies that have takings implications.

Regulatory Flexibility Act

The Chief Council for Regulation of the Department of Commerce certified to the Chief Council for Advocacy of the Small Business Administration that proposed regulations, if adopted, would not have a significant economic impact on a substantial number of small entities. NTIA received no comments on this certification, which remains unchanged.

Paperwork Reduction Act

The Paperwork Reduction Act (PRA) does not apply to these regulations because NTIA is not seeking information from 10 or more members of the Public (44 U.S.C. 3502(3)), and because administrative proceedings such as those conducted by the Technical Panel and dispute resolution boards are exempt from the PRA. *See* 44 U.S.C. 3518(c)(1).

Congressional Review Act

This rule has not been determined to be major under the Congressional Review Act, 5 U.S.C. 801 *et seq.*

Unfunded Mandates

This rule contains no Federal mandates (under the regulatory provision of Title II of the Unfunded Mandates Reform Act of 1995) for State, local, and tribal governments or the private sector. Thus, this rule is not subject to the requirements of sections 202 and 205 of the Unfunded Mandates Reform Act of 1995.

National Environmental Policy Act

Because this rule is not a major Federal action significantly affecting the quality of the human environment and in accordance with the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321 *et seq.*), an Environmental Impact Statement is not required.

Government Paperwork Elimination Act

NTIA is committed to compliance with the Government Paperwork Elimination Act, which requires Government agencies to provide the public the option of submitting information or transacting business electronically to the maximum extent possible.

Lists of Subjects in 47 CFR Part 301

Administrative practice and procedure, Communications Common Carriers, Communications equipment, Defense communications, Government employees, Satellites, Radio, Telecommunications.

Lawrence E. Strickling,

Assistant Secretary for Communications and Information Administration.

■ For the reasons set forth in the preamble, NTIA amends 47 CFR chapter III by adding part 301 to read as follows:

PART 301—RELOCATION OF AND SPECTRUM SHARING BY FEDERAL GOVERNMENT STATIONS

Subpart A—General Information

Sec.
301.1 Purpose.
301.10 Cross-reference.
301.20 Definitions.

Subpart B—Technical Panel

301.100 Membership.
301.110 Organization and operations.
301.120 Reports on Agency Transition Plans.
301.130 Technical assistance To Dispute Resolution Panels.

Subpart C—Dispute Resolution Boards

301.200 Requests to resolve disputes.
301.210 Establishment and operation of Dispute Resolution Board.
301.220 Dispute resolution.

Authority: National Telecommunications and Information Administration Organization Act, 47 U.S.C. 901 *et seq.,* as amended by the Middle Class Tax Relief and Job Creation Act of 2012, Pub. L. 112–96, Title VI, Subtitle G, 126 Stat. 245 (Feb. 22, 2012) (47 U.S.C. 923(g)–(i) and 928).

Subpart A—General Information

§ 301.1 Purpose.

Sections 113(g)–(i) and 118 of the National Telecommunications and Information Administration Organization Act (hereinafter ''NTIA Organization Act''), as amended (47 U.S.C. 923(g)–(i) and 928), govern the procedures and requirements related to the relocation of and sharing by Eligible Federal Entities' spectrum-related operations in certain spectrum bands reallocated from Federal to non-Federal use or to shared use. Pursuant to these statutory provisions, Eligible Federal Entities authorized to use Eligible Frequencies are entitled to payment from the Spectrum Relocation Fund for their documented relocation or sharing costs incurred as a result of planning for an auction of such frequencies or the reallocation of such frequencies from Federal use to exclusive non-Federal use or to shared use. The purpose of this part is to implement the particular provisions that mandate the adoption of such regulations, after public notice and comment, and that primarily affect non-Federal spectrum users, including the regulations herein governing Technical Panels and Dispute Resolution Boards.

§ 301.10 Cross-reference.

The Manual of Regulations and Procedures for Federal Radio Frequency Management (hereinafter referred to as the ''NTIA Manual'') issued by the Assistant Secretary of Commerce for Communications and Information, is incorporated by reference in § 300.1 of this chapter and available online at *http://www.ntia.doc.gov/osmhome/redbook/redbook.html.* Annex O of the NTIA Manual, as revised, contains information, policies and procedures applicable to Federal agencies that implement the statutory provisions referenced in § 301.1 of this subpart with regard to such agencies that operate authorized U.S. Government stations in Eligible Frequencies and that incur relocation costs or sharing costs because of planning for an auction or the reallocation of such frequencies from Federal use to exclusive non-Federal use or to shared use. The NTIA Manual applies only to Federal agencies and does not impact the rights or obligations of the public. Accordingly, this cross reference is for information purposes only.

§ 301.20 Definitions.

Assistant Secretary means the Assistant Secretary of Commerce for Communications and Information.

Auction means the competitive bidding process through which licenses are assigned by the Commission under section 309(j) of the Communications Act of 1934 (47 U.S.C. 309(j)).

Commission means the Federal Communications Commission.

Dispute Resolution Board means any board established pursuant to section 113(i) of the NTIA Organization Act (47 U.S.C. 923(i)) and subpart C of this part.

Eligible Federal Entity means any Federal Entity that:

(1) Operates a U.S. Government station authorized to use a band of eligible frequencies; and

(2) That incurs relocation costs or sharing costs because of planning for an auction of spectrum frequencies or the reallocation of spectrum frequencies from Federal use to exclusive non-Federal use or to shared use.

Eligible frequencies means any band of frequencies reallocated from Federal

use to non-Federal use or to shared use after January 1, 2003, that is assigned by auction.

Federal Entity means any department, agency, or other instrumentality of the U.S. Government that utilizes a Government station assignment obtained under section 305 of the 1934 Act (47 U.S.C. 305).

Non-Federal user means a Commission licensee authorized to use Eligible Frequencies or a winning bidder in a Commission auction for Eligible Frequencies that has fulfilled the Commission's requirements for filing a long-form license application and remitting its final bid payment.

NTIA means the National Telecommunications and Information Administration.

NTIA Manual means the Manual of Regulations and Procedures for Federal Radio Frequency Management issued by the Assistant Secretary of Commerce for Communications and Information and incorporated by reference in § 300.1 of this chapter (47 CFR 300.1).

OMB means the Office of Management and Budget.

Technical Panel means the panel established by section 113(h)(3)(A) of the NTIA Organization Act (47 U.S.C. 923(h)(3)(A)) and governed by subpart B of this part.

Transition Plan means the plan submitted by a Federal Entity pursuant to section 113(h)(1) of the NTIA Organization Act (47 U.S.C. 923(h)(1).

Subpart B—Technical Panel

§ 301.100 Membership.

(a) *Technical Panel membership.* The Technical Panel established by section 113(h)(3)(A) of the NTIA Organization Act (47 U.S.C. 923(h)(3)(A)) shall be composed of three (3) members, to be appointed as follows:

(1) One member to be appointed by the Director of OMB;

(2) One member to be appointed by the Assistant Secretary, with the approval of the Secretary of Commerce; and

(3) One member to be appointed by the Chairman of the Commission.

(b) *Qualifications.* (1) Each member of the Technical Panel shall be a radio engineer or a technical expert.

(2) The Assistant Secretary, in consultation with the Director of OMB and the Chairman of the Commission, may impose or suggest additional qualifications for one or more members of the Technical Panel as are necessary pursuant to section 113(g)(6) of the NTIA Organization Act (47 U.S.C. 923(g)(6)), including, but not limited to, the following:

(i) The member must have the appropriate and current security clearances to enable access to any classified or other sensitive information that may be associated with or relevant to agency Transition Plans;

(ii) The member should be a Federal employee as defined in 5 U.S.C. 2105(a) or a Special Government Employee as defined in 18 U.S.C. 202(a); and

(iii) The member should have the necessary expertise to perform his or her duties.

(c) *Term.* The term of a member of the Technical Panel shall be eighteen (18) months, and no individual may serve more than one (1) consecutive term.

(d) *Vacancies.* (1) Any member of the Technical Panel appointed to fill a vacancy occurring before the expiration of the term for which the member's predecessor was appointed shall be appointed only for the remainder of that term.

(2) A member of the Technical Panel may serve after the expiration of that member's term until a successor has taken office.

(3) A vacancy shall be filled in the manner in which the original appointment was made pursuant to paragraph (a) of this section.

(e) *Compensation.* (1) No member of the Technical Panel shall receive compensation for service on the Technical Panel.

(2) If any member of the Technical Panel is an employee of the agency of the official that appointed such member to the Technical Panel pursuant to paragraph (a) of this section, compensation in the member's capacity as a Federal employee shall not be considered compensation under paragraph (e)(1) of this section.

§ 301.110 Organization and operations.

(a) *Chair.* (1) The member of the Technical Panel appointed by the Assistant Secretary pursuant to § 301.100(a) of this subpart shall be the Chair of the Technical Panel.

(2) The Chair of the Technical Panel may designate a Vice-Chair who may act as Chair in the absence of the Chair.

(b) *Procedures of and actions by the Technical Panel.* (1) The Technical Panel may meet either in person or by some mutually agreeable electronic means to take action on the reports required by § 301.120 of this subpart or in providing technical assistance to a Dispute Resolution Board pursuant to § 301.130 of this subpart.

(2) Meetings of the Technical Panel may be convened as necessary for the efficient and timely dispatch of business by either NTIA or the Chair of the Technical Panel to consider reports and any action thereon and to provide technical assistance to a Dispute Resolution Board pursuant to § 301.130 of this subpart.

(3) The Technical Panel shall endeavour to reach its decisions unanimously. Absent unanimous consent of all three members of the Technical Panel, a concurring vote of a majority of the total panel membership constitutes an action of the Technical Panel.

(4) A majority of the Technical Panel members constitutes a quorum for any purpose.

(5) The Chair of the Technical Panel, in consultation with the other members, may adopt additional policies and procedures to facilitate the efficient and timely dispatch of panel business.

(6) The Technical Panel may consult Federal entity subject matter experts as necessary regarding Federal mission risks and other relevant issues while assessing the reasonableness of costs and timelines in the Federal entity's Transition Plans so long as such consultations are disclosed in the Technical Panel's report.

(c) *Administrative support.* NTIA shall provide the Technical Panel with the administrative support services necessary to carry out its duties under this part.

§ 301.120 Reports on agency Transition Plans.

(a) *Deadline for initial report.* Not later than thirty (30) days after the receipt of a Federal Entity's Transition Plan submitted in accordance with applicable procedures set forth in Annex O of the NTIA Manual, the Technical Panel shall submit to NTIA and to such Federal Entity the Technical Panel's report on the sufficiency of the Transition Plan.

(b) *Scope and content of initial report.* The Technical Panel's report shall include:

(1) A finding as to whether the Federal Entity's Transition Plan includes the information required by the applicable provisions set forth in Annex O of the NTIA Manual;

(2) An assessment of the reasonableness of the proposed timelines contained in the Federal Entity's Transition Plan;

(3) An assessment of the reasonableness of the estimated relocation or sharing costs itemized in the Federal Entity's Transition Plan, including the costs identified by such plan for any proposed expansion of the capabilities of the Federal Entity's system; and

(4) A conclusion, based on the finding and assessments pursuant to paragraphs

(b)(1) through (3) of this section, as to the sufficiency of the Transition Plan.

(c) *Insufficient Transition Plan.* In the event the Technical Panel's initial report concludes that the Federal Entity's Transition Plan is insufficient pursuant to paragraph (b) of this section, the report shall also include a description of the specific information or modifications that are necessary for the Federal entity to include in a revised Transition Plan.

(d) *Revised plan.* If the Technical Panel finds the plan insufficient, the applying Federal Entity has up to 90 days to submit to NTIA and the Technical Panel a revised plan.

(e) *Report on revised agency Transition Plans.* (1) Deadline for Supplemental Report. Not later than thirty (30) days after the receipt of a Federal Entity's revised Transition Plan submitted after an initial or revised plan was found by the Technical Panel to be insufficient pursuant to paragraph (c) of this section, the Technical Panel shall submit to NTIA and to such Federal Entity the Technical Panel's supplemental report on the sufficiency of the revised Transition Plan.

(2) Scope and content of supplemental report. The Technical Panel's supplemental report on the revised Transition Plan shall include:

(i) A finding as to whether the Federal Entity's revised Transition Plan includes the necessary information or modifications identified in the Technical Panel's initial report pursuant to paragraph (b)(1) of this section;

(ii) A reassessment, if required, of the reasonableness of the proposed timelines contained in the Federal Entity's revised Transition Plan;

(iii) A reassessment, if required, of the reasonableness of the estimated relocation or sharing costs itemized in the Federal Entity's revised Transition Plan; and

(iv) A conclusion, based on the finding and reassessments pursuant to paragraphs (e)(2)(i) through (iii) of this section, as to the sufficiency of the revised Transition Plan.

§ 301.130 Technical assistance to Dispute Resolution Boards.

Upon request of a Dispute Resolution Board convened pursuant to subpart C of this part, the Technical Panel shall provide the board with such technical assistance as requested.

Subpart C—Dispute Resolution Boards.

§ 301.200 Requests to resolve disputes.

(a) *Non-Federal User requests*—(1) *In general.* A Non-Federal User may submit a written request to NTIA in accordance with this section to establish a Dispute Resolution Board (hereinafter ''board'') to resolve an actual, unresolved dispute that has arisen between the Non-Federal User and a Federal Entity regarding the execution, timing, or cost of the Transition Plan submitted by the Federal Entity pursuant to section 113(h)(1) of the NTIA Organization Act (47 U.S.C. 923(h)(1)).

(2) *Negotiation, mediation and arbitration.* Any dispute arising out of the execution, timing, or cost of the Transition Plan submitted by a Federal Entity must be raised, in the first instance, with the officer or employee of the Federal Entity identified in the Transition Plan as being responsible for the relocation or sharing efforts of the entity and who is authorized to meet and negotiate with Non-Federal Users regarding the transition. To the extent that the parties cannot resolve such dispute on an informal basis or through good faith negotiation, they are strongly encouraged to use expedited alternative dispute resolution procedures, such as mediation or non-binding arbitration, before submitting a written request in accordance with this section to establish a board.

(3) *Eligibility to request the establishment of a board.* To submit a request to establish a board, a Non-Federal User must satisfy the definition of such term in § 301.20 of this part and the dispute must pertain to the execution, timing, or cost of the Transition Plan associated with the license or licenses subject to the winning bid or bids.

(4) *Contents of request.* In order to be considered by a board under this subpart, a request must include:

(i) Specific allegations of fact regarding the Federal Entity's deviation from the Transition Plan sufficient to support the requested resolution of the dispute. Such allegations of fact, except for those of which official notice may be taken by the board, shall be supported by affidavits of a person or persons having personal knowledge thereof;

(ii) A summary of the parties' prior efforts and attempts to resolve the dispute, including negotiation, mediation, or non-binding arbitration efforts pursuant to paragraph (a)(2) of this section;

(iii) A detailed description of each of the claims upon which a resolution is sought by and available to the Non-Federal User;

(iv) A detailed description of the requested resolution of the dispute;

(v) The requestor's contact information and a certificate of service showing to whom and when an identical copy of the request was provided to the Federal Entity; and

(vi) A meeting proposal setting forth the proposed date, time, and place (including suggested alternatives) for a meeting with the Federal Entity and the board, the date for which shall be no later than fifteen (15) days from the date the request is sent to NTIA.

(vii) A self-certification that the Non-Federal User is a licensee authorized to use Eligible Frequencies or winning bidder in an FCC auction for the Eligible Frequencies.

(5) *Federal Entity response.* A Federal Entity has the right to submit a response to the board prior to the date of the scheduled meeting. If so directed by the Chair of the board, the Federal Entity shall submit a written response to the Non-Federal User's request.

(b) *Federal Entity requests*—(1) *In general.* An Eligible Federal Entity may submit a written request in accordance with this section to establish a Dispute Resolution Board to resolve an actual dispute that has arisen between the Federal Entity and a Non-Federal User regarding the execution, timing, or cost of the Transition Plan submitted by the Federal Entity pursuant to section 113(h)(1) of the NTIA Organization Act (47 U.S.C. 923(h)(1)).

(2) *Eligibility to request the establishment of a board.* To submit a request to establish a board, a Federal Entity, as such term is defined in § 301.20 of this part, must have submitted a Transition Plan pursuant to section 113(h)(1) of the NTIA Organization Act (47 U.S.C. 923(h)(1)) and the dispute must pertain to the execution, timing, or cost of such plan in connection with that Non-Federal User's license or licenses to use the Eligible Frequencies.

(3) *Contents of request.* In order to be considered by a board under this subpart, a request must include:

(i) Specific allegations of fact regarding the factors hindering or affecting the plan's execution, timing, or cost sufficient to support the requested resolution of the dispute. Such allegations of fact, except for those for which official notice may be taken by the board, shall be supported by affidavits of a person or persons having personal knowledge thereof;

(ii) A summary of the parties' prior efforts and attempts to resolve the dispute;

(iii) A detailed description of each of the claims upon which a resolution is sought by and available to the Federal Entity;

(iv) A detailed description of the requested resolution of the dispute;

(v) The requestor's contact information and a certificate of service showing to whom and when an identical copy of the request was provided to the Non-Federal User; and

(vi) A meeting proposal setting forth the proposed date, time, and place (including suggested alternatives) for a meeting with the Non-Federal User and the board, the date for which shall be no later than fifteen (15) days from the date the request is sent to NTIA.

(4) *Non-Federal User response.* A Non-Federal User has the right to submit a response to the board prior to the date of the scheduled meeting. If so directed by the Chair of the board, the Non-Federal User shall submit a written response to the Federal Entity's request.

§ 301.210 Establishment and operation of a Dispute Resolution Board.

(a) *In general.* If NTIA receives a written request under § 301.200, it shall establish a Dispute Resolution Board in accordance with this section.

(b) *Board membership.* A board established under this section shall be composed of three (3) members, to be appointed as follows:

(1) A representative of OMB, to be appointed by the Director of OMB;

(2) A representative of NTIA, to be appointed by the Assistant Secretary; and

(3) A representative of the Commission, to be appointed by the Chairman of the Commission.

(c) *Qualifications.* The Assistant Secretary, in consultation with the Director of OMB and the Chairman of the Commission, may impose qualifications for one or more members of a board established under this section as are necessary pursuant to section 113(g)(6) of the NTIA Organization Act (47 U.S.C. 923(g)(6)), including, but not limited to, the following:

(1) The member has the appropriate and current security clearances to enable access to any classified or other sensitive information that may be associated with or relevant to the Transition Plan subject to dispute;

(2) The member must be an employee of the appointing agency;

(3) The member must be from a predetermined slate of not less than three (3) qualified candidates from NTIA, OMB, and the Commission and able to serve on a board immediately upon the notification of the establishment of a board under this section until it rules on the dispute that it was established to resolve; and

(4) The member may not simultaneously be a member of the Technical Panel governed by subpart B of this part or a former member of the Technical Panel that reviewed the Transition Plan subject to dispute.

(d) *Chair.* (1) The representative of OMB shall be the Chair of any board established under paragraph (a) of this section.

(2) The Chair may designate a Vice-Chair who may act as Chair in the absence of the Chair.

(e) *Term.* The term of a member of a board shall be until such board is terminated pursuant to paragraph (j) of this section or until a successor or replacement member is appointed under paragraph (b) of this section.

(f) *Vacancies.* Any vacancy on a board shall be filled in the manner in which the original appointment was made under paragraph (b) of this section.

(g) *Compensation.* (1) No member of a board shall receive any compensation for service on such board.

(2) Compensation in the member's capacity as an employee of the agency of the official that appointed such member to a board pursuant to paragraph (b) of this section shall not be considered compensation under paragraph (g)(1) of this section.

(h) *Procedures of and actions by a board.* (1) Except with respect to meetings with the parties pursuant to § 301.220(a), a board shall meet at the call of the Chair either in person or by some mutually agreeable electronic means to deliberate or rule on the dispute that it was established to resolve under paragraph (a) of this section or to receive technical assistance from the Technical Panel pursuant to § 301.130 of this part.

(2) A board shall endeavour to rule on the dispute that it was established to resolve under paragraph (a) of this section unanimously. Absent unanimous consent of all three members of a board, a concurring vote of a majority of the total board membership constitutes an action of such board.

(3) A majority of board members constitutes a quorum for any purpose.

(4) The Chair of a board, in consultation with the other members, may adopt additional policies and procedures to facilitate the efficient and timely resolution of the dispute that it was established to resolve under paragraph (a) of this section.

(i) *Administrative support.* NTIA shall provide any board established pursuant to paragraph (a) of this section with the administrative support services necessary to carry out its duties under this subpart.

(j) *Termination of a board.* (1) A board established pursuant to paragraph (a) of this section shall terminate after it rules on the dispute that it was established to resolve and the time for appeal of its decision under section 113(i)(7) of the NTIA Organization Act (47 U.S.C. 923(i)(7)) has expired, unless such an appeal has been taken.

(2) If such an appeal has been taken, the board shall continue to exist until the appeal process has been exhausted and the board has completed any action required by a court hearing the appeal.

§ 301.220 Dispute Resolution.

(a) *Meeting with parties.* In consideration of the proposal set forth in a request pursuant to either § 301.200(a)(4)(vi) or (b)(3)(vi) of or at another mutually convenient date, time, and place (including via teleconference or other electronics means), the Chair of the board established under this subpart shall call a meeting of the board to be held simultaneously with representatives of the parties to the dispute to discuss the dispute.

(b) *Additional written submissions.* The parties to the dispute shall provide the board with any additional written materials and documents as it may request. In cases where the dispute or an element thereof relates to the impact on the Federal Entity's national security, law enforcement, or public safety operations or functions, the board may request, and the Federal entity shall provide, additional written submissions concerning such impact.

(c) *Assistance from Technical Panel.* A board established under this subpart may request technical assistance, as necessary, from the Technical Panel governed by subpart B of this part.

(d) *Deadline for decision.* The board shall rule on the dispute not later than thirty (30) days from the date the request was received by the NTIA, unless the parties and the board all agree in writing, and subject to the approval of the Assistant Secretary, to extend this period for a specified number of days.

(e) *Board decision.* The decision of a board established under this subpart shall:

(1) Be in writing;

(2) Be limited to determinations related to the execution, timing, or cost of the Transition Plan submitted by the Federal entity;

(3) Be based only on the record before it, including the request; meeting(s) with the parties all at the same time; any additional written submissions requested by the board and served on the other party, including submissions from the Federal entity concerning the potential impact on its national security, law enforcement, or public safety operations or functions; input from the Technical Panel, and other matters and

material for which it may take official notice;

(4) Ensure that the decision does not have a detrimental impact on the Federal entity's operations or services that have national security, law enforcement, or public safety functions; and

(5) Be final upon issuance.

(f) *Recommendations.* A decision of the board may include recommendations for remedial or other corrective actions to the appropriate Federal agency with the legal authority to take such actions based on the board's findings.

[FR Doc. 2013–01564 Filed 1–24–13; 8:45 am]

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Proposed Rules

Federal Register
Vol. 78, No. 17
Friday, January 25, 2013

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.

FARM CREDIT ADMINISTRATION

12 CFR Part 652

RIN 3052–AC80

Federal Agricultural Mortgage Corporation Funding and Fiscal Affairs; Farmer Mac Capital Planning

AGENCY: Farm Credit Administration (FCA or Agency).

ACTION: Proposed rule.

SUMMARY: The FCA, through the Office of Secondary Market Oversight (OSMO), is proposing regulations to require the Federal Agricultural Mortgage Corporation (Farmer Mac) to submit a capital plan to OSMO on an annual basis and to require Farmer Mac to notify OSMO under certain circumstances before making a capital distribution. The proposed rule would revise the current capital adequacy planning requirements to increase our regulatory focus on the quality and level of Farmer Mac's capital base and promote best practices for capital adequacy planning and stress testing. We view high quality capital as the fundamental resource available to cover unexpected losses and ensure long-term financial flexibility and viability.

DATES: Please submit comments before March 26, 2013.

ADDRESSES: Commenters are encouraged to submit comments by email or through the FCA's Web site. As facsimiles (faxes) are difficult for us to process and achieve compliance with section 508 of the Rehabilitation Act, we no longer accept comments submitted by fax. Regardless of the method you use, please do not submit your comments multiple times via different methods. You may submit comments by any of the following methods:

- *Email:* Send an email to *reg-comm@fca.gov.*
- *FCA Web site: http://www.fca.gov.* Select ''Public Commenters,'' then ''Public Comments,'' and follow the directions for ''Submitting a Comment.''
- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Mail:* Laurie A. Rea, Director, Office of Secondary Market Oversight, Farm Credit Administration, 1501 Farm Credit Drive, McLean, VA 22102–5090.

You may review copies of all comments we receive at our office in McLean, Virginia or on our Web site at *http://www.fca.gov.* Once you are in the Web site, select ''Public Commenters,'' then ''Public Comments,'' and follow the directions for ''Reading Submitted Public Comments.'' We will show your comments as submitted, including any supporting data provided, but for technical reasons we may omit items such as logos and special characters. Identifying information that you provide, such as phone numbers and addresses, will be publicly available. However, we will attempt to remove email addresses to help reduce Internet spam.

FOR FURTHER INFORMATION CONTACT: Joseph T. Connor, Associate Director for Policy and Analysis, Office of Secondary Market Oversight, Farm Credit Administration, McLean, VA 22102–5090, (703) 883–4280, TTY (703) 883–4434; or Rebecca S. Orlich, Senior Counsel, Office of General Counsel, Farm Credit Administration, McLean, VA 22102–5090, (703) 883–4020, TTY (703) 883–4020.

SUPPLEMENTARY INFORMATION:

I. Objective

The objective of this proposed rule is to improve the long-term safety and soundness and continuity of Farmer Mac operations so that Farmer Mac may better fulfill its public mission under a range of economic conditions. To achieve this, FCA is proposing to revise operational and strategic business planning requirements to enhance capital adequacy planning. The proposed rule is designed to (i) establish minimum supervisory standards for the capital planning process, including stress testing, (ii) describe how the Farmer Mac board of directors (board) and senior management should implement the process and strategies, and (iii) provide FCA with notification of Farmer Mac's proposed capital distributions before they occur.

II. Background

Farmer Mac is an institution of the Farm Credit System, regulated by FCA through its Office of Secondary Market Oversight. Farmer Mac was established and chartered by Congress to create a secondary market for agricultural real estate mortgage loans, rural housing mortgage loans, and rural utilities loans, and it is a stockholder-owned instrumentality of the United States. Title VIII of the Farm Credit Act of 1971, as amended (Act), governs Farmer Mac.[1]

Farmer Mac Programs

Under the Farmer Mac I program, Farmer Mac guarantees prompt payment of principal and interest on securities representing interests in, or obligations backed by, mortgage loans secured by first liens on agricultural real estate or rural housing. It also purchases, or commits to purchase, qualified loans or securities backed by qualified loans directly from lenders. Under the Farmer Mac II program, Farmer Mac purchases and securitizes portions of certain loans guaranteed by the U.S. Department of Agriculture, including farm ownership and operating loans and rural business and community development loans. Farmer Mac also guarantees the timely payment of principal and interest on the securities created from these loans. In 2008, Congress authorized Farmer Mac to purchase and guarantee securities backed by loans to rural electric and telephone utility cooperatives.

III. Need for Enhanced Capital Planning

The fundamental purpose of bank capital is to provide a cushion to absorb unexpected losses and improve an institution's long-term resilience. The recent global financial crisis underscored the importance of capital adequacy planning, including maintaining high quality capital. In response to the crisis, the Basel Committee on Banking Supervision (BCBS) proposed the Basel III framework, which expands and clarifies international standards on regulatory capital with the intent to raise the quality, quantity, and transparency of regulatory capital.[2] The Basel III

[1] The Act is set forth at 12 U.S.C. 2001 *et seq.* Title VIII is in 12 U.S.C. 2279aa–2279cc.

[2] Bank for International Settlements, *Basel Committee on Banking Supervision, Basel III, A Global Regulatory Framework for More Resilient*

framework also requires banks to run stress tests to ensure they are able to sustain financial soundness under adverse market conditions. In the U.S., the Dodd-Frank Wall Street Reform and Consumer Protection Act (Dodd-Frank Act) was enacted in July 2010 to strengthen regulation of the financial sector. Section 165 of the Dodd-Frank Act requires certain financial companies whose total consolidated assets are in excess of $10 billion to conduct annual stress tests. The U.S. banking agencies (the Federal Reserve System (FRS), Federal Deposit Insurance Corporation (FDIC), the Office of the Comptroller of the Currency (OCC)) and the Federal Housing Finance Agency (FHFA) have issued proposed, and in some cases, final rules and guidance to enhance capital standards and stress testing.[3] This proposed rule reflects our general agreement with the rulemaking actions of other banking supervision authorities, both domestic and international, which emphasize high quality capital maintenance, robust planning, and stress testing as adding value to the existing regulatory framework for capital adequacy and capital planning.

Farmer Mac's statutory capital standards were enacted in 1991[4] and have not been updated since 1996.[5] Under the Act, Farmer Mac must operate at or above a minimum ''core capital'' level and a minimum ''regulatory capital'' level. ''Core capital'' is defined in section 8.31(2) of the Act as the par value of outstanding common and preferred stock, paid-in capital, and retained earnings. Farmer Mac's minimum core capital requirement is an amount equal to the sum of 2.75 percent of on-balance-sheet assets and 0.75 percent of off-balance-sheet obligations. ''Regulatory capital'' is defined in section 8.31(5) as core capital plus an allowance for losses and guarantee claims (ALL). Farmer Mac's minimum risk-based capital requirement is the amount of regulatory capital for interest rate and credit risk determined by applying a risk-based capital stress test (RBCST) as defined in section 8.32(a) of the Act, plus an additional 30 percent of that amount for management and operations risk.

The regulatory requirements of the RBCST were implemented in FCA's regulations at 12 CFR part 652, subpart B in 2002 and have been revised several times. While the RBCST provides a valuable alternative perspective as a risk index of Farmer Mac's operations from quarter to quarter, the Act prescribes several components of the model's design that constrain its usefulness as the only approach to calculating risk-based capital required by regulation. Under certain conditions, the Act's provisions do not impose a significant level of stress; for example, the Act's interest rate stress provisions do not impose a stressful scenario of interest rate shock in very low interest rate environments such as the current one.[6] Moreover, there are a number of areas of the statutory design requirements in the RBCST that may no longer reflect best practices in economic capital modeling, which has advanced considerably since the provisions were enacted. We believe applying current best practices for comprehensive and robust stress testing approaches is prudent and warranted for capital planning.

In addition, the Act's minimum regulatory capital standards do not necessarily ensure that Farmer Mac holds a sufficient amount of high quality capital—primarily common equity and retained earnings—to survive periods of high financial stress. The statutory definition of ''core capital'' broadly defines the types of capital instruments that may be included without distinguishing the quality of the capital instruments. More recent views of capital, including the Basel III framework for stock corporations, make much finer distinctions between, for example, different structures of preferred stock on the basis of the terms of their underlying contractual provisions. These finer distinctions include how much incentive is built into preferred stock terms for the issuer to redeem the shares. An example of such an incentive would be significant step-ups in dividend rates over time. Such provisions create greater uncertainty around the relative permanence of that capital and, therefore, how available it will be to cover unexpected losses in the future.

Consistent with the view that high quality capital is the fundamental resource available to cover unexpected losses and ensure long-term financial flexibility and viability, we propose to revise the current capital adequacy planning requirements to increase our regulatory focus on the quality and level of capital and advance best practices for capital adequacy planning and stress testing at Farmer Mac.

IV. Proposed Revisions

We propose to revise our regulation on Corporation Board Guidelines by deleting the provisions related to the capital adequacy plan that is part of the operational and strategic business plan requirement in existing § 652.60(b)(5) and (c) and creating a new § 652.61 with revised and expanded guidance on capital planning. In § 652.60(a), we propose to add the requirement that Farmer Mac's capital be sufficient to meet goals and objectives in a newly proposed element (in § 652.61(c)) of its operational and strategic business plan. We further propose to require Farmer Mac to notify the OSMO within 10 calendar days of determining that capital is not sufficient to meet this new requirement. In § 652.60(b), we propose to add several items that Farmer Mac must address in its business plan. These include a business and organizational overview and an assessment of management capabilities; an assessment of Farmer Mac's strengths and weaknesses; strategies for achieving mission, financial, and business goals and objectives; and a marketing plan. We propose to add to the required review of internal and external factors likely to affect Farmer Mac during the business planning period a required discussion of how factors might impact Farmer Mac's current financial position and business goals.

In new § 652.61, we propose to require Farmer Mac to develop and maintain an annual capital plan and to submit the plan for FCA review. The revisions generally refer to a required capital plan rather than the existing rule's references to capital adequacy planning, and the proposed requirements, while more specific and detailed, are very similar in their overall objective. As described more fully below, Farmer Mac would be required to calculate a high quality capital ratio as well as the ratios described in the Act and existing regulations. In proposed § 652.62, we would require Farmer Mac to notify the FCA prior to making a

Banks and Banking Systems, December 2010 (revised June 2011), *http://www.bis.org/publ/bcbs189.pdf.* The United States is a member of the BCBS.

[3] *See, e.g.,* the FRS's final rule, Capital Plans, 76 FR 74631 (December 1, 2011); the FRS's proposed rule, Enhanced Prudential Standards and Early Remediation Requirements for Covered Companies, 77 FR 594 (January 5, 2012); the U.S. banking agencies' joint proposed rule, Regulatory Capital Rules; Advanced Approaches Risk-Based Capital Rule; Market Risk Capital Rule, 77 FR 52978 (August 30, 2012); the FDIC's proposed rule, Annual Stress Test, 77 FR 3166 (December 23, 2012); the OCC's proposed rule, Annual Stress Test, 77 FR 3408 (January 24, 2012); and the FHFA's proposed rule, Stress Testing of Regulated Entities, 77 FR 60948 (October 5, 2012).

[4] Public Law 102–237, Title V, December 13, 1991.

[5] Public Law 104–105, Title I, February 10, 1996.

[6] Section 8.32(a)(2) requires interest rate shocks to be specified as the lesser of: (a) 50 percent of the 12-month average rates on 10-year Treasury obligations; or (b) 600 basis points. In the current interest rate environment, this requirement translates into an interest rate shock of just slightly more than 100 basis points.

capital distribution under certain circumstances.

A. Annual Capital Planning Requirement

We propose to define a capital plan as a written presentation of Farmer Mac's capital planning strategies and capital adequacy process that includes certain mandatory elements. The proposed capital plan would be organized into four main components, each with specified mandatory elements. The four mandatory elements are:

(1) An assessment of the expected uses and sources of capital over the planning horizon (at least 12 quarters, beginning with the quarter preceding the quarter in which Farmer Mac submits its capital plan) that reflects Farmer Mac's size, complexity, risk profile and scope of operations, assuming both expected and stressful conditions;

(2) A detailed description of Farmer Mac's process for assessing capital adequacy;

(3) Farmer Mac's capital policy; and

(4) A discussion of any expected changes to Farmer Mac's business plan that are likely to have a material impact on its capital adequacy or liquidity.

The first mandatory element, the assessment of uses and sources of capital, must contain the following components: (i) Estimates of projected revenues, losses, reserves, and pro forma capital levels, including any minimum statutory or regulatory capital ratio, a high-quality Tier 1 ratio as described below, and any additional capital measures deemed relevant by Farmer Mac, over the planning horizon under expected conditions and under a range of stressed scenarios, including any scenarios provided by FCA and at least two stressed scenarios developed by Farmer Mac appropriate to its business model and portfolios; such scenarios could include agricultural and general economic conditions that cause increases in delinquency rates caused by any variety of factors (*e.g.,* widespread, weather-related crop losses), interest rate spikes that could impact historically high cropland values and the cost of debt funding, changes in laws that affect plant-based renewable fuels subsidies, as well as liquidity-related stress such as reduced access to debt markets; and (ii) a description of all planned capital actions over the planning horizon. We propose to define a capital action as any issuance of a debt or equity capital instrument, a capital distribution, or any similar action that the FCA determines could impact Farmer Mac's capital. A capital distribution would include a redemption or repurchase of any debt or equity capital instrument, a dividend payment, a payment that may be temporarily or permanently suspended by Farmer Mac on any instrument that is eligible for inclusion in total equity (as reported in accordance with GAAP), and any similar transaction that the Agency determines to be in substance a distribution of capital.

The second mandatory element of the capital plan, the process for assessing capital adequacy, must contain the following components: (i) A discussion of how Farmer Mac will, under normal and stressful conditions, be able to maintain capital commensurate with its risks, maintain capital above the minimum statutory and regulatory capital ratios and above a Tier 1 ratio set in accordance with the board's clearly articulated risk tolerance policy; and (ii) a discussion of how Farmer Mac will, under both normal and stressful conditions, maintain sufficient capital to continue its operations by maintaining ready access to funding, meeting its obligations to creditors and other counterparties, and continuing to serve as secondary market for qualifying rural markets; and (iii) a discussion of the results of any stress test required by law or regulation, including the RBCST, and an explanation of how the capital plan takes these results into account.

We do not propose to establish a new regulatory minimum capital requirement in this rule. Rather, we propose to require Farmer Mac to establish an internal minimum standard in accordance with widely recognized approaches as a part of board policy on capital. To comply with the proposed requirements of the Tier 1 ratio, Farmer Mac must utilize an approach that is in accordance with an appropriate Basel framework (or frameworks), or comparable U.S. regulatory frameworks in effect (*e.g.,* Standardized or advanced internal ratings based (Advanced) approaches, or both).[7] The approach selected to calculate risk-weighted assets must be appropriate given Farmer Mac's business activities and must be consistent with broadly accepted banking practices and standards (*e.g.,* Basel accords or similar U.S. regulations, including those applied by Farm Credit System banks and associations under part 615 of the FCA's regulations). The OSMO strongly recommends that, for capital planning purposes, Farmer Mac calculate and report in its business plan the ratio of Tier 1 capital to risk-weighted assets using both the Basel Standardized approach and the Advanced approach to provide alternative perspectives on the Farmer Mac's risk-bearing capacity.

The third mandatory element of the capital plan, the capital policy, is a written assessment of the principles and guidelines used for capital planning, capital issuance, usage and distributions, including internal capital goals, the quantitative or qualitative guidelines for dividend and stock repurchases, the strategies for addressing potential capital shortfalls, and the internal governance procedures around capital policy principles and guidelines.

Finally, the fourth mandatory element of Farmer Mac's capital plan is a discussion of any expected changes to Farmer Mac's business plan that are likely to have a material impact on capital adequacy or liquidity. For example, the capital plan should reflect any expected material effects of new lines of business or activities on Farmer Mac's capital adequacy or liquidity, including revenue and losses.

We propose to require the board, at least annually, to review the robustness of the process for assessing capital adequacy, ensure that any deficiencies in the process for assessing capital adequacy are appropriately remedied, and approve the capital plan. The robustness of Farmer Mac's capital adequacy process should be evaluated based on the following elements:

(i) A sound risk management infrastructure that supports the identification, measurement, and assessment of all material risks arising from the business activities of Farmer Mac;

(ii) An effective process for translating risk measures into estimates of potential loss over a range of adverse scenarios and for aggregating those estimated losses across Farmer Mac;

(iii) A clear definition of available capital resources and an effective process for forecasting available capital resources over the same range of adverse scenarios used for loss forecasting;

(iv) A process for considering the impact of loss estimates on capital adequacy consistent with Farmer Mac's stated goals for the level and composition of capital and for taking into account any limitations of the company's capital adequacy process and its components;

(v) A process, supported by Farmer Mac's capital policy, to use its assessments of the impact of loss and

[7] Publications by the BCBS explaining these approaches include: (1) International Convergence of Capital Measurement and Capital Standards, A Revised Framework Comprehensive Version, June 2006; (2) Enhancements to the Basel II framework July 2009; and (3) Basel III, A Global Regulatory Framework for More Resilient Banks and Banking Systems, December 2010 (revised June 2011).

resource estimates on capital adequacy to make key decisions regarding the current level and composition of capital, specific capital actions, and capital contingency plans as they affect capital adequacy;

(vi) Sound internal controls governing the capital adequacy process, including sufficient documentation, model validation and independent review, and audit testing; and

(vii) Effective board and senior management oversight of Farmer Mac's capital adequacy process, including periodic review of capital goals, assessment of the appropriateness of adverse scenarios considered in capital planning, regular review of any limitations and uncertainties in the process, and approval of planned capital actions.

B. FCA's Review of Capital Plans

FCA expects to consider the following factors in reviewing Farmer Mac's capital plan: (1) The comprehensiveness of the capital plan, including the extent to which the analysis underlying the capital plan captures and addresses potential risks stemming from activities across Farmer Mac's operations and its capital policy; (2) the reasonableness of its assumptions and analysis underlying the capital plan and its methodologies for reviewing the robustness of its capital adequacy process; and (3) its ability to maintain capital above the board-established minimum Tier 1 Capital to risk-weighted assets ratio on a pro forma basis under both normal and stressful conditions throughout the planning horizon, including but not limited to any stressed scenarios required under this rule.

The FCA would also consider the following information in reviewing Farmer Mac's capital plan:

(i) Relevant supervisory information about Farmer Mac and its subsidiaries;

(ii) Farmer Mac's regulatory and financial reports, as well as supporting data that will allow for an analysis of the loss, revenue, and reserve projections;

(iii) Compliance with statutory and regulatory minimum capital standards;

(iv) As applicable, the FCA's own pro forma estimates of Farmer Mac's potential losses, revenues, reserves, and resulting capital adequacy under both normal and stressful conditions, including but not limited to any stressed scenarios required under the final rule, as well as the results of any stress tests conducted by Farmer Mac or the FCA; and

(v) Other information requested or required by the FCA, as well as any other information relevant to Farmer Mac's capital adequacy.

C. FCA Action on a Capital Plan

OSMO would review the capital plan and provide an assessment to Farmer Mac of the capital adequacy and planning process through its normal examination and oversight program. In determining whether a capital plan or proposed capital distributions would constitute an unsafe or unsound practice, the FCA will consider whether Farmer Mac is and will remain in sound financial condition after giving effect to the capital plan and proposed capital distributions.

OSMO may require Farmer Mac to submit additional data about planning assumptions, stress test strategies, and other qualitative and quantitative information. OSMO may also require Farmer Mac to revise and re-submit its capital plan.

D. Farmer Mac's Response to OSMO's Review

We propose to require Farmer Mac to take into account the results of the stress tests conducted under the requirements of this section, as well as OSMO's assessment, in making changes as appropriate to Farmer Mac's capital structure (including the level and composition of capital); its exposures, concentrations, and risk positions; any plans for recovery and resolution; and overall risk management. In addition, Farmer Mac must document in writing any changes it makes to its capital structure such as issuance or retirement of equity securities, as well as decisions not to make such changes with respect to any shortcomings noted in OSMO's assessment.

V. Prior Notice Requirements

A. Notice to OSMO of Capital Distributions

We believe an enhanced level of dialogue between the Agency and Farmer Mac in advance of capital distributions will improve the level of FCA's oversight of, and communication with, regulated entity. Such enhanced dialogue would provide the board with valuable external perspective on such decisions from both a safety and soundness and mission achievement points of view. In new § 652.62, we propose to require Farmer Mac to provide OSMO with notice 15 calendar days prior to a board action to declare a capital distribution. We expect such notice to include a description of the capital distribution including, for redemptions or repurchases of securities, the gross consideration to be paid and the terms and sources of funding for the transaction, and for dividends, the amount of the dividend, as well as any additional information requested by OSMO (which could include, among other things, an assessment of Farmer Mac's capital adequacy under a stress scenario specified by OSMO.) There would be an exception to the notice requirement for dividends on common and preferred stock when there is no change from the amount of the dividends paid in the previous period.

VI. Regulatory Flexibility Act

Farmer Mac has assets and annual income in excess of the amounts that would qualify it as a small entity. Therefore, Farmer Mac is not a ''small entity'' as defined in the Regulatory Flexibility Act. Pursuant to section 605(b) of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*), the FCA hereby certifies that the proposed rule will not have a significant economic impact on a substantial number of small entities.

List of Subjects in 12 CFR Part 652

Agriculture, Banks, Banking, Capital, Investments, Rural areas.

For the reasons stated in the preamble, part 652 of chapter VI, title 12 of the Code of Federal Regulations is proposed to be amended as follows:

PART 652—FEDERAL AGRICULTURAL MORTGAGE CORPORATION FUNDING AND FISCAL AFFAIRS

■ 1. The authority citation for part 652 continues to read as follows:

Authority: Secs. 4.12, 5.9, 5.17, 8.11, 8.31, 8.32, 8.33, 8.34, 8.35, 8.36, 8.37, 8.41 of the Farm Credit Act (12 U.S.C. 2183, 2243, 2252, 2279aa–11, 2279bb, 2279bb–1, 2279bb–2, 2279bb–3, 2279bb–4, 2279bb–5, 2279bb–6, 2279cc); sec. 514 of Pub. L. 102–552, 106 Stat. 4102; sec. 118 of Pub. L. 104–105, 110 Stat. 168.

■ 2. Revise § 652.60 to read as follows:

§ 652.60 Corporate business planning.

(a) Your board of directors is responsible for ensuring that you maintain capital at a level that is sufficient to ensure continued financial viability and provide for growth. In addition, your capital must be sufficient to meet statutory and regulatory requirements as well as the goals and objectives in the required element of your capital plan in § 652.61(c)(2)(i)(B). You must notify the OSMO within 10 calendar days of determining that capital is not sufficient to meet those goals and objectives.

(b) No later than 65 days after the end of each calendar year, your board of

directors must adopt an operational and strategic business plan for at least the next 3 years. The plan must include:

(1) A mission statement;

(2) A business and organizational overview and an assessment of management capabilities;

(3) An assessment of Farmer Mac's strengths and weaknesses;

(4) A review of the internal and external factors that are likely to affect you during the planning period;

(5) Measurable goals and objectives;

(6) A discussion of how these factors might impact Farmer Mac's current financial position and business goals;

(7) Forecasted income, expense, and balance sheet statements for each year of the plan;

(8) A marketing plan, and

(9) A capital plan in accordance with § 652.61.

3. Add new §§ 652.61 and 652.62 to read as follows:

§ 652.61 Capital planning.

(a) *Purpose.* This section establishes capital planning requirements for Farmer Mac.

(b) *Definitions.* For purposes of this section and § 652.62, the following definitions apply:

Basel III means the Basel Committee on Banking Supervision's document ''Basel III: A Global Regulatory Framework for More Resilient Banks and Banking Systems,'' June 2011 and as it may be updated from time to time.

Capital action means any issuance of a debt or equity capital instrument, and any capital distribution, as well as any similar action that OSMO determines could impact Farmer Mac's consolidated capital.

Capital distribution means a redemption or repurchase of any debt or equity capital instrument, a payment of common or preferred stock dividends, a payment that may be temporarily or permanently suspended by the issuer on any instrument that is eligible for inclusion in the numerator of any minimum capital ratio, and any similar transaction that OSMO determines to be in substance a distribution of capital.

Capital plan means a written presentation of Farmer Mac's capital planning strategies and capital adequacy process that includes the mandatory elements set forth in paragraph (c)(2) of this section.

Capital policy means Farmer Mac's written assessment of the principles and guidelines used for capital planning, capital issuance, usage and distributions, including internal capital goals; the quantitative or qualitative guidelines for dividend and stock repurchases; the strategies for addressing potential capital shortfalls; and the internal governance procedures around capital policy principles and guidelines.

Planning horizon means the period of at least 12 quarters, beginning with the quarter preceding the quarter in which Farmer Mac submits its capital plan, over which the relevant projections extend.

Tier 1 Capital means the components meeting the criteria of Common Equity Tier 1 Capital and Additional Tier 1 Capital and the regulatory adjustments as set forth in Basel III, or Tier 1 Capital as defined in regulations of the Office of the Comptroller of the Currency, the Board of Governors of the Federal Reserve, or the Federal Deposit Insurance Corporation, as revised from time to time; or another capital standard to measure high quality capital as approved for use under this regulation by the Director of OSMO.

Tier 1 ratio means the ratio of Farmer Mac's Tier 1 Capital to Total Risk-Weighted Assets.

Total Risk-Weighted Assets means a risk-weighting approach that is appropriate given Farmer Mac's business activities and consistent with broadly accepted banking practices and standards (*e.g.,* one of the frameworks of the Basel Committee on Banking Supervision or similar U.S. regulations).

(c) *General requirements.*

(1) *Annual capital planning.*

(i) Farmer Mac must develop and maintain a capital plan each year.

(ii) Farmer Mac must submit its complete annual capital plan to OSMO by March 1 or such later date as directed by OSMO, after consultation with the FCA Board.

(iii) Prior to submission of the capital plan under paragraph (c)(1)(ii) of this section, Farmer Mac's board of directors must:

(A) Review the robustness of Farmer Mac's process for assessing capital adequacy,

(B) Ensure that any deficiencies in Farmer Mac's process for assessing capital adequacy are appropriately remedied; and

(C) Approve Farmer Mac's capital plan.

(2) *Mandatory elements of capital plan.* The capital plan must contain at least the following elements:

(i) An assessment of the expected uses and sources of capital over the planning horizon that reflects Farmer Mac's size, complexity, risk profile, and scope of operations, assuming both expected and stressful conditions, including:

(A) Projected revenues, losses, reserves, and pro forma capital levels, including the core capital and regulatory capital ratios required by sections 8.32 and 8.33 of the Act, the Tier 1 ratio as defined in this section, and any additional capital measures deemed relevant by Farmer Mac, over the planning horizon under expected conditions and under a range of at least two progressively severe stress scenarios developed by Farmer Mac appropriate to its business model and portfolios, as well as any scenarios provided by the Director of OSMO. At least 15 calendar days prior to this stress testing, Farmer Mac must provide to OSMO a description of the expected and stressed scenarios that Farmer Mac intends to use to conduct its annual stress test under this section.

(B) A description of all planned capital actions over the planning horizon.

(ii) A detailed description of Farmer Mac's process for assessing capital adequacy, including:

(A) A discussion of how Farmer Mac will, under expected and stressed conditions, maintain capital commensurate with its risks, maintain capital above the minimum core capital and regulatory capital ratios and above the Tier 1 ratio set in accordance with a well-articulated risk tolerance policy established by the board of directors;

(B) A discussion of how Farmer Mac will, under expected and stressed conditions, maintain sufficient capital to continue its operations by maintaining ready access to funding, meeting its obligations to creditors and other counterparties, and continuing to serve its statutory purposes; and

(C) A discussion of the results of the risk-based stress test required by section 8.32 of the Act and the stress tests required by this section, as well as any other stress test required by law or regulation, and an explanation of how the capital plan takes these results into account.

(iii) Farmer Mac's capital policy; and

(iv) A discussion of any expected changes to Farmer Mac's business plan that are likely to have a material impact on the Corporation's capital adequacy or liquidity.

(d) *Review of capital plan by OSMO.*

(1) OSMO will consider the following factors in reviewing Farmer Mac's capital plan:

(i) The comprehensiveness of the capital plan, including the extent to which the analysis underlying the capital plan captures and addresses risks stemming from activities across Farmer Mac's operations;

(ii) The reasonableness of Farmer Mac's assumptions and analysis underlying the capital plan and its methodologies for reviewing the

robustness of its capital adequacy process; and

(iii) Farmer Mac's ability to maintain capital above the minimum core capital and regulatory capital ratios and above a Tier 1 ratio set in accordance with a well-articulated risk tolerance policy established by the board of directors on a pro forma basis under expected and stressful conditions throughout the planning horizon, including but not limited to any stressed scenarios required under paragraph (c)(2)(i)(A) and (c)(2)(ii) of this section.

(iv) All supervisory information about Farmer Mac and its subsidiaries;

(v) Farmer Mac's regulatory and financial reports, as well as supporting data that would allow for an analysis of its loss, revenue, and projections;

(vi) As applicable, OSMO's own pro forma estimates of Farmer Mac's potential losses, revenues, and resulting capital adequacy measurements under expected and stressful conditions, including but not limited to any stressed scenarios required under paragraphs (c)(2)(i)(A) and (c)(2)(ii) of this section, as well as the results of any other stress tests conducted by Farmer Mac or OSMO; and

(vii) Other information requested or required by OSMO, as well as any other information relevant to Farmer Mac's capital adequacy.

(e) *OSMO action on a capital plan.*

(1) OSMO will review the capital plan and provide an assessment to Farmer Mac of the capital adequacy and planning process through its ongoing examination and oversight process.

(2) Upon a request by OSMO, Farmer Mac must provide OSMO with sufficient information regarding its planning assumptions, stress test strategies and results and any other relevant qualitative or quantitative information requested by OSMO to facilitate review of Farmer Mac's capital plan under this section.

(3) OSMO may require Farmer Mac to revise and re-submit its capital plan.

(f) *Farmer Mac response to OSMO's assessment.* Regardless of whether re-submission is required, Farmer Mac must take the results of the stress tests conducted under paragraph (c)(2)(i)(A) and (c)(2)(ii) of this section (including any revisions required under paragraph (e)(3) of this section) as well as OSMO's assessment into account in making changes, as appropriate, to Farmer Mac's capital structure (including the level and composition of capital); its exposures, concentrations, and risk positions; any plans for recovery and resolution; and to improve overall risk management. Farmer Mac must document in writing its actions in response to the stress tests and assessment, as well as decisions not to take actions in response to any issues raised in the assessment.

§ 652.62 Notice to OSMO of capital distributions.

(a) Farmer Mac must provide OSMO with notice 15 calendar days prior to a board consideration of a declaration of a capital distribution or any material changes in capital distributions policies.

(b) Notice under paragraph (a) of this section is not required with respect to a regular periodic payment of dividends on common stock and preferred stock when there is no change in the amount of payment per share from the previous period.

Dated: January 18, 2013.

Dale L. Aultman,

Secretary, Farm Credit Administration Board.

[FR Doc. 2013–01500 Filed 1–24–13; 8:45 am]

BILLING CODE 6705–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2012–0853; Airspace Docket No. 12–ANM–23]

Proposed Amendment of Class E Airspace; Astoria, OR

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Supplemental notice of proposed rulemaking (SNPRM).

SUMMARY: The FAA is issuing a SNPRM for the notice of proposed rulemaking (NPRM) published on October 9, 2012, in order to elicit comments addressing the proposed airspace modification west of the airport to accommodate aircraft using Area Navigation (RNAV) Global Positioning System (GPS) standard instrument approach procedures. The FAA has reassessed the NPRM and finds that extension of the Class E airspace area west of the airport to within 11 miles north of the airport 268° degree bearing is necessary for the safety and management of instrument flight rules (IFR) operations in the Astoria, OR, area.

DATES: Comments must be received on or before March 11, 2013.

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–2012–0853; Airspace Docket No. 12–ANM–23, 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:

History

On October 9, 2012, the FAA published a NPRM to modify Class E airspace, extending upward from 700 feet or more above the surface, at Astoria Regional Airport, Astoria, OR (77 FR 61306). The comment period closed November 23, 2012. No comments were received. Subsequent to publication, the Western Flight Procedures Office reassessed the proposal and modified the north extension west of the airport from within 6 miles north to within 11 miles north of the airport 268° degree bearing. The airspace extension would accommodate missed approach holding for RNAV (GPS) standard instrument approach procedures.

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 2012–0853 and Airspace Docket No. 12–ANM–23) 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–2012–0853 and Airspace Docket No. 12–ANM–23''. 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 NPRM's

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 9:00 a.m. and 5:00 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 NPRM's 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 Supplemental Proposal

The FAA is proposing an amendment to Title 14 Code of Federal Regulations (14 CFR) part 71 by modifying Class E airspace extending upward from 700 feet above the surface at Astoria Regional Airport, Astoria, OR, to accommodate aircraft using RNAV (GPS) standard instrument approach procedures at Astoria Regional Airport. Additionally, from the Astoria Regional Airport 268° bearing from the 7-mile radius to 17.5 miles west, the airspace would be changed from within 6 miles north of the 268° bearing to within 11 miles north. This action would enhance the safety and management of IFR operations and missed approach holding procedures for RNAV (GPS) standard instrument approach procedures at the airport.

Class E airspace designations are published in paragraph 6005, of FAA Order 7400.9W, dated August 8, 2012, and effective September 15, 2012, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designation listed in this document will be published subsequently in this Order.

The FAA has determined that this proposed regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. 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 that this proposed rule, when promulgated, would not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the 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 would modify airspace at Astoria Regional Airport, Astoria, OR.

This proposal will be subject to an environmental analysis in accordance with FAA Order 1050.1E, ''Environmental Impacts: Policies and Procedures'' prior to any FAA final regulatory action.

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 71.1 of the Federal Aviation Administration Order 7400.9W, Airspace Designations and Reporting Points, dated August 8, 2012, and effective September 15, 2012 is amended as follows:

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

* * * * *

ANM OR E5 Astoria, OR [Modified]

Astoria Regional Airport, Astoria, OR
(Lat. 46°09′29″ N., long. 123°52′43″ W.)
Seaside Municipal Airport
(Lat. 46°00′54″ N., long. 123°54′28″ W.)

That airspace extending from 700 feet above the surface within a 7-mile radius of Astoria Regional Airport; and within 11 miles north and 8.3 miles south of the Astoria Regional Airport 268° bearing extending from the 7-mile radius to 17.5 miles west of Astoria Regional Airport, excluding the portion within a 1.8-mile radius of Seaside Municipal Airport; and within 4 miles northeast and 8.3 miles southwest of the Astoria Regional Airport 326° bearing extending from the 7-mile radius to 21.4 miles northwest of Astoria Regional Airport; and within 4 miles each side of the Astoria Regional Airport 096° bearing extending from the 7-mile radius to 12 miles east of Astoria Regional Airport; and within 8.3 miles north and 4 miles south of the Astoria Regional Airport 096° bearing from 12 miles east, to 28.3 miles east of Astoria Regional Airport; and within a 15.9-mile radius of Astoria Regional Airport extending clockwise from the 326° bearing to the 347° bearing of the airport; and within a 23.1-mile radius of Astoria Regional Airport extending clockwise from the 347° bearing to the 039° bearing of the airport extending from the 15.9-mile radius to a 23.1-mile radius of Astoria Regional Airport extending clockwise from the airport 039° bearing to the airport 185° bearing.

Issued in Seattle, Washington, on December 21, 2012.

Harry S. Karnes,

Acting Manager, Operations Support Group, Western Service Center.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 886

[Docket No. FDA–2012–N–1238]

Medical Devices; Ophthalmic Devices; Classification of the Scleral Plug

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA or Agency) is proposing to classify the scleral plug into class II (special controls), and proposing to exempt the scleral plugs composed of surgical grade stainless steel (with or without coating in gold, silver, or titanium) from premarket notification (510(k)) and to continue to require premarket notification (510(k)) for all other scleral plugs in order to provide a reasonable assurance of safety and effectiveness of the device. The scleral plug is a prescription device used to provide temporary closure of a scleral incision during an ophthalmic surgical procedure.

DATES: Submit either electronic or written comments by April 25, 2013. See section IV of this document for the proposed effective date of a final rule that may issue based on this proposal.

ADDRESSES: You may submit comments, identified by Docket No. FDA–2012–N–1238, by any of the following methods:

Electronic Submissions

Submit electronic comments in the following way:

• *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.

Written Submissions

Submit written submissions in the following way:

• *Mail/Hand delivery/Courier (for paper or CD–ROM submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the Agency name and Docket No. FDA–2012–N–1238 for this rulemaking. All comments received may be posted without change to *http://www.regulations.gov,* including any personal information provided. For additional information on submitting comments, see the ''Comments'' heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or comments received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Tina Kiang, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 2414, Silver Spring, MD 20993–0002, 301–796–6860, *Tina.Kiang@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

A. Statutory and Regulatory Authorities

The Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 301 *et seq.*), as amended by the Medical Device Amendments of 1976 (the 1976 amendments) (Pub. L. 94–295), the Safe Medical Devices Act of 1990 (Pub. L. 101–629), the Food and Drug Administration Modernization Act of 1997 (FDAMA) (Pub. L. 105–115), among other amendments, established a comprehensive system for the regulation of medical devices intended for human use. Section 513 of the FD&C Act (21 U.S.C. 360c) established three categories (classes) of devices, depending on the regulatory controls needed to provide reasonable assurance of their safety and effectiveness. The three categories of devices are class I (general controls), class II (special controls), and class III (premarket approval).

Under section 513 of the FD&C Act, FDA refers to devices that were in commercial distribution before May 28, 1976 (the date of enactment of the 1976 amendments), as ''preamendments devices.'' FDA classifies these devices after the Agency takes the following steps: (1) Receives a recommendation from a device classification panel (an FDA advisory committee); (2) publishes the panel's recommendation for comment, along with a proposed regulation classifying the device; and (3) publishes a final regulation classifying the device. FDA has classified most preamendments devices under these procedures.

FDA refers to devices that were not in commercial distribution before May 28, 1976, as ''postamendments devices.'' These devices are classified automatically by statute (section 513(f) of the FD&C Act (21 U.S.C. 360c(f)) into class III without any FDA rulemaking process. These devices remain in class III and require premarket approval, unless and until: (1) FDA reclassifies the device into class I or II; (2) FDA issues an order classifying the device into class I or II in accordance with section 513(f)(2) of the FD&C Act, as amended by FDAMA; or (3) FDA issues an order finding the device to be substantially equivalent, under section 513(i) of the FD&C Act (21 U.S.C. 360c(i)), to a predicate device that does not require premarket approval. The Agency determines whether new devices are substantially equivalent to predicate devices by means of premarket notification procedures in section 510(k) of the FD&C Act and part 807 of the regulations (21 CFR Part 807).

A person may market a preamendments device that has been classified into class III through premarket notification procedures, without submission of a premarket approval application (PMA) until FDA issues a final regulation under section 515(b) of the FD&C Act (21 U.S.C. 360e(b)) requiring premarket approval.

Section 510(m) of the FD&C Act provides that a class II device may be exempted from the premarket notification requirements under section 510(k) of the FD&C Act, if the Agency determines that premarket notification is not necessary to assure the safety and effectiveness of the device. FDA has determined that premarket notification is not necessary to assure the safety and effectiveness of scleral plugs if the material is a surgical grade stainless steel with or without a gold, silver, or titanium coating.

B. Regulatory History of the Device

After the enactment of the Medical Device Amendments of 1976, FDA commenced to identify and classify all preamendments devices, in accordance with section 513(b) (21 U.S.C. 360c(b)) of the FD&C Act. In the **Federal Register** of September 2, 1987 (52 FR 33346), FDA classified a total of 109 generic types of ophthalmic devices. The scleral plug was not identified in this initial effort. FDA has regulated scleral plugs as devices requiring premarket notification (510(k)). Scleral plugs currently on the market have been determined to be substantially equivalent to devices that were in commercial distribution prior to May 28, 1976. Currently, FDA regulates scleral plugs as devices requiring premarket notification (510(k)). There have been ten 510(k) submissions received and cleared under product code LXP (scleral plugs).

Consistent with the FD&C Act and the regulations, FDA consulted with the Ophthalmic Devices Panel (the Panel), an FDA advisory committee, regarding

the classification of this device type on January 22, 1996 (Ref. 1). At the panel meeting, the Panel recommended scleral plugs as classification as class I, 510(k) exempt. Two 510(k) submissions have been cleared since the panel meeting.

II. Recommendation of the Panel

During a public meeting which was held on January 22, 1996, the Panel made recommendations regarding the classification and regulatory controls for the scleral plug. FDA is proposing the following identification based on the Panel's recommendations and the Agency's review:

A. Identification

A scleral plug is a prescription device intended to provide temporary closure of a scleral incision during an ophthalmic surgical procedure. These plugs prevent intraocular fluid and pressure loss when instruments are withdrawn from the eye. Scleral plugs include a head portion remaining above the sclera, which can be gripped for insertion and removal, and a shaft that fits inside the scleral incision. Scleral plugs are removed before completing the surgery. Therefore, they are generally only used in operating rooms. These devices are often made of surgical grade stainless steel and can be coated in gold, silver, or titanium.

Scleral plugs have a long and established history of clinical use. They are routinely used in many ophthalmic surgeries (specifically, vitreoretinal surgeries). One common type of vitreoretinal surgery is vitrectomy. Vitrectomy is estimated to be the third most frequently performed ophthalmic surgical operation, after cataract and excimer laser refractive surgery (Ref. 2). Approximately 225,000 vitrectomies are done in the United States each year (Ref. 2).

B. Recommended Classification of the Panel

Although the Panel was informed that scleral plugs have historically been treated as class II devices, the Panel recommended that a scleral plug made of a material previously used in legally marketed devices be classified into class I (general controls) and be exempt from premarket notification because the biocompatibility and ability to be sterilized have already been established. The Panel's rationale for suggesting that the scleral plug be classified into class I was because general controls would provide reasonable assurance of the safety and effectiveness of the device type if it is made from a material established to be readily sterilized and biocompatible. During the panel discussion, a distinction was made that scleral plugs consisting of other materials (i.e., materials that are not already included in legally marketed medical devices to the date of the classification regulation) should be classified into class II and require biocompatibility testing as a special control.

As a result of the distinction between materials used for this device, the Panel recommended that, unless new materials are proposed, the device should be exempt from premarket notification.

C. Summary of Reasons for Recommendation

The Panel considered FDA's extensive regulatory experience with the device type and the Panel members' personal knowledge of and clinical experience with the device type. The Panel also considered the long history of safety and effectiveness of the device over many years of clinical use. The Panel recommended that the scleral plug be classified into class I because it concluded that general controls would provide reasonable assurance of the safety and effectiveness of the device type if it was made from a material established to be readily sterilized and biocompatible. The Panel also recommended that scleral plugs be exempt from premarket notification requirements if the proposed device does not introduce new materials (i.e., materials that are not established to be safe for this type of application).

However, FDA believes that a class II classification is appropriate and consistent with the intent of the Panel to establish requirements (such as biocompatibility and sterility) for these devices. Although the Panel identified potential risks and the measures that could be taken to mitigate these risks, the Panel's recommendation of class I would not permit FDA to establish as special controls the mitigation measures discussed (biocompatibility, sterility). Therefore, while FDA is not adopting the Panel's recommendation of classification into class I, the Agency agrees with the concerns and mitigation measures discussed by the Panel that would support a classification under class II.

D. Risks to Health

Based on the Panel's discussion and recommendations and FDA's experience with the device, the risks to health associated with the scleral plugs made from surgical grade stainless steel with or without gold, silver, or titanium coating and the proposed measures to mitigate these risks are identified in table 1 of this document.

TABLE 1—HEALTH RISKS AND MITIGATION MEASURES FOR THE SCLERAL PLUG MADE FROM SURGICAL GRADE STAINLESS STEEL

[With or without a gold, silver, or titanium coating]

Identified risk	Mitigation measures
Infection	Sterility Testing.
Adverse Tissue Reaction.	Biocompatibility Testing.
Loss, breakage, or migration of the plug.	Labeling.

For scleral plugs that are made of surgical grade stainless steel (with or without a gold, silver, or titanium coating) the following special controls, in addition to general controls, can address the risks to health in table 1 of this document and provide reasonable assurance of safety and effectiveness of the device: (1) Performance data must demonstrate the sterility and shelf life of the device; (2) the device must be demonstrated to be biocompatible; and (3) labeling must include all information required for the safe and effective use of the device, including specific instructions regarding the proper incision size, placement, and removal of the device.

Because of the varying properties of other materials and the potential impact on safety and effectiveness, FDA has identified additional special controls for devices made of materials other than surgical grade stainless steel. Based on the Panel's discussion and recommendations and FDA's experience with the device, the risks to health associated with the scleral plugs made from materials other than surgical grade stainless steel and the proposed measures to mitigate these risks are identified in table 2 of this document.

TABLE 2—HEALTH RISKS AND MITIGATION MEASURES FOR SCLERAL PLUGS MADE FROM MATERIALS OTHER THAN SURGICAL GRADE STAINLESS STEEL

Identified risk	Mitigation measures
Infection	Sterility Testing. Shelf-life Testing.
Adverse Tissue Reaction.	Biocompatibility testing. Material characterization. Performance testing to determine the level of extractables.

TABLE 2—HEALTH RISKS AND MITIGATION MEASURES FOR SCLERAL PLUGS MADE FROM MATERIALS OTHER THAN SURGICAL GRADE STAINLESS STEEL—Continued

Identified risk	Mitigation measures
Loss, breakage, or migration of the plug.	Material characterization. Performance testing for Mechanical Properties. Labeling.

The Agency believes that the following special controls, in addition to general controls, will provide reasonable assurance of safety and effectiveness for scleral plugs that are composed of a material other than surgical grade stainless steel, as outlined in table 2: (1) Performance data must demonstrate the sterility and shelf life of the device; (2) the device must be demonstrated to be biocompatible; (3) characterization of the device materials must be performed; (4) performance data must demonstrate acceptable mechanical properties under simulated clinical use conditions including insertion and removal of the device; (5) performance data must demonstrate adequately low levels of the extractables or residues from manufacturing (or processing) of the device; and (6) labeling must include all information required for the safe and effective use of the device, including specific instructions regarding the proper incision size, placement, and removal of the device. In addition, the scleral plug is a prescription device and must be used in accordance with 21 CFR 801.109.

III. Proposed Classification and FDA's Finding

Adverse events involving scleral plugs are rare, as evidenced by the fact that FDA identified only a single adverse event in our reporting systems and two adverse events in the published literature (Refs. 3 and 4). The one adverse event reported to FDA resulted in no persistent adverse effects to the patient and, according to the report, this specific type of non-metallic scleral plug was discontinued and replaced with surgical grade stainless steel scleral plugs.

FDA believes that a class II classification is consistent with the intent of the Panel to establish requirements (such as biocompatibility and sterility) for these devices. The identified special controls mitigate the known risks of the device that were identified by the Panel. However, the FDA does not agree with the Panel that all materials included in legally marketed scleral devices can be exempted from 510(k) due to the potential for safety concerns in some materials that will require specific material information and performance data to provide a reasonable assurance of safety and effectiveness. FDA believes this type of information should be reviewed by FDA prior to a device being marketed in the United States.

FDA proposes the scleral plug be classified into class II. The special controls, in addition to general controls, will provide reasonable assurance of the safety and effectiveness of the device. FDA also agrees, in part, with the Panel's recommendation that premarket notification is not necessary to assure the safety and effectiveness of scleral plugs if new materials are not introduced and, therefore, the Agency is giving notice of intent to exempt the scleral plug device from premarket notification requirements if the device is made from surgical grade stainless steel (with or without a gold, silver, or titanium coating).

IV. Proposed Effective Date

FDA proposes that any final regulation based on this proposal become effective 30 days after its date of publication in the **Federal Register**.

V. Environmental Impact

The Agency has determined under 21 CFR 25.34(b) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VI. Analysis of Impacts

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

The Regulatory Flexibility Act requires Agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because the proposed regulation will classify a previously unclassified pre-Amendment device type, there are only five registered establishments listed in the Establishment Registration and Device Listing database, and the proposed regulation designating the classification of scleral plugs as class II is consistent with the historical regulatory oversight given to this device type, the Agency proposes to certify that the final rule will not have a significant economic impact on a substantial number of small entities.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that Agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing ''any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year.'' The current threshold after adjustment for inflation is $139 million, using the most current (2011) Implicit Price Deflator for the Gross Domestic Product. FDA does not expect this proposed rule to result in any 1-year expenditure that would meet or exceed this amount.

The proposed rule would impact current manufacturers if they were to make changes to their existing products and any manufacture wanting to market a new scleral plug. If the new or changed product is made of surgical grade stainless steel with or without gold, silver, or titanium coating, manufacturers could begin marketing after they complied with the proposed special controls. They would not need to submit an application to the Agency for preapproval. There would be no change from current requirements for new products made of alternative materials; they would need premarket notification before marketing.

VII. Paperwork Reduction Act of 1995

This proposed rule establishes special controls that refer to currently approved collections of information found in other FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 807, subpart E, have been approved under OMB control number 0910–0120; the collections of information in 21 CFR part 801 have been approved under OMB control

number 0910–0485; the collections of information in 21 CFR part 807 have been approved under OMB control number 0910–0387.

VIII. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments regarding this document. It is only necessary to send one set of comments. 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.

IX. References

The following references have been placed 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 and are available electronically at *http://www.regulations.gov.* (FDA has verified the Web site addresses of the following references, but FDA is not responsible for any subsequent changes to the Web site after this document publishes in the **Federal Register**.)

1. Transcript from the Food and Drug Administration Ophthalmic Devices Panel Meeting, January 22, 1996.

2. Chang, Stanley, ''LXII Edward Jackson Lecture: Open Angle Glaucoma After Vitrectomy,'' *American Journal of Ophthalmology,* vol. 141(6): pp. 1033–1043, June 2006, available at *http://www.sciencedirect.com/science/article/pii/S0002939406002546.*

3. Stewart, M. W., ''Intraoperative Radiographic Detection of a 'Lost' Scleral Plug,'' *Retina,* vol. 25(4): pp. 526–527, June 2005.

4. Bovino, J. A. and D. F. Marcus, ''Intraocular Foreign-Body Hazard During Vitrectomy,'' *American Journal of Ophthalmology,* vol. 93 (3): p. 366, March 1982.

List of Subjects in 21 CFR Part 886

Medical devices, Ophthalmic goods and services.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, FDA proposes to amend part 886 as follows:

PART 886—OPHTHALMIC DEVICES

■ 1. The authority citation for 21 CFR part 886 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

■ 2. In subpart E, add § 886.4155 to read as follows:

§ 886.4155 Scleral plug.

(a) *Identification.* A scleral plug is a prescription device intended to provide temporary closure of a scleral incision during an ophthalmic surgical procedure. These plugs prevent intraocular fluid and pressure loss when instruments are withdrawn from the eye. Scleral plugs include a head portion remaining above the sclera, which can be gripped for insertion and removal, and a shaft that fits inside the scleral incision. Scleral plugs are removed before completing the surgery.

(b) *Classification.* Class II (special controls). The special controls for the scleral plug are:

(1) The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 886.9 if the material is a surgical grade stainless steel with or without a gold, silver, or titanium coating. The special controls for the surgical grade stainless steel scleral plug (with or without a gold, silver, or titanium coating) are:

(i) The device must be demonstrated to be sterile during the labeled shelf life;

(ii) The device must be demonstrated to be biocompatible; and

(iii) Labeling must include all information required for the safe and effective use of the device, including specific instructions regarding the proper sizing, placement, and removal of the device.

(2) The device is not exempt from premarket notification procedures if it is composed of a material other than surgical grade stainless steel (with or without a gold, silver, or titanium coating). The special controls for scleral plugs made of other materials are:

(i) The device must be demonstrated to be sterile during the labeled shelf life;

(ii) The device must be demonstrated to be biocompatible;

(iii) Characterization of the device materials must be performed;

(iv) Performance data must demonstrate acceptable mechanical properties under simulated clinical use conditions including insertion and removal of the device;

(v) Performance data must demonstrate adequately low levels of the extractables or residues from manufacturing (or processing) of the device; and

(vi) Labeling must include all information required for the safe and effective use of the device, including specific instructions regarding the proper sizing, placement, and removal of the device.

Dated: January 17, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–01447 Filed 1–24–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF EDUCATION

34 CFR Chapter III

Proposed Priorities and Definitions—NIDRR DRRP—Community Living and Participation, Health and Function, and Employment of Individuals With Disabilities

AGENCY: Office of Special Education and Rehabilitative Services, Department of Education.

ACTION: Proposed priorities and definitions.

CFDA Numbers: 84.133A–3, 84.133A–4, and 84.133A–5.

SUMMARY: The Assistant Secretary for Special Education and Rehabilitative Services proposes funding priorities and definitions for the Disability and Rehabilitation Research Projects and Centers Program administered by the National Institute on Disability and Rehabilitation Research (NIDRR). Specifically, this document proposes priorities for a Disability and Rehabilitation Research Project (DRRP) on Community Living and Participation of Individuals with Disabilities (Proposed Priority 1), a DRRP on Health and Function of Individuals with Disabilities (Proposed Priority 2), and a DRRP on Employment of Individuals with Disabilities (Proposed Priority 3). If an applicant proposes to conduct research under these priorities, the research must be focused on one of the four stages of research. This document proposes definitions for the four stages of research: exploration and discovery, intervention development, intervention efficacy, and scale-up evaluation. The Assistant Secretary may use one or more of these priorities and definitions for competitions in fiscal year (FY) 2013 and later years. We take this action to focus research attention on areas of national need. We intend these priorities and definitions to contribute to improved employment and independent living outcomes for individuals with disabilities.

DATES: We must receive your comments on or before February 25, 2013.

ADDRESSES: Address all comments about this document to Marlene Spencer, U.S. Department of Education, 400 Maryland Avenue SW., Room 5133, Potomac

Center Plaza (PCP), Washington, DC 20202–2700.

If you prefer to send your comments by email, use the following address: *marlene.spencer@ed.gov.* You must include the phrase ''Proposed Priorities for Combined RRTC Notice'' in the subject line of your electronic message.

FOR FURTHER INFORMATION CONTACT: Marlene Spencer. Telephone: (202) 245–7532 or by email: *marlene.spencer@ed.gov.*

If you use a telecommunications device for the deaf (TDD) or a text telephone (TTY), call the Federal Relay Service (FRS), toll free, at 1–800–877–8339.

SUPPLEMENTARY INFORMATION: This notice of proposed priorities and definitions is in concert with NIDRR's currently approved Long-Range Plan (Plan). The currently approved Plan, which was published in the **Federal Register** on February 15, 2006 (71 FR 8165), can be accessed on the Internet at the following site: *http://www2.ed.gov/legislation/FedRegister/other/2006-1/021506d.pdf.*

Through the implementation of the currently approved Plan, NIDRR seeks to: (1) Improve the quality and utility of disability and rehabilitation research; (2) foster an exchange of expertise, information, and training to facilitate the advancement of knowledge and understanding of the unique needs of traditionally underserved populations; (3) determine best strategies and programs to improve rehabilitation outcomes for underserved populations; (4) identify research gaps; (5) identify mechanisms of integrating research and practice; and (6) disseminate findings.

This document proposes three priorities and four definitions that NIDRR intends to use for a DRRP competition in FY 2013 and possibly later years. However, nothing precludes NIDRR from publishing additional priorities and definitions, if needed. Furthermore, NIDRR is under no obligation to make an award using any of these priorities. The decision to make an award will be based on the quality of applications received and available funding.

Invitation to Comment: We invite you to submit comments regarding this document. To ensure that your comments have maximum effect in developing the notice of final priorities, we urge you to identify clearly the specific priority or definition that each comment addresses.

We invite you to assist us in complying with the specific requirements of Executive Orders 12866 and its overall requirement of reducing regulatory burden that might result from these proposed priorities and definitions. Please let us know of any further ways we could reduce potential costs or increase potential benefits while preserving the effective and efficient administration of the program.

During and after the comment period, you may inspect all public comments about this document in Room 5133, 550 12th Street SW., PCP, Washington, DC, between the hours of 8:30 a.m. and 4:00 p.m., Washington, DC time, Monday through Friday of each week except Federal holidays.

Assistance to Individuals with Disabilities in Reviewing the Rulemaking Record: On request we will provide an appropriate accommodation or auxiliary aid to an individual with a disability who needs assistance to review the comments or other documents in the public rulemaking record for this document. If you want to schedule an appointment for this type of accommodation or auxiliary aid, please contact the person listed under **FOR FURTHER INFORMATION CONTACT**.

Purpose of Program: The purpose of the Disability and Rehabilitation Research Projects and Centers Program is to plan and conduct research, demonstration projects, training, and related activities, including international activities, to develop methods, procedures, and rehabilitation technology, that maximize the full inclusion and integration into society, employment, independent living, family support, and economic and social self-sufficiency of individuals with disabilities, especially individuals with the most severe disabilities, and to improve the effectiveness of services authorized under the Rehabilitation Act of 1973, as amended (Rehabilitation Act).

Disability and Rehabilitation Research Projects

The purpose of NIDRR's DRRPs, which are funded through the Disability and Rehabilitation Research Projects and Centers Program, is to improve the effectiveness of services authorized under the Rehabilitation Act by developing methods, procedures, and rehabilitation technologies that advance a wide range of independent living and employment outcomes for individuals with disabilities, especially individuals with the most severe disabilities. DRRPs carry out one or more of the following types of activities, as specified and defined in 34 CFR 350.13 through 350.19: Research, training, demonstration, development, dissemination, utilization, and technical assistance.

An applicant under this program must demonstrate in its application how it will address, in whole or in part, the needs of individuals with disabilities from minority backgrounds (34 CFR 350.40(a)). The approaches an applicant may take to meet this requirement are found in 34 CFR 350.40(b). Additional information on the DRRP program can be found at: *www.ed.gov/rschstat/research/pubs/res-program.html#DRRP.*

Program Authority: 29 U.S.C. 762(g) and 764(a).

Applicable Program Regulations: 34 CFR part 350.

Proposed Priorities

This document contains three proposed priorities. Each priority reflects a major area or domain of NIDRR's research agenda. These domains include community living and participation, health and function, and employment of individuals with disabilities.

If the applicant proposes to conduct research under these priorities, the research must be focused on a specific stage of research. If the DRRP is to conduct research that can be categorized under more than one stage, or research that progresses from one stage to another, those stages must be clearly specified. For purposes of these priorities, the stages of research (i.e., exploration and discovery, intervention development, intervention efficacy, and scale-up evaluation) are defined in the DEFINITIONS section of this document.

Proposed Priority 1—Disability Rehabilitation Research Project on Community Living and Participation of Individuals With Disabilities

Background

The United States Supreme Court's Olmstead decision, 527 U.S. 581 (1999), requires States to provide services ''in the most integrated setting appropriate to the needs of qualified individuals with disabilities,'' except in the rare instances where the individual objects or competent professionals consider it inappropriate. Id. at 607. Federal efforts to support the implementation of this decision have included, among others, the New Freedom Initiative, the Year of Community Living, Community First Choice, and the Money Follows the Person demonstration program. Despite these national efforts, individuals with disabilities of all ages continue to experience significant barriers to living in the community and participating in the typical educational, employment, recreational, and civic and social activities (Reinhart, et al., 2011;

Houtenville et al., 2011; Brault, 2008; National Council on Disability (NCD), 2004; Rimmer et al., 2004; Gibson, 2003). Barriers to community living and participation include, but are not limited to, insufficient affordable home and community-based long-term services and supports (LTSS), such as personal assistance, assistance for family caregivers, assistive technologies and devices, and home modifications; shortages of affordable and accessible housing; inadequate transportation services; limited personal knowledge of community resources; and poor health status (Cooper, O'Hara & Zovistowski, 2011; Reinhart et al., 2011; NCD, 2004; Rimmer, et al., 2004; Gibson, 2003).

U.S. Census Bureau data indicate that an estimated 8 million adults in the non-institutionalized population need personal assistance with activities of daily living (e.g., bathing, dressing, and toileting) (U.S. Census Bureau, 2009). By 2030, this number is estimated to increase to between 8.8 million and 12.3 million (U.S. Census Bureau, 2009). In addition, while studies show that most adults requiring assistance with daily activities prefer to live with support in their own homes (Salomon, 2010; Gibson, 2003), there is a growing disparity between the need for and supply of paid and informal direct care workers and family caregivers (Paraprofessional Healthcare Institute (PHI), 2008; Hewitt et al., 2008; U.S. Department of Health and Human Services, 2003). In a 2007 national survey, 86 percent of States considered the shortage of direct care workers to be a serious issue affecting their ability to meet the growing demand for long-term services and supports among adults with disabilities (PHI, 2009).

Individuals with disabilities, especially those with more significant disabilities, report feeling socially isolated and lonely in their communities (Price, Stephenson, Krantz & Ward, 2011). They are less satisfied with their community participation than their counterparts without disabilities (National Organization on Disability, 2000; Sheppard-Jones, Prout & Kleinert, 2005), and participate in fewer community activities than their counterparts without disabilities. For example, despite the evidence of benefits of regular physical activity for health and functioning, individuals with disabilities are far less likely to engage in physically active lifestyles than are individuals without disabilities (Rimmer, et al., 2004; Spivock, et al., 2008). Similarly, individuals with disabilities are much less likely than those without disabilities to be actively engaged in the workforce. Approximately 18 percent of individuals with disabilities who are age 16 or older are employed, compared to 64 percent of those without disabilities (U.S. Department of Labor, 2012). To address disparities in community participation, and to improve the opportunities and abilities of individuals with disabilities to live as integrated members of their communities, NIDRR proposes to fund one or more Disability Rehabilitation Research Project(s) (DRRPs) on Community Living and Participation for Individuals with Disabilities.

NIDRR has funded a wide range of disability research and development projects related to the community living and participation of individuals with disabilities. In accordance with NIDRR's Plan, NIDRR seeks to build on these investments by supporting innovative and well-designed research and development projects that fall under one or more of NIDRR's general ''community living and participation'' priority areas, as described in the following proposed priority. NIDRR hopes to increase competition and innovation by allowing applicants to specify the research topics under the broad priority areas within the community living and participation domain. If an applicant proposes to conduct research activities, the applicant must identify the relevant priority area or areas, indicate the stage or stages of the proposed research (i.e., exploration and discovery, intervention development, intervention efficacy, and scale-up evaluation), justify the need and rationale for research at the proposed stage or stages, and describe fully an appropriate methodology or methodologies for the proposed research.

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Proposed Priority 1

The Assistant Secretary for Special Education and Rehabilitative Services proposes a priority for a Disability Rehabilitation Research Project (DRRP) on Community Living and Participation of Individuals with Disabilities. The DRRPs must contribute to the outcome of maximizing the community living and participation outcomes of individuals with disabilities.

(1) To contribute to this outcome, the DRRP must—

(a) Conduct either research activities or development activities, in one or more of the following priority areas:

(i) Technology to improve community living and participation outcomes for individuals with disabilities, generally or within specific disability or demographic groups.

(ii) Individual and environmental factors associated with improved community living and participation outcomes for individuals with disabilities generally or within specific disability or demographic groups.

(iii) Interventions that contribute to improved community living and participation outcomes for individuals with disabilities generally or within specific disability or demographic groups. Interventions include any strategy, practice, program, policy, or tool that, when implemented as intended, contributes to improvements in outcomes for individuals with disabilities.

(iv) Effects of government policies and programs on community living and participation outcomes for individuals with disabilities generally or in specific disability or demographic groups.

(v) Research, knowledge translation, and capacity building for improved community living and participation outcomes for individuals with disabilities generally or within specific disability or demographic groups.

(vi) Practices and policies that contribute to improved community living and participation outcomes for transition-aged youth with disabilities;

(b) If conducting research under paragraph (1)(a) of this priority, focus its research on a specific stage of research. If the DRRP is to conduct research that can be categorized under more than one stage, including research that progresses from one stage to another, those stages must be clearly specified. These stages, exploration and discovery, intervention development, intervention efficacy, and scale-up evaluation, are defined in this document;

(c) Conduct knowledge translation activities (i.e., training, technical assistance, utilization, dissemination) in order to facilitate stakeholder (e.g., individuals with disabilities, employers, policymakers, practitioners) use of the interventions, programs, technologies, or products that resulted from the research or development activities conducted under paragraph (1)(a) of this priority; and

(d) Involve key stakeholder groups in the activities conducted under paragraph (1)(a) of this priority in order to maximize the relevance and usability of the research or development products to be developed under this priority.

Proposed Priority 2—Disability Rehabilitation Research Project on Health and Function of Individuals With Disabilities

Background

In the United States, approximately 56.7 million individuals have a disability, including 38.3 million who have a severe disability (Brault, 2012). Research has contributed to a wide variety of policies, programs, services, interventions, and products to enhance the health and function of individuals with disabilities. Despite this work, a large number of individuals with disabilities with significant health conditions and functional limitations lack adequate access to health care, personal assistance services, and rehabilitation services (National Council on Disability, 2009). Maximizing the health and function of individuals with disabilities is critical to their general well-being and their fulfillment of personal aspirations in areas such as employment and community participation (Henry et al., 2007; Waghorn et al., 2008).

Adults with disabilities are substantially more likely than adults without disabilities to be in fair or poor health (as opposed to excellent, very good, or good health), and to experience a wide variety of diseases and chronic conditions (Bureau for Health Information, Statistics, Research, and Evaluation, 2011). Health risks often vary by condition. For example, individuals with significant vision loss or with an intellectual disability have a greater prevalence of obesity, hypertension, and heart disease than individuals without disabilities (Capella-McDonnall, 2007; Stancliffe et al., 2011). Such risks often have major adverse health outcomes, including reduced longevity. For example, 60 percent of individuals with serious mental illness die 25 or more years earlier than the general population due to preventable or treatable chronic diseases (Colton, Manderschied, 2006). Despite their substantial health needs and elevated risk of adverse health outcomes, individuals with disabilities are at a substantial disadvantage in obtaining access to needed health care services compared to those without disabilities (National Council on Disability, 2009; Yee, 2011).

In addition to health impairments, individuals with disabilities experience a wide range of functional limitations that jeopardize their access to employment and other forms of community participation. According to the U.S. Census Bureau 5 million adults need assistance from another person to perform one or more activities of daily living, such as getting around inside the home, getting into or out of bed, bathing, dressing, eating, and toileting. Approximately 15 million individuals have difficulty with one or more instrumental activities of daily living such as going outside the home, managing money, preparing meals, doing housework, taking prescription medication, and using the phone (Brault, 2012). As the number of individuals with disabilities in the United States continues to grow (Institute on Medicine, 2007), it will be necessary to improve the Nation's capacity to meet their needs and access their talents. This will require the development and refinement of policies, programs, practices, and technologies that reduce functional limitations and improve health outcomes for these individuals.

NIDRR has funded a wide range of disability research and development projects related to the health and functional outcomes of individuals with disabilities. In accordance with NIDRR's Plan, NIDRR seeks to build on these investments by supporting innovative and well-designed research and development projects that fall under one or more of NIDRR's general ''health and function'' priority areas, as described in the following proposed priority. NIDRR hopes to increase competition and innovation by allowing applicants to specify the research topics under the broad priority areas within the health and function domain. If an applicant proposes to conduct research activities, the applicant must identify the relevant priority area or areas, indicate the stage or stages of the proposed research in its application (i.e., exploration and discovery, intervention development, intervention efficacy, and scale-up evaluation), justify the need and rationale for research at the proposed stage or stages, and describe fully an appropriate methodology or methodologies for the proposed research.

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Proposed Priority 2

The Assistant Secretary for Special Education and Rehabilitative Services proposes a priority for a Disability and Rehabilitation Research Project (DRRP) on Health and Function of Individuals with Disabilities. The DRRPs must contribute to the outcome of maximizing health and function outcomes of individuals with disabilities.

(1) To contribute to this outcome, the DRRP must—

(a) Conduct either research activities or development activities in one or more of the following priority areas:

(i) Technology to improve health and function outcomes for individuals with disabilities, generally or within specific disability or demographic groups.

(ii) Individual and environmental factors associated with improved access to rehabilitation and healthcare and improved health and function outcomes for individuals with disabilities generally or within specific disability or demographic groups.

(iii) Interventions that contribute to improved health and function outcomes for individuals with disabilities generally or within specific disability or demographic groups. Interventions include any strategy, practice, program, policy, or tool that, when implemented as intended, contributes to improvements in outcomes for individuals with disabilities.

(iv) Effects of government policies and programs on health care access and on health and function outcomes for individuals with disabilities generally or within specific disability or demographic groups.

(v) Research, knowledge translation, and capacity building for improved health and function outcomes for individuals with disabilities generally or within specific disability groups.

(vi) Practices and policies that contribute to improved health and function outcomes for transition-aged youth with disabilities;

(b) If conducting research under paragraph (1)(a) of this priority, focus its research on a specific stage of research. If the DRRP is to conduct research that can be categorized under more than one stage, including research that progresses from one stage to another, those stages must be clearly specified. These stages, exploration and discovery, intervention development, intervention efficacy, and scale-up evaluation, are defined in this document;

(c) Conduct knowledge translation activities (i.e., training, technical assistance, utilization, dissemination) in order to facilitate stakeholder (e.g., individuals with disabilities, employers, policymakers, practitioners) use of the interventions, programs, technologies, or products that resulted from the research or development activities conducted under paragraph (1)(a) of this priority; and

(d) Involve key stakeholder groups in the activities conducted under paragraph (1)(a) of this priority in order to maximize the relevance and usability of the research or development products to be developed under this priority.

Proposed Priority 3—Disability Rehabilitation Research Project on Employment of Individuals With Disabilities

Background

Despite the enactment of legislation and the implementation of a variety of policy and program efforts at the Federal and State levels to improve employment outcomes for individuals with disabilities, the employment rate for individuals with disabilities remains substantially lower than the rate for those without disabilities.

Approximately 18 percent of individuals with a disability aged 16 years and older are employed, compared to 64 percent of individuals of the same age without a disability. The unemployment rate for these two populations is 13.5 percent, and 7.3 percent, respectively (U.S. Department of Labor, 2012). The economic downturn in recent years has disproportionately impacted employment outcomes of individuals with disabilities; among individuals 25 to 54 years of age during the recent recession, the unemployment rate of

individuals with a disability ranged from 2.0 to 2.3 times that of individuals without a disability (Fogg, Harrington, McMahon, 2010). Not only are individuals with a disability much less likely to be employed, the median earnings for individuals with a disability who are employed are $19,735 per year as compared to $30,285 per year earned by persons without a disability (U.S. Census Bureau, 2011).

NIDRR has funded a wide range of disability research and development projects related to the employment outcomes of individuals with disabilities. In accordance with NIDRR's Plan, NIDRR seeks to build on these investments by supporting innovative and well-designed research and development projects that fall under one or more of NIDRR's general employment priority areas as described in the following proposed priority. NIDRR hopes to increase competition and innovation by allowing applicants to specify the research topics under the broad priority areas within the employment domain. If an applicant proposes to conduct research activities, the applicant must identify the relevant priority area or areas, indicate the stage or stages of the proposed research in its application (i.e., exploration and discovery, intervention development, intervention efficacy, and scale-up evaluation), justify the need and rationale for research at the proposed stage or stages and describe fully an appropriate methodology or methodologies for the proposed research.

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Proposed Priority 3

The Assistant Secretary for Special Education and Rehabilitative Services announces a priority for a Disability and Rehabilitation Research Project (DRRP) on Employment of Individuals with Disabilities. The DRRPs must contribute to the outcome of maximizing employment outcomes of individuals with disabilities.

(1) To contribute to this outcome, the DRRP must—

(a) Conduct either research activities or development activities, in one or more of the following priority areas:

(i) Technology to improve employment outcomes for individuals with disabilities, generally or within specific disability or demographic groups.

(ii) Individual and environmental factors associated with improved employment outcomes for individuals with disabilities generally or within specific disability or demographic groups.

(iii) Interventions that contribute to improved employment outcomes for individuals with disabilities generally or within specific disability or demographic groups. Interventions include any strategy, practice, program, policy, or tool that, when implemented as intended, contributes to improvements in outcomes for individuals with disabilities.

(iv) Effects of government policies and programs on employment outcomes for individuals with disabilities generally or in specific disability or demographic groups.

(v) Research, knowledge translation, and capacity building for improved employment outcomes for individuals with disabilities generally or within specific disability groups.

(vi) Practices and policies that contribute to improved employment outcomes for transition-aged youth with disabilities.

(vii) Vocational rehabilitation (VR) practices that contribute to improved employment outcomes for individuals with disabilities;

(b) If conducting research under paragraph(1)(a) of this priority, focus its research on a specific stage of research. If the DRRP is to conduct research that can be categorized under more than one stage, including research that progresses from one stage to another, those stages must be clearly specified. These stages, exploration and discovery, intervention development, intervention efficacy, and scale-up evaluation, are defined in this document;

(c) Conduct knowledge translation activities (i.e., training, technical assistance, utilization, dissemination) in order to facilitate stakeholder (e.g., individuals with disabilities, employers, policymakers, practitioners) use of the interventions, programs, technologies, or products that resulted from the research activities, development activities, or both, conducted under paragraph (1)(a) of this priority; and

(d) Involve key stakeholder groups in the activities conducted under paragraphs (1)(a) of this priority in order to maximize the relevance and usability of the research or development products to be developed under this priority.

Types of Priorities

When inviting applications for a competition using one or more priorities, we designate the type of each priority as absolute, competitive preference, or invitational through a notice in the **Federal Register**. The effect of each type of priority follows:

Absolute priority: Under an absolute priority, we consider only applications that meet the priority (34 CFR 75.105(c)(3)).

Competitive preference priority: Under a competitive preference priority, we give competitive preference to an application by (1) awarding additional points, depending on the extent to which the application meets the priority (34 CFR 75.105(c)(2)(i)); or (2) selecting an application that meets the priority over an application of comparable merit that does not meet the priority (34 CFR 75.105(c)(2)(ii)).

Invitational priority: Under an invitational priority, we are particularly interested in applications that meet the priority. However, we do not give an application that meets the priority a preference over other applications (34 CFR 75.105(c)(1)).

Proposed Definitions

Background

For the purpose of NIDRR's DRRPs and other programs that NIDRR uses to sponsor research activities, definitions of the four stages of research (i.e., exploration and discovery, intervention development, intervention efficacy, and scale-up evaluation) are proposed in this document.

Proposed Definitions

The Assistant Secretary for Special Education and Rehabilitative Services proposes the following definitions for this program. We may apply one or more of these definition in any year in which this program is in effect.

Exploration and discovery means the stage of research that generates hypotheses or theories by conducting new and refined analyses of data, producing observational findings, and creating other sources of research-based information. This research stage may include identifying or describing the barriers to and facilitators of improved outcomes of individuals with disabilities, as well as identifying or describing existing practices, programs, or policies that are associated with important aspects of the lives of

individuals with disabilities. Results achieved under this stage of research may inform the development of interventions or lead to evaluations of interventions or policies. The results of the exploration and discovery stage of research may also be used to inform decisions or priorities.

Intervention development means the stage of research that focuses on generating and testing interventions that have the potential to improve outcomes for individuals with disabilities. Intervention development involves determining the active components of possible interventions, developing measures that would be required to illustrate outcomes, specifying target populations, conducting field tests, and assessing the feasibility of conducting a well-designed interventions study. Results from this stage of research may be used to inform the design of a study to test the efficacy of an intervention.

Intervention efficacy means the stage of research during which a project evaluates and tests whether an intervention is feasible, practical, and has the potential to yield positive outcomes for individuals with disabilities. Efficacy research may assess the strength of the relationships between an intervention and outcomes, and may identify factors or individual characteristics that affect the relationship between the intervention and outcomes. Efficacy research can inform decisions about whether there is sufficient evidence to support ''scaling-up'' an intervention to other sites and contexts. This stage of research can include assessing the training needed for wide-scale implementation of the intervention, and approaches to evaluation of the intervention in real world applications.

Scale-up evaluation means the stage of research during which a project analyzes whether an intervention is effective in producing improved outcomes for individuals with disabilities when implemented in a real-world setting. During this stage of research, a project tests the outcomes of an evidence-based intervention in different settings. It examines the challenges to successful replication of the intervention, and the circumstances and activities that contribute to successful adoption of the intervention in real-world settings. This stage of research may also include well-designed studies of an intervention that has been widely adopted in practice, but that lacks a sufficient evidence-base to demonstrate its effectiveness.

Final Priorities and Definitions

We will announce the final priorities and definitions in a notice in the **Federal Register**. We will determine the final priorities and definitions after considering responses to this document and other information available to the Department. This document does not preclude us from proposing additional priorities, requirements, definitions, or selection criteria, subject to meeting applicable rulemaking requirements.

Note: This document does *not* solicit applications. In any year in which we choose to use one or more of these priorities and definitions, we invite applications through a notice in the **Federal Register**.

Executive Orders 12866 and 13563

Regulatory Impact Analysis

Under Executive Order 12866, the Secretary must determine whether this regulatory action is ''significant'' and, therefore, subject to the requirements of the Executive order and subject to review by the Office of Management and Budget (OMB). Section 3(f) of Executive Order 12866 defines a ''significant regulatory action'' as an action likely to result in a rule that may—

(1) Have an annual effect on the economy of $100 million or more, or adversely affect a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local or tribal governments or communities in a material way (also referred to as an ''economically significant'' rule);

(2) Create serious inconsistency or otherwise interfere with an action taken or planned by another agency;

(3) Materially alter the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or

(4) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles stated in the Executive order.

This proposed regulatory action is not a significant regulatory action subject to review by OMB under section 3(f) of Executive Order 12866.

We have also reviewed this proposed regulatory action under Executive Order 13563, which supplements and explicitly reaffirms the principles, structures, and definitions governing regulatory review established in Executive Order 12866. To the extent permitted by law, Executive Order 13563 requires that an agency—

(1) Propose or adopt regulations only on a reasoned determination that their benefits justify their costs (recognizing that some benefits and costs are difficult to quantify);

(2) Tailor its regulations to impose the least burden on society, consistent with obtaining regulatory objectives and taking into account—among other things and to the extent practicable—the costs of cumulative regulations;

(3) In choosing among alternative regulatory approaches, select those approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity);

(4) To the extent feasible, specify performance objectives, rather than the behavior or manner of compliance a regulated entity must adopt; and

(5) Identify and assess available alternatives to direct regulation, including economic incentives—such as user fees or marketable permits—to encourage the desired behavior, or provide information that enables the public to make choices.

Executive Order 13563 also requires an agency ''to use the best available techniques to quantify anticipated present and future benefits and costs as accurately as possible.'' The Office of Information and Regulatory Affairs of OMB has emphasized that these techniques may include ''identifying changing future compliance costs that might result from technological innovation or anticipated behavioral changes.''

We are issuing these proposed priorities and definitions only on a reasoned determination that their benefits would justify their costs. In choosing among alternative regulatory approaches, we selected those approaches that maximize net benefits. Based on the analysis that follows, the Department believes that this regulatory action is consistent with the principles in Executive Order 13563.

We also have determined that this regulatory action would not unduly interfere with State, local, and tribal governments in the exercise of their governmental functions.

In accordance with both Executive orders, the Department has assessed the potential costs and benefits, both quantitative and qualitative, of this regulatory action. The potential costs are those resulting from statutory requirements and those we have determined as necessary for administering the Department's programs and activities.

The benefits of the Disability and Rehabilitation Research Projects and Centers Programs have been well established over the years in that similar projects have been completed successfully. These proposed priorities and definitions would generate new

knowledge through research and development. Another benefit of these proposed priorities and definitions is that the establishment of new DRRPs would improve the lives of individuals with disabilities. The new DRRPs would generate, disseminate, and promote the use of new information that would improve outcomes for individuals with disabilities.

Intergovernmental Review: This program is not subject to Executive Order 12372 and the regulations in 34 CFR part 79.

Accessible Format: Individuals with disabilities can obtain this document in an accessible format (e.g., braille, large print, audiotape, or compact disc) on request to the program contact person listed under **FOR FURTHER INFORMATION CONTACT**.

Electronic Access to This Document: The official version of this document is the document published in the **Federal Register**. Free Internet access to the official edition of the **Federal Register** and the Code of Federal Regulations is available via the Federal Digital System at: *www.gpo.gov/fdsys.* At this site you can view this document, as well as all other documents of this Department published in the **Federal Register**, in text or Adobe Portable Document Format (PDF). To use PDF you must have Adobe Acrobat Reader, which is available free at the site.

You may also access documents of the Department published in the **Federal Register** by using the article search feature at: *www.federalregister.gov.* Specifically, through the advanced search feature at this site, you can limit your search to documents published by the Department.

Dated: January 18, 2013.

Michael Yudin,

Acting Assistant Secretary for Special Education and Rehabilitative Services.

[FR Doc. 2013–01418 Filed 1–24–13; 8:45 am]

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DEPARTMENT OF EDUCATION

34 CFR Chapter II

[Docket ID ED–2012–OESE–0033]

Proposed Priorities, Requirements, Definitions, and Selection Criteria—Enhanced Assessment Instruments

AGENCY: Office of Elementary and Secondary Education, Department of Education.

ACTION: Proposed priorities, requirements, definitions, and selection criteria.

Catalog of Federal Domestic Assistance (CFDA) Number: 84.368

SUMMARY: The Assistant Secretary for Elementary and Secondary Education proposes priorities, requirements, definitions, and selection criteria under the Enhanced Assessment Instruments Grant program, also called the Enhanced Assessment Grants (EAG) program. The Assistant Secretary may use one or more of these priorities, requirements, definitions, and selection criteria for competitions using funds from fiscal year (FY) 2012 and later years. The Department takes these actions in order to establish priorities, requirements, definitions, and selection criteria that are likely to recognize high-quality proposals and to help focus Federal financial assistance on the pressing needs of, and promising developments in, developing or enhancing assessments under the Elementary and Secondary Education Act of 1965, as amended (ESEA).

DATES: We must receive your comments on or before February 25, 2013, and we encourage you to submit comments well in advance of this date.

ADDRESSES: Submit your comments through the Federal eRulemaking Portal or via postal mail, commercial delivery, or hand delivery. We will not accept comments by fax or by email. To ensure we do not receive duplicate comments, please submit your comments only once. In addition, please include the Docket ID and the term ''Enhanced Assessment Grants—Comments'' at the top of your comments.

Federal eRulemaking Portal: Go to *www.regulations.gov* to submit your comments electronically. Information on using Regulations.gov, including instructions for accessing agency documents, submitting comments, and viewing the docket, is available on the site under ''How To Use This Site.''

Postal Mail, Commercial Delivery, or Hand Delivery: If you mail or deliver your comments about these proposed priorities, requirements, definitions, and selection criteria, address them to the Office of Elementary and Secondary Education (Attention: Enhanced Assessment Grants—Comments), U.S. Department of Education, 400 Maryland Avenue SW., room 3w110, Washington, DC 20202–6132.

Privacy Note: The Department's policy is to make all comments received from members of the public available for public viewing in their entirety on the Federal eRulemaking Portal at *www.regulations.gov.* Therefore, commenters should be careful to include in their comments only information that they wish to make publicly available.

FOR FURTHER INFORMATION CONTACT: Erin Shackel. Telephone: (202) 453–6423 or by email: *erin.shackel@ed.gov.*

If you use a telecommunications device for the deaf (TDD), call the Federal Relay Service (FRS), toll free, at 1–800–877–8339.

SUPPLEMENTARY INFORMATION:

Invitation to Comment: We invite you to submit comments regarding this notice. To ensure that your comments have maximum effect in developing the notice of final priorities, requirements, definitions, and selection criteria, we urge you to identify clearly the specific proposed priority, requirement, definition, or selection criterion that each comment addresses.

Please note that we have included existing requirements and selection criteria in this document to provide context and to make it easier to comment on the requirements and selection criteria we are proposing. We seek comment only on the proposed priorities, requirements, definitions, and selection criteria.

We invite you to assist us in complying with the specific requirements of Executive Order 12866 and its overall requirement of reducing regulatory burden that might result from these proposed priorities, requirements, definitions, and selection criteria. Please let us know of any further ways the Department could reduce potential costs or increase potential benefits while preserving the effective and efficient administration of the program.

During and after the comment period, you may inspect all public comments about this notice in room 3W110, 400 Maryland Avenue SW., Washington, DC, between the hours of 8:30 a.m. and 4:00 p.m., Washington, DC time, Monday through Friday of each week except Federal holidays.

Assistance to Individuals with Disabilities in Reviewing the Rulemaking Record: On request the Department will provide an appropriate accommodation or auxiliary to aid an individual with a disability who needs assistance to review the comments or other documents in the public rulemaking record for this notice. If you want to schedule an appointment for this type of accommodation or auxiliary aid, please contact the person listed under **FOR FURTHER INFORMATION CONTACT**.

Purpose of Program: The purpose of the EAG program is to enhance the quality of assessment instruments and systems used by States for measuring the academic achievement of elementary and secondary school students.

Program Authority: 20 U.S.C. 7301a.

Proposed Priorities:

This notice contains two proposed priorities. The Department may apply one or more of these priorities in any year in which a competition for program funds is held.

Background:

Section 6112 of the ESEA authorizes the Department, through the EAG program, to make competitive grant awards to State educational agencies (SEAs) and consortia of SEAs to help them enhance the quality of their assessment instruments and assessment systems. The EAG program includes the following four statutory priorities:

(a) Collaborating with institutions of higher education, other research institutions, or other organizations to improve the quality, validity, and reliability of State academic assessments beyond the requirements for such assessments described in section 1111(b)(3) of the ESEA;

(b) Measuring student academic achievement using multiple measures of student academic achievement from multiple sources;

(c) Charting student progress over time; and

(d) Evaluating student academic achievement through the development of comprehensive academic assessment instruments, such as performance- and technology-based academic assessments.

An applicant for EAG funds must address one or more of these statutory priorities to be eligible for an award.

Through this notice, the Department proposes two additional priorities that are designed to support States' assessment work in early learning. The Department believes that a high-quality State early learning system involves several key components. These include, among other elements, early learning and development standards (as defined in this notice) that reflect the essential domains of school readiness (as defined in this notice) and a comprehensive early learning assessment system (as defined in this notice). Such an assessment system, when well-designed and properly implemented, can inform teaching and program improvement and contribute to better outcomes for children.[1]

The priorities we propose in this notice focus on one piece of a comprehensive early learning assessment system—the kindergarten entry assessment (KEA). In particular, these priorities will support the development or enhancement of KEAs and promote collaboration among States in the development or enhancement of a common KEA.

A KEA is a critical piece of a comprehensive early learning assessment system because it provides a snapshot of children's learning and development at kindergarten entry. A well-designed and properly implemented KEA also can provide data to suggest areas where children may need interventions or additional supports in order to be successful in the early grades. Over time, when included as part of a comprehensive early learning assessment system, a KEA can provide data that will inform State efforts to improve child learning outcomes and help close achievement gaps.

Over the last decade, States have demonstrated an increased interest in understanding children's learning and development at kindergarten entry. Approximately half of States have instituted some form of early learning assessment.[2] However, these assessments vary widely in their alignment with early learning and development standards, in the depth and scope of the domains they address, and in how the data generated are used.[3]

The priorities proposed in this notice build on the Department's efforts to fund States collaborating to support children and youth across the cradle-through-college-to-career continuum. Grants under three Department programs, including the EAG program, currently support State-led efforts to develop common assessments among States. The Department has funded two EAG awards to support States collaborating to develop English language proficiency (ELP) assessment systems. The assessments in the systems developed under these EAG–ELP grants must be aligned with English language proficiency standards that correspond to a common set of college- and career-ready standards in English language arts and mathematics. The Department also is funding projects involving large consortia of States through the Race to the Top Assessment (RTTA) program and companion projects through the General Supervision Enhancement Grants (GSEG) program under the Individuals with Disabilities Education Act (IDEA) to develop both general and alternate assessments that are aligned with a common set of college- and career-ready standards in English language arts and mathematics.

In addition, the Department is maintaining support for the beginning of the cradle-through-college-to-career continuum through the Race to the Top—Early Learning Challenge (RTT–ELC) program. Jointly administered with the U.S. Department of Health and Human Services, RTT–ELC reflects the Departments' commitment to supporting America's youngest learners in developing the knowledge, skills, and dispositions toward learning they need to enter kindergarten ready to succeed in school and in life. To date, 14 States have been awarded RTT–ELC grants to fund education reform through developing or enhancing coordinated State systems of early learning. These RTT–ELC grants specifically support States' efforts to increase the number of children with high needs enrolled in high-quality early learning and development programs.

Recipients of RTT–ELC grants are eligible to apply for grants under the EAG program, including competitions (if any) using the KEA priority. However, the Department expects that these applicants will propose activities that are consistent with but do not duplicate activities included in their RTT–ELC applications.

Proposed Priority 1—Kindergarten Entry Assessment

Background: The Department believes that a high-quality KEA should provide critical information about children's learning and development across all the essential domains of school readiness (as defined in this notice), inform instruction at kindergarten entry and throughout the year, and support efforts to close the school-readiness gap. Families should be able to use this information to provide support for children at home. Teachers should be able to use this information to modify instruction at kindergarten entry and throughout the year, adapt curricula, and focus professional development needs. In addition, a high-quality KEA should provide information to support effective programmatic decisions and better target investments in the years before kindergarten. Proposed Priority 1

[1] National Research Council (2008). Early Childhood Assessment: Why, What, and How. Committee on Developmental Outcomes and Assessments for Young Children, C.E. Snow and S.B. Van Hemel, Editors. Board on Children, Youth, and Families, Board on Testing and Assessment, Division of Behavioral and Social Sciences and Education. Washington, DC: The National Academies Press. Available at *www.nap.edu/catalog.php?record_id=12446.*

[2] J. Stedron & A. Berger. 2010. NCSL Technical Report: State Approaches to School Readiness Assessment (updated August 2010). Denver, CO: National Conference of State Legislators. *www.ncsl.org/documents/Educ/KindergartenAssessment.pdf.*

[3] S. Daily, M. Burkhauser, & T. Halle. 2010. ''A Review of School Readiness Practices in the States: Early Learning Guidelines and Assessments.'' Early Childhood Highlights 1 (3). Available at *www.childtrends.org/Files/Child_Trends-2010_06_18_ECH_SchoolReadiness.pdf.*

would support the development or enhancement of high-quality KEAs. These assessments would be integrated into States' student assessment systems and, if they exist, into the States' early learning assessment systems.

Under the proposed priority a KEA would be administered to children soon enough after their enrollment in kindergarten so that results could be used to inform instruction at kindergarten entry and throughout the year, adapt curricula, and focus professional development to help close any educational gaps.

The proposed priority also would require that the KEA be aligned with States' high-quality early learning and development standards (as defined in this notice), which are aligned with the States' K–3 academic content standards in, at a minimum, early literacy and mathematics. In addition, KEAs developed under the proposed priority must measure each child's development across the full range of the essential domains of school readiness (as defined in this notice).

A KEA developed or enhanced under this proposed priority must be of high technical quality and be consistent with the guidelines on early childhood assessments made by the National Research Council.[4] We propose to require that these KEAs be consistent with the National Research Council guidelines in light of the direction we received from Congress for the RTT–ELC program that States receiving grants under that program provide an assurance that any use of early childhood assessments conform to National Research Council reports on early childhood.[5] We believe that Congress would also expect that any early learning assessments developed under the EAG program would be similarly aligned with the National Research Council findings.

Further, a KEA developed or enhanced under this proposed priority must not be used to prevent children's entry into kindergarten.

In short, the proposed priority is intended to produce KEAs that provide a snapshot of information on children's learning and development across multiple domains and can be integrated into States' student assessment systems, and if they exist, included in a States' comprehensive early learning assessment systems. The data generated from a KEA developed or enhanced through this grant would inform and support educators in providing effective learning opportunities to every child, and prevent or close achievement gaps.

Proposed Priority 1: Kindergarten Entry Assessment.

To meet this priority, an applicant must propose a project that supports the development or enhancement of a KEA that meets the following requirements:

(a) Purpose. The KEA must—

(1) Yield information that enables State and local agencies to effectively target investments for early learning and development systems serving children in the years before kindergarten;

(2) Yield information that enables programmatic decision-making at the school level, such as identifying individual children's needs and providing necessary supports to children and teachers in order to meet those needs at kindergarten entry and throughout the year;

(3) Yield information to guide individualized instruction for children enrolled in kindergarten and throughout the school year;

(4) Provide families with information about their children's learning and development based on the essential domains of school readiness (as defined in this notice); and

(5) Not be used to prevent children's entry into kindergarten.

(b) Design. The KEA must—

(1) Be a component of a State's student assessment system, including, a State's comprehensive early learning assessment system (as defined in this notice) for each State included in an application in which a comprehensive early learning assessment system exists;

(2) Be aligned with a set of early learning and development standards (as defined in this notice);

(3) Measure the full range of learning and development across the essential domains of school readiness (as defined in this notice);

(4) Measure children's learning and development against a set of levels of performance where the levels of performance encompass descriptors of what a child knows and is able to do for each level, are common statewide, and, if the applicant State applies on behalf of a consortium, are common across States in the consortium;

(5) Provide a summative assessment of each child's learning and development at kindergarten entry across the essential domains of school readiness (as defined in this notice);

(6) Be capable of assessing all children in the applicant State, and if the State applies as part of a consortium, all children in the consortium;

(7) Be developed consistent with universal design principles to be accessible to all children, including children with disabilities or developmental delays and English learners (as defined in this notice);

(8) As needed, provide appropriate accommodations and supports for children with disabilities or developmental delays and English learners (as defined in this notice) (e.g., augmentative communication devices and assistive technologies);

(9) Be administered soon enough after a child's enrollment into kindergarten to achieve the purposes for which the assessment was developed, including the purposes specified in paragraph (a) of this priority;

(10) Use multiple methods (e.g., performance tasks, selected responses, observational ratings) to measure children's performance and development;

(11) Be administered by a trained assessor or assessors;

(12) Be designed to incorporate technology in the collection of student data and in the process of assessing children's performance on learning and development tasks; and

(13) Be cost-effective to administer, maintain, and enhance during and after the project period.

(c) Technical Quality. The KEA must measure children's learning and development at kindergarten entry in ways that—

(1) Are consistent with nationally recognized professional and technical standards for assessment;

(2) Are consistent with the recommendations of the National Research Council report on early childhood assessments;[6]

(3) Are valid, reliable, and appropriate for their intended purposes;

(4) Provide a valid and reliable measure across the performance spectrum of each child's learning and development at kindergarten entry, including children with disabilities or developmental delays and English learners.

(d) Data. The KEA must produce data and information that—

(1) Allow, at kindergarten entry, for a valid and reliable interpretation of each child's learning and development across the essential domains of school readiness (as defined in this notice) with each domain making a significant

[4] See *www.nap.edu/catalog.php?record_id=12446.*

[5] See Department of Defense and Full-Year Continuing Appropriations Act, 2011, Division B, § 1832(b), Public Law 112–10 (April 15, 2011).

[6] National Research Council. (2008). Early Childhood Assessment: Why, What, and How. Committee on Developmental Outcomes and Assessments for Young Children, C.E. Snow and S.B. Van Hemel, Editors. Board on Children, Youth, and Families, Board on Testing and Assessment, Division of Behavioral and Social Sciences and Education. Washington, DC: The National Academies Press. Available at *www.nap.edu/catalog.php?record_id=12446.*

contribution to the overall comprehensive score;

(2) Can be reported to and easily understood and used by various stakeholders, including families, teachers, administrators, early learning providers, and policy-makers, consistent with requirements of Federal, State, and local privacy laws; and

(3) Can be incorporated into a State's longitudinal data system (SLDS) and a State's early learning data system (if it is separate from an SLDS), consistent with requirements of Federal, State, and local privacy laws.

(e) Compatibility. The KEA must use approaches to assessment design and implementation (e.g., use of technology, assessment administration, scoring, and reporting) that facilitate the integration of the KEA with a State's student assessment system, including a State's comprehensive early learning assessment system (as defined in this notice) for each State included in an application in which a comprehensive early learning assessment system exists.

Proposed Priority 2—Early Learning Collaborative Efforts Among States

Background: The Department values the benefits derived from States working together and, therefore, proposes collaborative efforts among States as a priority for the development or enhancement of KEAs. As noted earlier, States are working together in consortia under the RTTA program to develop new assessment systems that measure student knowledge and skills against a common set of college- and career-ready standards in English language arts and mathematics. States are also collaborating under the GSEG program to develop companion alternate assessments based on alternate achievement standards. With assistance from the EAG program, States also are working together to develop ELP assessments aligned with common ELP standards.

Similarly, because of the complexity of developing or enhancing a KEA, States in collaboration may yield better results than those undertaking this effort alone. States working in collaboration can build on each State's expertise and experience and generate efficiencies in development, costs, implementation, and uses of results.

In addition, data produced by a KEA administered across multiple States are more meaningful when the early learning and development standards (as defined in this notice) are the same across States, and can provide a common framework for understanding the level of children's learning and development at kindergarten entry.

The Department is considering using this priority as a competitive preference priority in the FY 2013 competition. An applicant would receive a higher number of points based on the extent to which it includes a greater number of States in the consortium, with three to four States representing a low number of States, five to seven States representing an intermediate number of States, and eight or more States representing a high number of States.

Proposed Priority 2: Early Learning Collaborative Efforts Among States.

To meet this priority, an applicant must—

(a) Include a minimum of three States in the consortium and propose developing or enhancing a common KEA for those States. An applicant will receive a greater number of points under this priority based on the extent to which it includes a greater number of States in its consortium;

(b) Adopt or propose a plan for all States in the consortium to adopt a set of early learning and development standards (as defined in this notice) that, for at least the year prior to kindergarten entry, are substantially identical across all States in the consortium;

(c) Adopt or propose a plan for all States in the consortium to adopt the common KEA; and

(d) Provide in the memorandum of understanding or other binding agreement executed by each State in the consortium an assurance that, as a condition of remaining in the consortium, the State will, no later than the end of the project period, adopt the common KEA developed under this priority and the set of early learning and development standards (as defined in this notice) upon which the KEA is based.

Types of Priorities:

When inviting applications for a competition using one or more priorities, we designate the type of each priority as absolute, competitive preference, or invitational through a notice in the **Federal Register**. The effect of each type of priority follows:

Absolute priority: Under an absolute priority, the Department considers only applications that meet the priority (34 CFR 75.105(c)(3)).

Competitive preference priority: Under a competitive preference priority, we give competitive preference to an application by (1) awarding additional points, depending on the extent to which the application meets the priority (34 CFR 75.105(c)(2)(i)); or (2) selecting an application that meets the priority over an application of comparable merit that does not meet the priority (34 CFR 75.105(c)(2)(ii)).

Invitational priority: Under an invitational priority, we are particularly interested in applications that meet the priority. However, we do not give an application that meets the priority a preference over other applications (34 CFR 75.105(c)(1)).

Proposed Requirement:

Background: The proposed requirement is designed to support the transition to ongoing operational administration of assessments developed under the EAG program.

We would add this proposed requirement to the existing requirements for the EAG program established on April 19, 2011 (76 FR 21986). We list the existing requirements below to provide context and make commenting on the proposed requirement easier. We invite comment on the proposed requirement only. The existing requirements are that an eligible applicant awarded a grant under this program must:

(a) Evaluate the validity, reliability, and fairness of any assessments or other assessment-related instruments developed under a grant from this competition, and make available documentation of evaluations of technical quality through formal mechanisms (e.g., peer-reviewed journals) and informal mechanisms (e.g., newsletters), both in print and electronically;

(b) Actively participate in any applicable technical assistance activities conducted or facilitated by the Department or its designees, coordinate with the RTTA program in the development of assessments under this program, and participate in other activities as determined by the Department;

(c) Develop a strategy to make student-level data that result from any assessments or other assessment-related instruments developed under a grant from this competition available on an ongoing basis for research, including for prospective linking, validity, and program improvement studies;[7]

(d) Ensure that any assessments or other assessment-related instruments developed under a grant from this competition will be operational (ready for large-scale administration) at the end of the project period;

(e) Ensure that funds awarded under the EAG program are not used to support the development of standards,

[7] Eligible applicants awarded a grant under this program must comply with the Family Educational Rights and Privacy Act (FERPA) and 34 CFR Part 99, as well as State and local requirements regarding privacy.

such as under the English language proficiency assessment system priority or any other priority;

(f) Maximize the interoperability of any assessments and other assessment-related instruments developed with funds from this competition across technology platforms and the ability for States to move their assessments from one technology platform to another by doing the following, as applicable, for any assessments developed with funds from this competition by—

(1) Developing all assessment items in accordance with an industry-recognized open-licensed interoperability standard that is approved by the Department during the grant period, without non-standard extensions or additions; and

(2) Producing all student-level data in a manner consistent with an industry-recognized open-licensed interoperability standard that is approved by the Department during the grant period;

(g) Unless otherwise protected by law or agreement as proprietary information, make any assessment content (i.e., assessments and assessment items) and other assessment-related instruments developed with funds from this competition freely available to States, technology platform providers, and others that request it for purposes of administering assessments, provided that those parties receiving assessment content comply with consortium or State requirements for test or item security; and

(h) For any assessments and other assessment-related instruments developed with funds from this competition, use technology to the maximum extent appropriate to develop, administer, and score the assessments and report results.

Proposed Requirement:

The Assistant Secretary proposes the following requirement for this program. The Department may apply this requirement in any year in which this program is in effect:

(i) Adopt and implement any assessments, other assessment-related instruments developed or enhanced under the proposed project, and any standards upon which they are based. In addition, if the applicant State applies as, or on behalf of a consortium of States, it must provide in any memorandum of understanding or other binding agreement executed by each State in the consortium an assurance that, to remain in the consortium, the State will adopt and implement any assessments or other assessment-related instruments developed or enhanced under the proposed project and any standards upon which they are based by the end of the project period.

Proposed Definitions:

Background:

Several important terms associated with the priorities, requirements, definitions, and selection criteria proposed in this notice are not defined in the EAG statute. We would add the proposed definitions to the existing definitions for the EAG program established on April 19, 2011 (76 FR 21986), though we are proposing to modify the definition of ''English learner'' established in 2011 in order to broaden the definition to include young children.

Proposed Definitions:

The Assistant Secretary proposes definitions for the EAG program. The Department may apply one or more of these new definitions, and any previously established definitions, in any year in which this program is in effect.

Comprehensive early learning assessment system means a coordinated and comprehensive system of multiple assessments, each of which is valid and reliable for its specified purpose and for the population with which it will be used, that organizes information about the process and context of young children's learning and development in order to help teachers make informed instructional and programmatic decisions and that conforms with the recommendations of the National Research Council report on early childhood assessments [8] by including, at a minimum: (a) Screening measures (as defined in this notice); (b) formative assessments; (c) measures of environmental quality (as defined in this notice); (d) measures of the quality of adult-child interactions (as defined in this notice); and (e) a kindergarten entry assessment (KEA).

Early learning and development standards means a set of expectations, guidelines, or developmental milestones that—

(a) Describe what all children from birth to kindergarten entry should know and be able to do and their dispositions toward learning;

(b) Are appropriate for each age group (e.g., infants, toddlers, and preschoolers); for English learners; and for children with disabilities or developmental delays;

(c) Cover all essential domains of school readiness (as defined in this notice);

(d) Are universally designed and developmentally, culturally, and linguistically appropriate; and

(e) Are aligned with the State's K–3 academic standards in, at a minimum, early literacy and mathematics.

English learner means a child, including a child aged three and younger, who is an English learner consistent with the definition of a child who is ''limited English proficient,'' as applicable, in section 9101(25) of the Elementary and Secondary Education Act of 1965, as amended.

Essential domains of school readiness means the domains of language and literacy development, cognition and general knowledge (including early mathematics and early scientific development), approaches toward learning, physical well-being and motor development (including adaptive skills), and social and emotional development.

Formative assessment (also known as a classroom-based or ongoing assessment) means assessment questions, tools, and processes—

(a) That are—

(1) Specifically designed to monitor children's progress;

(2) Valid and reliable for their intended purposes and their target populations; and

(3) Linked directly to the curriculum; and

(b) The results of which are used to guide and improve instructional practices.

Measures of environmental quality means valid and reliable indicators of the overall quality of the early learning environment.

Measures of the quality of adult-child interactions means the measures obtained through valid and reliable processes for observing how teachers and caregivers interact with children, where such processes are designed to promote child learning and to identify strengths and areas for improvement for early learning professionals.

Screening measures means age and developmentally appropriate, valid, and reliable instruments that are used to identify children who may need follow-up services to address developmental, learning, or health needs in, at a minimum, the areas of physical health, behavioral health, oral health, child development, vision, and hearing.

Proposed Selection Criteria:

Background: The Department intends that the selection criteria used for competitions for EAG funds will ensure

[8] National Research Council (2008). Early Childhood Assessment: Why, What, and How. Committee on Developmental Outcomes and Assessments for Young Children, C.E. Snow and S.B. Van Hemel, Editors. Board on Children, Youth, and Families, Board on Testing and Assessment, Division of Behavioral and Social Sciences and Education. Washington, DC: The National Academies Press. Available at *www.nap.edu/catalog.php?record_id=12446.*

that EAG projects address the most critical needs of education. The Department also expects that the selection criteria used for competitions for EAG funds will ensure that any assessments funded under this program will be of high technical quality. We established selection criteria for the EAG program on April 19, 2011 (76 FR 21986), and April 30, 2012 (77 FR 25470). The 2011 selection criteria addressed the assessment design and the assessment development plan; however, those criteria are not appropriate for entry assessments within a KEA. Therefore, we are proposing two new selection criteria that address similar issues but with a focus on kindergarten children.

The proposed selection criteria (h) and (i) would be used in combination with the selection criteria that have already been established. The Department notes that the 2011 assessment design selection criterion (b) is inconsistent with both the proposed kindergarten entry assessment design criterion (h) and the purposes of the proposed KEA priority, and the Department does not intend to use selection criterion (b) with the proposed KEA priority.

The Department also notes that the 2011 assessment development plan selection criterion (c) is inconsistent with both the proposed kindergarten entry assessment development plan selection criterion (i) and the purposes of the proposed KEA priority, and the Department does not intend to use the 2011 selection criterion (c) with the proposed KEA priority.

We list the existing selection criteria below to provide context and to make commenting on the proposed selection criteria easier. We invite comments on the proposed selection criteria only.

The existing selection criteria are:

(a) *Theory of action.* The Secretary reviews each application to determine the extent to which the eligible applicant's theory of action is logical, coherent, and credible, and will result in improved student outcomes. In determining the extent to which the theory of action has these attributes, we will consider the description of, and rationale for—

(1) How the assessment results will be used (e.g., at the State, local educational agency, school, classroom, and student levels);

(2) How the assessments and assessment results will be incorporated into coherent educational systems (i.e., systems that include standards, assessments, curriculum, instruction, and professional development) of the State(s) participating in the grant; and

(3) How those educational systems as a whole will improve student achievement.

(b) *Assessment design.* The Secretary reviews each application to determine the extent to which the design of the eligible applicant's proposed assessments is innovative, feasible, and consistent with the theory of action. In determining the extent to which the design has these attributes, we will consider—

(1) The number and types of assessments, as appropriate (e.g., diagnostic assessments, summative assessments);

(2) How the assessments will measure student knowledge and skills against the full range of the relevant standards, including the standards against which student achievement has traditionally been difficult to measure, provide an accurate measure of student proficiency on those standards, including for students who are high- and low-performing in academic areas, and provide an accurate measure of student progress in the relevant area over a full academic year;

(3) How the assessments will produce the required student performance data, as described in the priority;

(4) How and when during the academic year different types of student data will be available to inform and guide instruction, interventions, and professional development;

(5) The types of data that will be produced by the assessments, which must include student achievement data and other data specified in the relevant priority;

(6) The uses of the data that will be produced by the assessments, including (but not limited to)—

(i) Determining individual student achievement and student progress; determining, as appropriate and as one of multiple measures, individual principal and teacher effectiveness, if applicable; and professional development and support needs;

(ii) Informing teaching, learning, and program improvement; and

(7) The frequency and timing of administration of the assessments, and the rationale for these;

(8) The number and types of items (e.g., performance tasks, selected responses, observational rating, brief or extended constructed responses) and the distribution of item types within the assessments, including the extent to which the items will be varied and elicit complex student demonstrations or applications of knowledge, skills, and approaches to learning, as appropriate (descriptions should include a concrete example of each item type proposed); and the rationale for using these item types and their distributions;

(9) The assessments' administration mode (e.g., paper-and-pencil, teacher rating, computer-based, or other electronic device), and the rationale for the mode;

(10) The methods for scoring student performance on the assessments, the estimated turnaround times for scoring, and the rationale for these; and

(11) The reports that will be produced based on the assessments, and for each report: the key data it will present; its intended use; target audience (e.g., students, parents, teachers, administrators, policymakers); and its presentation in an understandable and uniform format and, to the extent practicable, in a language that parents can understand.

(c) *Assessment development plan.* The Secretary reviews each application to determine the extent to which the eligible applicant's plan for developing the proposed assessments will ensure that the assessments are ready by the end of the grant period for wide-scale administration in a manner that is timely, cost-effective, and consistent with the proposed design and incorporates a process for ongoing feedback and improvement. In determining the extent to which the assessment development plan has these attributes, the Department will consider—

(1)(i) The approaches for developing assessment items (e.g., evidence-centered design, universal design) and the rationale for using those approaches; and the development phases and processes to be implemented consistent with the approaches; and

(ii) The types of personnel (e.g., practitioners, content experts, assessment experts, experts in assessing English learners, linguists, experts in second language acquisition, experts in assessing students with disabilities, psychometricians, cognitive scientists, institution of higher education representatives, experts on career readiness standards, and other key stakeholders) involved in each development phase and process;

(2) The approach and strategy for designing and developing accommodations, accommodation policies, and methods for standardizing the use of those accommodations for students with disabilities;

(3) The approach and strategy for ensuring scalable, accurate, and consistent scoring of items, including the approach and moderation system for any human-scored items and the extent to which teachers are trained and

involved in the administration and scoring of assessments;

(4) The approach and strategy for developing the reporting system; and

(5) The overall approach to quality control and the strategy for field-testing assessment items, accommodations, scoring systems, and reporting systems, including, with respect to assessment items and accommodations, the use of representative sampling of all types of student populations, taking into particular account high- and low-performing students, different types of English learners (e.g., recently arrived English learners, former English learners, migratory English learners, and English learners with disabilities), and students with disabilities.

(d) *Research and evaluation.* The Secretary reviews each application to determine the extent to which the eligible applicant's research and evaluation plan will ensure that the assessments developed are valid, reliable, and fair for their intended purposes. In determining the extent to which the research and evaluation plan has these attributes, we will consider—

(1) The plan for identifying and employing psychometric techniques suitable for verifying, as appropriate to each assessment, its construct, consequential, and predictive validity; external validity; reliability; fairness; precision across the full performance continuum; and comparability within and across grade levels; and

(2) The plan for determining whether the assessments are being implemented as designed and the theory of action is being realized, including whether the intended effects on individuals and institutions are being achieved.

(e) *Professional capacity and outreach.* The Secretary reviews each application to determine the extent to which the eligible applicant's plan for implementing the proposed assessments is feasible, cost-effective, and consistent with the theory of action. In determining the extent to which the implementation plan has these attributes, we will consider—

(1) The plan for supporting teachers and administrators in implementing the assessments and for developing, in an ongoing manner, their professional capacity to use the assessments and results to inform and improve instructional practice; and

(2) The strategy and plan for informing the public and key stakeholders (including teachers, administrators, families, legislators, and policymakers) in each State or in each member State within a consortium about the assessments and for building support from the public and those stakeholders.

(f) *Technology approach.* The Secretary reviews each application to determine the extent to which the eligible applicant would use technology effectively to improve the quality, accessibility, cost-effectiveness, and efficiency of the proposed assessments. In determining the extent to which the eligible applicant is using technology effectively, we will consider—

(1) The description of, and rationale for, the ways in which technology will be used in assessment design, development, administration, scoring, and reporting; the types of technology to be used (including whether the technology is existing and commercially available or is being newly developed); and how other States or organizations can re-use in a cost-effective manner any technology platforms and technology components developed under this grant; and

(2) How technology-related implementation or deployment barriers will be addressed (e.g., issues relating to local access to internet-based assessments).

(g) *Project management.* The Secretary reviews each application to determine the extent to which the eligible applicant's project management plan will result in implementation of the proposed assessments on time, within budget, and in a manner that is financially sustainable over time. In determining the extent to which the project management plan has these attributes, we will consider—

(1) The project workplan and timeline, including, for each key deliverable (e.g., necessary procurements and any needed approvals for human subjects research, assessment, scoring and moderation system, professional development activities), the major milestones, deadlines, and entities responsible for execution;

(2) The approach to identifying, managing, and mitigating risks associated with the project;

(3) The extent to which the eligible applicant's budget is adequate to support the development of assessments that meet the requirements of the priority and includes costs that are reasonable in relation to the objectives, design, and significance of the proposed project and the number of students to be served;

(4) For each applicant State or for each member State within a consortium, the estimated costs for the ongoing administration, maintenance, and enhancement of the operational assessments after the end of the project period for the grant and a plan for how the State will fund the assessments over time (including by allocating to the assessments funds for existing State or local assessments that will be replaced by the new assessments); and

(5) The quality and commitment of the personnel who will carry out the proposed project, including the qualifications, relevant training, and experience of the project director and other key project personnel, and the extent to which the time commitments of the project director and other key project personnel are appropriate and adequate to meet the objectives of the proposed project.

Proposed Selection Criteria:

The Assistant Secretary proposes the following selection criteria for evaluating an application under this program. We may apply these criteria or any of the existing selection criteria in any year in which this program is in effect. In the notice inviting applications and the application package, the Department will announce the selection criteria to be applied and the maximum possible points assigned to each criterion.

(h) *Kindergarten entry assessment design.*

The Secretary reviews each application to determine the extent to which the design of the eligible applicant's proposed assessment is innovative, feasible, and consistent with the theory of action. In determining the extent to which the design has these attributes, the Department will consider—

(1) How the assessment will measure child performance and development against early learning and development standards (as defined in this notice);

(2) The steps proposed for ensuring that the assessment is aligned with the specific early learning and development standards on which the assessment is based;

(3) The extent to which data from the assessment can be incorporated into a State's longitudinal data system (SLDS) and a State's early learning data system (if it is separate from an SLDS) through the use of or connection to common data elements and definitions, such as the Common Education Data Standards (*https://ceds.ed.gov/*), consistent with requirements of Federal, State, and local privacy laws;

(4) The intended uses of the data to be generated by the assessment, which must include, but need not be limited to—

(i) Determining the level of individual child learning and development;

(ii) Identifying teacher professional development and support needs;

(iii) Informing teaching, learning, and program improvement; and

(iv) Engaging families in the early learning of their children;

(5) The number and types of items (e.g., performance tasks, selected responses, observational ratings) and the distribution of item types within the assessment, including the variation of the items and the rationale for using these item types and their distributions;

(6) The assessment's administration mode(s) (e.g., direct, observation, or administered using an electronic device), and the rationale for the mode(s);

(7) The methods for scoring child performance on the assessments, the estimated turnaround times for scoring, and the rationale(s) for these;

(8) The applicant's plan to set levels of performance for the assessment, where the levels of performance encompass descriptors of what a child knows and is able to do for each level, and for how the applicant will meaningfully engage and solicit stakeholder input on the development of levels of performance that are valid and reliable for children's learning and development; and

(9) The reports and interpretation guides that will be produced based on the assessments, and for each report and interpretation guide: the key data it will present; its intended use; its target audience (e.g., families, teachers, administrators, policymakers, and other stakeholders); and how its presentation will be in an understandable and uniform format and, to the extent practicable, in a language that families can understand.

(i) *Kindergarten entry assessment development plan.* The Secretary reviews each application to determine the extent to which the eligible applicant's plan for developing the proposed KEA will ensure that the assessments are ready by the end of the grant period for wide-scale administration in a manner that is timely, cost-effective, and consistent with the proposed design and incorporates a process for ongoing feedback and improvement. In determining the extent to which the assessment development plan has these attributes, the Department will consider—

(1)(i) The approaches for developing assessment items (e.g., evidence-centered design, universal design), the rationale for using those approaches, and the development phases and processes to be implemented consistent with the approaches;

(ii) The types of personnel involved in each development phase and process (e.g., practitioners, experts in early learning and development, experts in the assessment of young children, content experts, assessment experts, experts in assessing children with disabilities or developmental delays and English learners, psychometricians, cognitive scientists, and other key stakeholders);

(2) The approach and strategy for designing and developing accommodations, accommodation policies, and methods for standardizing the use of those accommodations for children with disabilities or developmental delays and English learners (as defined in this notice);

(3) The approach and strategy for ensuring scalable, accurate, and consistent scoring of items, including the approach and moderation system for any items not scored by machine and the extent to which teachers are trained and involved in the administration and scoring of assessments;

(4) The approach and strategy for developing the reporting system; and

(5) The overall approach to quality control, maintaining the integrity of the assessment process, field-testing assessment items, accommodations, scoring systems, and reporting systems, including, with respect to assessment items and accommodations, the use of representative sampling of all types of child populations, taking into particular account the full range of learning and development across the essential domains of school readiness (as defined in this notice), and including children with disabilities or developmental delays and English learners (as defined in this notice).

Final Priorities, Requirements, Definitions, and Selection Criteria:

We will announce the final priorities, requirements, definitions, and selection criteria in a notice in the **Federal Register**. We will determine the final priorities, requirements, definitions, and selection criteria after considering responses to this notice and other information available to the Department. This notice does not preclude us from proposing additional priorities, requirements, definitions, or selection criteria, subject to meeting applicable rulemaking requirements.

Note: This notice does *not* solicit applications. In any year in which the Department chooses to use these priorities, requirements, definitions, or selection criteria, we invite applications through a notice in the **Federal Register**.

Executive Order 12866 and 13563

Regulatory Impact Analysis

Under Executive Order 12866, the Secretary must determine whether this regulatory action is ''significant'' and, therefore, subject to the requirements of the Executive Order and subject to review by the Office of Management and Budget (OMB). Section 3(f) of Executive Order 12866 defines a ''significant regulatory action'' as an action likely to result in a rule that may—

(1) Have an annual effect on the economy of $100 million or more, or adversely affect a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local or tribal governments or communities in a material way (also referred to as an ''economically significant'' rule);

(2) Create serious inconsistency or otherwise interfere with an action taken or planned by another agency;

(3) Materially alter the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or

(4) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

This proposed regulatory action is not a significant regulatory action subject to review by OMB under section 3(f) of Executive Order 12866.

We have also reviewed this proposed regulatory action under Executive Order 13563, which supplements and explicitly reaffirms the principles, structures, and definitions governing regulatory review established in Executive Order 12866. To the extent permitted by law, Executive Order 13563 requires that an agency—

(1) Propose or adopt regulations only upon a reasoned determination that their benefits justify their costs (recognizing that some benefits and costs are difficult to quantify);

(2) Tailor its regulations to impose the least burden on society, consistent with obtaining regulatory objectives and taking into account—among other things and to the extent practicable—the costs of cumulative regulations;

(3) In choosing among alternative regulatory approaches, select those approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity);

(4) To the extent feasible, specify performance objectives, rather than the behavior or manner of compliance a regulated entity must adopt; and

(5) Identify and assess available alternatives to direct regulation, including economic incentives—such as user fees or marketable permits—to encourage the desired behavior, or provide information that enables the public to make choices.

Executive Order 13563 also requires an agency ''to use the best available techniques to quantify anticipated present and future benefits and costs as accurately as possible.'' The Office of Information and Regulatory Affairs of OMB has emphasized that these techniques may include ''identifying changing future compliance costs that might result from technological innovation or anticipated behavioral changes.''

We are issuing these proposed priorities, requirements, definitions, and selection criteria only on a reasoned determination that their benefits would justify their costs. In choosing among alternative regulatory approaches, the Department selected those approaches that would maximize net benefits. Based on the analysis that follows, the Department believes that this regulatory action is consistent with the principles in Executive Order 13563.

We also have determined that this regulatory action would not unduly interfere with State, local, and tribal governments in the exercise of their governmental functions.

In accordance with both Executive orders, the Department has assessed the potential costs and benefits, both quantitative and qualitative, of this regulatory action. The potential costs are those resulting from statutory requirements and those we have determined as necessary for administering the Department's programs and activities.

The proposed priority for KEAs and the other proposed priority, along with the associated proposed requirement, definitions, and selection criteria, would benefit individual children by supporting the development or enhancement of KEAs that would provide educators with timely and useful information to guide individualized instruction for children at kindergarten entry and throughout the year. In addition, the resulting assessments would benefit educators, administrators, and other stakeholders by yielding information that can be used to target investments for the education systems serving children in the years before kindergarten. A KEA would also support the implementation of State reform efforts in the area of early learning.

The proposed priority for early learning collaborative efforts among States would encourage States to work together on developing a common KEA rather than developing or using separate KEAs, thus pooling expertise and experience while also creating efficiencies, including cost-efficiencies. The priority would also help ensure that a KEA developed by a consortium is made available for use by multiple States. It also would support the collection of comparable data regarding the level of children's learning and development at kindergarten entry.

The proposed selection criteria would help ensure that the assessments developed by grantees are of high quality, meet relevant technical standards, and align with other assessment work funded by the Department.

Intergovernmental Review: This program is subject to Executive Order 12372 and the regulations in 34 CFR part 79. One of the objectives of the Executive Order is to foster an intergovernmental partnership and a strengthened federalism. The Executive Order relies on processes developed by State and local governments for coordination and review of proposed Federal financial assistance.

This document provides early notification of our specific plans regarding this program.

Accessible Format: Individuals with disabilities can obtain this document in an accessible format (e.g., braille, large print, audiotape, or compact disc) on request to the program contact person listed under **FOR FURTHER INFORMATION CONTACT**.

Electronic Access to This Document: The official version of this document is the document published in the **Federal Register**. Free Internet access to the official edition of the **Federal Register** and the Code of Federal Regulations is available via the Federal Digital System at: *www.gpo.gov/fdsys.* At this site you can view this document, as well as all other documents of this Department published in the **Federal Register**, in text or Adobe Portable Document Format (PDF). To use PDF you must have Adobe Acrobat Reader, which is available free at the site.

You may also access documents of the Department published in the **Federal Register** by using the article search feature at: *www.federalregister.gov.* Specifically, through the advanced search feature at this site, you can limit your search to documents published by the Department.

Dated: January 22, 2013.

Deborah S. Delisle,

Assistant Secretary for Elementary and Secondary Education.

[FR Doc. 2013–01567 Filed 1–24–13; 8:45 am]

BILLING CODE 4000–01–P

LIBRARY OF CONGRESS

United States Copyright Office

37 CFR Parts 201 and 210

[Docket No. 2012–1]

Copyright Office Fees

AGENCY: U.S. Copyright Office, Library of Congress.

ACTION: Notice of proposed rulemaking: Extension of reply comment periods.

SUMMARY: The United States Copyright Office is extending the deadline for filing reply comments regarding its notice of proposed rulemaking concerning the establishment of a fee schedule for filing cable and satellite statements of account for use of the statutory licenses that provide for the secondary transmission of broadcast programming by cable and satellite companies.

DATES: Reply comments on the proposed regulation must be received in the Office of the General Counsel of the Copyright Office no later than 5 p.m. Eastern Daylight Time (EDT) on February 15, 2013.

ADDRESSES: The Copyright Office strongly prefers that reply comments be submitted electronically. A comment submission page is posted on the Copyright Office Web site at *http://www.copyright.gov/docs/newfees/comments/*. The Web site interface requires submitters to complete a form specifying name and other required information, and to upload comments as an attachment. To meet accessibility standards, all comments must be uploaded in a single file in either the Adobe Portable Document File (PDF) format that contains searchable, accessible text (not an image); Microsoft Word; WordPerfect; Rich Text Format (RTF); or ASCII text file format (not a scanned document). The maximum file size is 6 megabytes (MB). The name of the submitter and organization should appear on both the form and the face of the comments. All comments will be posted publicly on the Copyright Office Web site exactly as they are received, along with names and organizations if provided. If electronic submission of comments is not feasible, please contact

the U.S. Copyright Office at (202) 707–8380 for special instructions.

FOR FURTHER INFORMATION CONTACT: Megan Rivet, Budget Analyst, or Melissa Dadant, Senior Advisor for Operations and Special Projects, at (202) 707–8350.

SUPPLEMENTARY INFORMATION: On December 6, 2012, the U.S. Copyright Office published a notice of proposed rulemaking (''NPRM'') announcing a revised schedule of fees for filing semi-annual statements of account pursuant to 17 U.S.C. 111, 119, and 122 based upon a new cost study. 77 FR 72,788 (December 6, 2012). Comments to the proposed fees were due on January 7, 2013 and the Office received three comments at that time, including a comment from the National Cable & Telecommunications Association (''NCTA'').

In its comment, NCTA noted that it had submitted on December 13, 2012 a request pursuant to the Freedom of Information Act (''FOIA'') for the cost studies referenced in the Office's December 6 notice announcing new proposed fees. Subsequently, NCTA filed a motion on January 14, 2013 requesting an extension of the January 22, 2013 date for filing reply comments in anticipation of a response from the Office to its FOIA request. The Office is extending the time to file reply comments to 5:00 p.m. EST February 15, 2013 in order to provide additional time for stakeholders to prepare reply comments after the Office resolves the pending FOIA request.

Dated: January 16, 2013.

Tanya M. Sandros,

Deputy General Counsel.

[FR Doc. 2013–01291 Filed 1–24–13; 8:45 am]

BILLING CODE 1410–30–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R01–OAR–2009–0433; EPA–R01–OAR–2012–0149; A–1–FRL–9754–7]

Approval and Promulgation of Air Quality Implementation Plans; Massachusetts and New Hampshire; Enhanced Motor Vehicle Inspection and Maintenance Program

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing to approve State Implementation Plan (SIP) revisions submitted by the Commonwealth of Massachusetts and the State of New Hampshire. These revisions include regulations to update the enhanced motor vehicle inspection and maintenance (I/M) programs in Massachusetts and New Hampshire. The revised programs in Massachusetts and New Hampshire include a test and repair network for an on-board diagnostic (OBD2) testing program for model year 1996 and newer vehicles. The intended effect of this action is to propose approval of the revised programs into the Massachusetts and New Hampshire SIPs. This action is being taken under the Clean Air Act.

DATES: Written comments must be received on or before February 25, 2013.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R01–OAR–2009–0433 for comments pertaining to our proposed approval action for Massachusetts or EPA–R01–OAR–2012–0149 for comments pertaining to our proposed approval action for New Hampshire by one of the following methods:

1. *www.regulations.gov:* Follow the on-line instructions for submitting comments.
2. *Email: arnold.anne@epa.gov.*
3. *Fax:* (617) 918–0047.
4. *Mail:* ''Docket Identification Number EPA–R01–OAR–2009–0433 or EPA–R01–OAR–2012–0149,'' Anne Arnold, U.S. Environmental Protection Agency, EPA New England Regional Office, 5 Post Office Square—Suite 100, (Mail code OEP05–2), Boston, MA 02109–3912.
5. *Hand Delivery or Courier.* Deliver your comments to: Anne Arnold, Manager, Air Quality Planning Unit, Office of Ecosystem Protection, U.S. Environmental Protection Agency, EPA New England Regional Office, 5 Post Office Square—Suite 100, (Mail code OEP05–2), Boston, MA 02109–3912. Such deliveries are only accepted during the Regional Office's normal hours of operation. The Regional Office's official hours of business are Monday through Friday, 8:30 to 4:30, excluding legal holidays.

Please see the direct final rule which is located in the Rules Section of this **Federal Register** for detailed instructions on how to submit comments.

FOR FURTHER INFORMATION CONTACT: Ariel Garcia, Air Quality Planning Unit, U.S. Environmental Protection Agency, EPA New England Regional Office, 5 Post Office Square, Suite 100 (Mail code: OEP05–2), Boston, MA 02109–3912., telephone number (617) 918–1660, fax number (617) 918–0660, email *garcia.ariel@epa.gov.*

SUPPLEMENTARY INFORMATION: In the Final Rules Section of this **Federal Register**, EPA is approving the State's SIP submittal as a direct final rule without prior proposal because the Agency views this as a noncontroversial submittal and anticipates no adverse comments. A detailed rationale for the approval is set forth in the direct final rule. If no adverse comments are received in response to this action, no further activity is contemplated. If EPA receives adverse comments, the direct final rule will be withdrawn and all public comments received will be addressed in a subsequent final rule based on this proposed rule. EPA will not institute a second comment period. Any parties interested in commenting on this action should do so at this time. Please note that if EPA receives adverse comment on an amendment, paragraph, or section of this rule and if that provision may be severed from the remainder of the rule, EPA may adopt as final those provisions of the rule that are not the subject of an adverse comment.

For additional information, see the direct final rule which is located in the Rules Section of this **Federal Register**.

Dated: November 15, 2012.

H. Curtis Spalding,

Regional Administrator, EPA New England.

[FR Doc. 2013–00930 Filed 1–24–13; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R07–OAR–2012–0763; FRL–9772–5]

Approval and Promulgation of Implementation Plans; State of Missouri; Control of Sulfur Emissions From Stationary Boilers

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA proposes to approve revisions to the Missouri State Implementation Plan (SIP) submitted October 27, 2009. This revision adds a new rule to reduce the concentration of fine particles ($PM_{2.5}$) in the St. Louis nonattainment area by limiting sulfur dioxide (SO_2) emissions (a precursor pollutant to $PM_{2.5}$), from industrial boilers. EPA is approving this revision because it strengthens the Missouri SIP. EPA's approval of this SIP revision is being done in accordance with the requirements of the Clean Air Act (CAA).

DATES: Comments on this proposed action must be received in writing by February 25, 2013.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R07–OAR–2012–0763, by mail to Amy Bhesania, Environmental Protection Agency, Air Planning and Development Branch, 11201 Renner Boulevard, Lenexa, Kansas 66219. Comments may also be submitted electronically or through hand delivery/courier by following the detailed instructions in the **ADDRESSES** section of the direct final rule located in the rules section of this **Federal Register**.

FOR FURTHER INFORMATION CONTACT: Amy Bhesania, Environmental Protection Agency, Air Planning and Development Branch, 11201 Renner Boulevard, Lenexa, Kansas 66219 at (913) 551–7147, or by email at *bhesania.amy@epa.gov.*

SUPPLEMENTARY INFORMATION: In the final rules section of the **Federal Register**, EPA is approving the state's SIP revision as a direct final rule without prior proposal because the Agency views this as a noncontroversial revision amendment and anticipates no relevant adverse comments to this action. A detailed rationale for the approval is set forth in the direct final rule. If no relevant adverse comments are received in response to this action, no further activity is contemplated in relation to this action. If EPA receives relevant adverse comments, the direct final rule will be withdrawn and all public comments received will be addressed in a subsequent final rule based on this proposed action. EPA will not institute a second comment period on this action. Any parties interested in commenting on this action should do so at this time. Please note that if EPA receives adverse comment on part of this rule and if that part can be severed from the remainder of the rule, EPA may adopt as final those parts of the rule that are not the subject of an adverse comment. For additional information, see the direct final rule which is located in the rules section of this **Federal Register**.

Dated: January 9, 2013.

Karl Brooks,

Regional Administrator, Region 7.

[FR Doc. 2013–01462 Filed 1–24–13; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 85, 86, 600

[EPA–HQ–OAR–2009–0472; FRL–9772–7]

Denial of Reconsideration Petition on Model Year 2012–2016 Light Duty Vehicle Greenhouse Gas Emissions Standards

AGENCY: Environmental Protection Agency (EPA).

ACTION: Denial of petition for reconsideration.

SUMMARY: The Environmental Protection Agency (EPA or Agency) is providing notice that it is denying the petition of the Pacific Legal Foundation (PLF) to reconsider the final rules establishing greenhouse gas emissions standards from light duty motor vehicles for model years 2012–2016.

DATES: This action is effective on January 25, 2013.

ADDRESSES: EPA's docket for this action is Docket ID No. EPA–HQ–OAR–2009–0472. All documents in the docket are listed on the *http://www.regulations.gov* Web site. Although listed in the index, some information is not publicly available, *e.g.,* confidential business information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically through *http://www.regulations.gov* or in hard copy at EPA's Docket Center, Public Reading Room, EPA West Building, Room 3334, 1301 Constitution Avenue NW., Washington, DC 20004. This Docket Facility 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: Steven Silverman, Office of General Counsel, Environmental Protection Agency, 1200 Pennsylvania Avenue NW., Washington, DC 20460; telephone number: (202) 564–5523; email address: *silverman.steven@epa.gov.*

SUPPLEMENTARY INFORMATION:

Acronyms and Abbreviations. The following acronyms and abbreviations are used in this Decision.

APA Administrative Procedures Act
API American Petroleum Institute
CAA Clean Air Act
CO_2 Carbon dioxide
CH_4 Methane
EPA Environmental Protection Agency
FOIA Freedom of Information Act
FR **Federal Register**
GHG Greenhouse gas
HFC Hydrofluorocarbon
LDVR Light Duty Vehicle Rule
MY Model year
N_2O Nitrous oxide
NHTSA National Highway Traffic Safety Administration
PLF Pacific Legal Foundation
SAB Science Advisory Board

I. Introduction

On May 7, 2010, the EPA published final rules establishing standards limiting emissions of carbon dioxide (CO_2), methane (CH_4), nitrous oxide (N_2O) and hydrofluorocarbons (HFCs) from new light duty motor vehicles, including passenger cars, medium duty passenger vehicles, and light trucks for model years 2012–2016. 75 FR 25324. In this joint rulemaking, the National Highway Traffic Safety Administration (NHTSA), on behalf of the Department of Transportation, issued rules to reduce fuel consumption from these vehicles. Together these rules comprise a coordinated and comprehensive National Program designed to address the urgent and closely intertwined challenges of reducing dependence on oil, achieving energy security, and ameliorating global climate change. PLF petitioned EPA to reconsider its greenhouse gas standards. Because the petition does not state grounds which satisfy the requirements of section 307(d)(7)(B) of the Clean Air Act, EPA is denying the petition.

II. Standard for Reconsideration

Section 307(d)(7)(B) of the Clean Air Act (CAA) states that: ''Only an objection to a rule or procedure which was raised with reasonable specificity during the period for public comment (including any public hearing) may be raised during judicial review. If the person raising an objection can demonstrate to the Administrator that it was impracticable to raise such objection within such time or if the grounds for such objection arose after the period for public comment (but within the time specified for judicial review) and if such objection is of central relevance to the outcome of the rule, the Administrator shall convene a proceeding for reconsideration of the rule and provide the same procedural rights as would have been afforded had the information been available at the time the rule was proposed. If the Administrator refuses to convene such a proceeding, such person may seek review of such refusal in the United States court of appeals for the

appropriate circuit. Such reconsideration shall not postpone the effectiveness of the rule. The effectiveness of the rule may be stayed pending such reconsideration, however, by the Administrator or the court for a period not to exceed three months.''

Thus, reconsideration is required only if a petition for reconsideration shows that the objection or claim could not have been presented during the comment period—either because it was impracticable to raise the objection during that time or because the grounds for raising the objection arose after the period for public comment but within 60 days of publication of the final action (i.e. ''the time specified for judicial review''). To be of central relevance to the outcome of a rule, an objection must provide substantial support for the argument that the promulgated regulation should be revised. See *Coalition for Responsible Regulation* v. *EPA,* 684 F.3d 102, 125 (D.C. Cir. 2012); see also 76 FR 28318 (May 17, 2011) and other actions there cited.

Because all of the objections or claims raised in PLF's petition could have been presented to EPA during the comment period for the rulemaking, and because PLF has failed to demonstrate that its objection is of central relevance to the outcome of the rulemaking, EPA is denying the request for reconsideration.

III. PLF's Petition for Reconsideration

In its petition, PLF alleges that EPA failed to comply with the requirements of 42 U.S.C. section 4365(c)(1). This provision states that ''[t]he Administrator, at the time any proposed criteria document, standard, limitation or regulation under the Clean Air Act, the Federal Water Pollution Control Act, the Resource Conservation Recovery Act, the Noise Control Act, the Toxic Substances Control Act, or the Safe Drinking Water Act, or under any other authority of the Administrator, is provided to any other Federal agency for formal review and comment, shall make available to the [Science Advisory Board, or SAB] such proposed criteria document, standard, limitation, or regulation, together with relevant scientific and technical information in the possession of the Environmental Protection Agency on which the proposed action is based.'' Section 4365(c)(2) then provides that ''[t]he Board may make available to the Administrator, within the time specified by the Administrator, its advice and comments on the adequacy of the scientific and technical basis of the proposed criteria document, standard, limitation, or regulation, together with any pertinent information in the Board's possession.''

PLF maintains that EPA failed to make the proposed model years (MYs) 2012–2016 light duty vehicle greenhouse gas (GHG) rule available to the SAB. PLF then argues that this alleged failure is of central relevance to the outcome of the rulemaking, arguing that an ''utter failure'' of EPA to comply with a procedural requirement imposed by a statute other than the Clean Air Act is of central relevance if there is any uncertainty as to the impact of the failure (Petition pp. 7, 17–18), or in the alternative that there is a substantial likelihood that the rule would have significantly changed absent the alleged procedural error by EPA (*Id.* pp. 8, 18–21). PLF maintains that there is a substantial likelihood that the rule would have changed by assuming that the SAB would have provided scientific and technical advice to EPA of sufficient import to change the rule's outcome, consistent with the SAB's august scientific standing and the Congressional purpose in establishing the opportunity for SAB review. *Id.* PLF further maintains that it could not raise its objection to EPA until after the close of the public comment period to the rulemaking, stating that it did not become aware of the issue until November 10, 2010, when EPA replied to PLF's Freedom of Information Act request seeking copies of ''[a]ll documents, memorandums (sic) or correspondences (sic) dealing with the question of whether EPA should submit, or should have submitted, information to the Science Advisory Board in connection with the promulgation of the [light duty vehicle rule] LDVR''. PLF FOIA Request of September 15, 2010 p. 1.

IV. EPA's Response

1. PLF has failed to demonstrate that ''it was impracticable to raise [its] objection'' during the period for public comment in the rulemaking, or in the time specified for seeking judicial review (i.e. within 60 days of the rule's publication—July 10, 2010), as required by CAA section 307(d)(7)(B).

PLF's objection is legal in nature, and thus could be raised at any time. PLF maintains that it could not raise its objection until receiving a response to its Freedom of Information Act request, but this is not correct. PLF's public comments could simply have stated PLF's belief that 42 U.S.C. section 4365(c) requires EPA to submit the proposed rule to the SAB, and that any failure to do so is error. PLF states that it required an answer to its FOIA request before raising its objection because only then did it learn that EPA had not submitted the light duty vehicle proposal to the SAB. Petition p. 13. But its objection does not require this answer. Moreover, PLF did not submit its FOIA request until September 15, 2010, well after the rule was signed, disseminated electronically, and published, and after the period for seeking judicial review of the rule had expired. Thus, even under its view, the grounds for PLF's objection did not arise until after the time period for judicial review so that PLF's objection was raised in an untimely manner regardless of its argument concerning its FOIA petition. In addition, EPA's FOIA response does not provide PLF with information necessary to raise its objection, since the FOIA request asked whether EPA ''submitted'' the proposed rule and related documents to the SAB. The statutory requirement in section 4365(c) is for EPA to ''make available'' certain proposals to the SAB, as discussed below. Thus, PLF was in essentially the same position after receiving EPA's FOIA response as it was before its request. The same objection it raised in the petition could have been raised during the public comment period.

2. PLF fails to demonstrate that its objection is of central relevance to the outcome of the rulemaking, as required by section 307(d)(7)(B).

First, PLF fails to demonstrate that 42 U.S.C. 4365(c)(1) is applicable. That provision applies only when EPA submits certain documents to other agencies ''for formal review and comment.'' The light duty vehicle GHG rule implements section 202(a) of the Clean Air Act. That provision contains no requirement that implementing regulations be submitted to other federal agencies for formal review and comment, nor did EPA do so. EPA submitted the draft of the proposed rule to the Office of Management and Budget for informal interagency review, pursuant to Executive Order 12866, but this is not the type of formal review to which section 4365(c)(1) speaks. See *Coalition for Responsible Regulation* v. *EPA,* 684 F. 3d at 124 (noting this distinction); compare CAA section 202(a) with 49 U.S.C. section 32902(b) and (j) requiring the Secretary of Transportation to consult with the Secretary of Energy and the Administrator of EPA before prescribing average fuel economy standards for light duty motor vehicles, and requiring the Secretary of Transportation to provide a period of time for the Secretary of Energy to submit comments and for those comments to be included in any proposal issued by the Secretary of

Transportation; see also CAA section 231(a)(1)(B)(i) (''The Administrator shall consult with the Administrator of the Federal Aviation Administration on aircraft engine emission standards'').

Second, even assuming that the provision applies, EPA did make the proposed regulation and supporting information available to the SAB in advance of the public comment period. Documents are made available when they are ''accessible'' or ''obtainable.'' Collins English Dictionary—Complete and Unabridged (Harper Collins 2003) (definition of ''available''). EPA made the proposed rule and underlying support documents accessible and obtainable by publication of the proposed rule in the **Federal Register**, and via mass electronic dissemination by posting both the proposed rule and all of the scientific and technical support documents on the Agency's Web site essentially contemporaneously with their signature by the Administrator.[1]

Third, even assuming arguendo that EPA committed a procedural error, PLF has failed to demonstrate that its objection provides substantial support for the argument that the promulgated regulation should be revised, and therefore is of central relevance to the outcome of the rule. CAA section 307(d)(7)(B).

PLF argues that there is a substantial likelihood that the rule would have changed if EPA had followed the claimed procedure, by assuming that the SAB would have provided scientific and technical advice to EPA of sufficient import to change the rule's outcome, consistent with the SAB's scientific standing and the Congressional purpose in establishing the opportunity for SAB review. Petition pp. 8, 21. This is unpersuasive. The SAB explicitly declined to consider and ''make available * * * advice and comments on the adequacy of the scientific and technical basis'' on the proposed light duty vehicle GHG standards for model years 2017 to 2025 in response to EPA's communication to SAB about the proposal and supporting documents.[2] That proposal built upon and was closely related to the rulemaking that established the standards for MYs 2012–2016, the subject of PLF's petition here. Moreover, as in the MYs 2017–2025 rulemaking, substantial issues of pure science were not presented in the MYs 2012–2016 rulemaking. Instead the critical issues were what technologies are available for light-duty vehicles to reduce greenhouse gases for MYs 2012–2016, the cost and effectiveness of those technologies, and their availability in the lead time provided by the rule, making SAB participation both less likely and less pertinent. See 75 FR at 25403–04. Indeed, none of the public comments in the MY2012–2016 rulemaking took serious issue that EPA had overestimated potential technology availability, penetration and cost. [3] See EPA, *Light Duty Vehicle Emission Standards and Corporate Average Fuel Economy Standards: EPA Response to Comment Document* (EPA–420–R–10–012, April 2010), section 3. There were no judicial challenges to the rule's substantive standards at all. See *Coalition for Responsible Regulation,* 684 F.3d at 126. Given these circumstances, EPA does not see any significant likelihood that SAB involvement would have occurred or would have changed significantly the technology-based standards adopted in the rule. The petitioner has therefore failed to carry its burden of showing that its objection provides substantial support for the argument that the promulgated regulation should be revised and therefore is of central relevance to the rule. CAA section 307(d)(7)(B).

Notwithstanding the clear requirement in section 307(d)(7)(B) that its objection must be of central relevance to the outcome of the rule, PLF argues that it does not have to make a showing to that effect. PLF argues instead that the test under section 307(d)(7)(B) varies depending on whether the procedural requirement at issue derives from the CAA or from another statutory provision. While PLF's argument is not exactly clear, PLF argues that for procedural requirements imposed by a statute other than the CAA, an ''utter failure'' to comply with a required procedure is not harmless error under section 307(d)(7)(B) if there is any uncertainty of the impact of the error. For procedural requirements imposed by the CAA, PLF argues that the explicit test of section 307(d)(8) applies, ''substantial likelihood that the rule would have been significantly changed if such errors had not been made.'' PLF argues that this case falls under the first asserted principle, as the procedural requirement derives from a statute other than the CAA. PLF thus argues there was an utter failure to comply with 42 U.S.C. section 4365(c), and there is some uncertainty of the impact of the failure. In the alternative, they argue that even if the second test applies, this case meets the criteria of section 307(d)(8), citing to *Kennecott Corp.* v. *EPA,* 684 F.2d 1007 (D.C. Cir. 1982)

EPA disagrees that this bifurcated scheme is the appropriate test to apply. Section 307(d)(7)(B) is the applicable provision here, and its test is whether PLF's objection provides substantial support for the argument that the promulgated regulation should be revised. There is no basis in the text of section 307(d)(7)(B) to draw a distinction based on whether a procedural requirement is imposed by the Clean Act or by another statute. Section 307(d)(7)(B) establishes the same requirements irrespective of the statutory source of the procedural requirement a petitioner points to. Section 307(d)(7)(B), like section 307(d)(8), embodies a significant hurdle for administrative reconsideration, and reflects the value placed on preserving the finality of EPA decision making. 75 FR 49556, 49560–62 (August 13, 2010). This is so whether the procedural requirement derives from the CAA or from another statute.

The cases cited by PLF do not support their view of a bifurcated scheme under section 307(d)(7)(B). PLF argues that ''[w]hen an administrative agency utterly fails to comply with a procedural rulemaking requirement imposed by a statute other than the one under which the rule is being promulgated, the failure cannot be considered harmless error if there is any uncertainty regarding what the rule may have been but for the failure.'' Petition p. 7. PLF cites *New Jersey* v. *EPA,* 626 F. 2d 1038, 1049–50 (D.C. Cir. 1980) and *Sugar Cane Growers Coop. of Fla.* v. *Veneman,* 289 F. 3d 89, 96 (D.C. Cir. 2002) for this proposition. However these cases do not pronounce the general rule petitioners claim, and are not on point. Both *State of New Jersey* and *Sugar Cane Growers* concerned rules that were not subject to section 307(d) at all, so the cases do not address and are not relevant to the

[1] EPA is aware that the D.C. Circuit, in holding that EPA had not made available a proposed regulation to the SAB, stated that EPA had not ''submitted'' the proposed regulation to the Board. *American Petroleum Inst.* v. *EPA,* 665 F.2d 1176, 1189 (D.C. Cir. 1981). This case, however, antedated the present period of instantaneous availability of documents via electronic dissemination. EPA believes that by publishing and posting the proposed regulation and the scientific and technical support documents those materials have been made available to the SAB.

[2] PLF did not present either oral or written statements to the SAB at its public meeting, even though the meeting was publically noticed, comments were solicited by the SAB, and other entities submitted an oral and written statement to the SAB (addressing a different proposed rule). See 77 FR 12579, 12580 (March 1, 2012) and EPA–HQ–OAR–2010–0799–11793.

[3] PLF indicates that its interest in the rulemaking is that its members are light duty vehicle users and may incur greater costs as a result of the light duty vehicle rule's stringency, Petition pp. 2–3, although it submitted no comments on these issues.

requirement imposed by section 307(d)(7)(B). Rather, both cases dealt with a failure of the government agency to follow the notice and comment procedures required for rulemaking under the Administrative Procedure Act (APA). The views of the court on the lack of harmless error under those specific circumstances addressed that violation of the APA, and did not provide a more general rule applicable to any and all other procedural violations or other statutes. Here, EPA fully complied with the rulemaking procedures required under CAA section 307(d). There was no ''utter failure'' to conduct notice and comment rulemaking procedures.

As discussed above, EPA was not required to but did make the proposed rule available to the SAB pursuant to 42 U.S.C. section 4365(c)(1). Under that statute there is no requirement or expectation that the SAB will in fact voluntarily provide advice and comments to EPA and in this case, as discussed above, subsequent SAB action concerning the MY2017–2025 rulemaking proposal to control greenhouse gases indicates just the opposite. The *New Jersey* and *Sugar Cane* cases thus addressed wholly different circumstances, and provide no basis to find that the requirement of CAA section 307(d)(7)(B) does not apply to this rulemaking according to its terms or that the test it sets for reconsideration has been met.

Moreover, the D.C. Circuit recently held with respect to 42 USC section 4365(c)(1) itself that a petitioner ''must sho[w] that this error was 'of such central relevance to the rule that there is a substantial likelihood that the rule would have been significantly changed if such errors had not been made.' '' This was not satisfied when petitioners provided no more of a showing than alleging that EPA had failed to comply with this provision. *Coalition for Responsible Regulation* v. *EPA,* 684 F.3d at 124. The Court applied the test in section 307(d)(8) without drawing any distinction based on the statute that was the source of the procedural requirement. The same applies under section 307(d)(7)(B), and as with section 307(d)(8), more must be shown than simply alleging that EPA failed to comply.

The petitioner's citation of *Small Refiners Lead Phase-Down Task Force* v. *EPA,* 705 F.2d 506, 522–23 (D.C. Cir. 1983) also does not support its argument. The petition argues that the 1977 amendments to the Clean Air Act were intended to supplement the procedural requirements of the Administrative Procedure Act, not replace them. Petition p. 9. Construing section 307(d)(8)'s requirement that a procedural error creates a ''substantial likelihood that the rule would have been significantly changed'', the court stated that ''[a]t a minimum, failure to observe the basic APA procedures, if reversible error under the APA, is reversible error under the Clean Air Act as well.'' The court immediately cautioned, however, ''[o]n the other hand, section 307(d)(8) sets a restrictive tone for our review of procedural errors that would not violate the APA'', citing *Sierra Club* v. *Costle (657* F.2d at 391) for the proposition that ''the essential message of so rigorous a standard for procedural reversal is that Congress was concerned that EPA's rulemaking not be casually overturned for procedural reasons.'' 705 F.2d at 523. Since the APA itself contains a harmless error provision (5 USC section 706), requiring petitioners to show a likelihood that the rule would have changed is not a diminution of the APA but a gloss on it. Thus, the holding in *Small Refiners* was limited to violations of the notice and comment requirements of the APA, and, contrary to PLF's claim, the court did not pronounce a general rule establishing a different test for any and all procedural requirements imposed by other statutes. Rather, in discussing procedural requirements other than the APA, the court indicated that section 307(d)(8) applied and set a restrictive tone for judicial review of such errors.

More basically, the D.C. Circuit has twice held that failure to comply with the requirements of section 4365(c)(1) is not reversible error where petitioners fail to show that the error is of such central relevance to the proceeding that there is a substantial likelihood that the rule would have significantly changed but for the (claimed) procedural violation. *Coalition for Responsible Regulation* v. *EPA,* 684 F.3d at 124; *API* v. *EPA,* 665 F.2d at 1188–89. The fact that the procedural requirement at issue in those cases stems from a statute other than the CAA made no difference and did not change the burden on the petitioner to prevail on their objection. The same applies under section 307(d)(7)(B).

Finally, PLF points to *Kennecott Corp.* v. *EPA,* 684 F.2d 1007 (D.C. Cir. 1982) as support for its claim that EPA's alleged failure to comply with this statutory provision satisfies the requirements of section 307(d)(8). As noted above, this same claim was recently rejected in *Coalition for Responsible Regulation* v. *EPA,* 684 F.3d at 124. Here, PLF does no more than describe the purpose of this provision, with no showing of any likelihood of an impact or change on the rulemaking. As discussed above, all of the indications point the other way and indicate no such likelihood, even if one assumes a procedural error was committed.

V. Conclusion

The objections or claims raised in PLF's petition could have been presented to EPA during the comment period for the rulemaking, and the grounds for the objections did not arise after the period for public comment but within the time specified for judicial review. In addition, PLF has failed to demonstrate that its objection provides substantial support for the argument that the promulgated regulation should be revised and therefore has failed to demonstrate that its objection is of central relevance to the outcome of the rulemaking. Based on this, EPA is denying the request for reconsideration.

Dated: January 14, 2013.

Lisa P. Jackson,

Administrator.

[FR Doc. 2013–01415 Filed 1–24–13; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 239 and 258

[EPA–R01–RCRA–2012–0944; FRL–9771–6]

Adequacy of Massachusetts Municipal Solid Waste Landfill Permit Program

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA Region 1 proposes to approve Massachusetts's modification of its approved Municipal Solid Waste Landfill Program. On March 22, 2004, EPA issued final regulations allowing research, development, and demonstration (RD&D) permits to be issued to certain municipal solid waste landfills by approved states. On December 7, 2012 Massachusetts submitted an application to EPA Region 1 seeking Federal approval of its RD&D requirements.

DATES: Comments on this proposed action must be received in writing on or before March 26, 2013.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R01–RCRA–2012–0944, by one of the following methods:

- *www.regulations.gov:* Follow the on-line instructions for submitting comments.
- *Email: Hsieh.juiyu@epa.gov.*
- *Fax:* (617) 918–0646, to the attention of Juiyu Hsieh.

• *Mail:* Send written comments to Juiyu Hsieh, RCRA Waste Management and UST Section, Office of Site Remediation and Restoration (OSRR07–1), EPA New England—Region 1, 5 Post Office Square, Suite 100, Boston, MA 02109–3912

• *Hand Delivery or Courier:* Deliver your comments to: Juiyu Hsieh, RCRA Waste Management and UST Section, Office of Site Restoration and Remediation (OSRR07–1), EPA New England—Region 1, 5 Post Office Square, Suite 100, Boston, MA 02109–3912. Such deliveries are only accepted during the Office's normal hours of operation.

For detailed instructions on how to submit comments, please see the direct final rule which is located in the Rules section of this **Federal Register**.

FOR FURTHER INFORMATION CONTACT: Juiyu Hsieh at (617) 918–1646 or by email at *hsieh.juiyu@epa.gov.*

SUPPLEMENTARY INFORMATION: In the Rules section of this **Federal Register**, EPA is approving Massachusetts's Research Development and Demonstration (RD&D) permit program through a direct final rule without prior proposal because the Agency views this as a noncontroversial action and anticipates no adverse comments to this action. Unless we get written adverse comments which oppose this approval during the comment period, the direct final rule will become effective on the date it establishes, and we will not take further action on this proposal. If EPA receives adverse comments, the direct final rule will be withdrawn and all public comments received will be addressed in a subsequent final rule. EPA will not institute a second comment period on this action. Any parties interested in commenting on this action should do so at this time. For additional information, see the direct rule which is located in the Rules section of this **Federal Register**.

Dated: January 4, 2013.

Ira W. Leighton,

Acting Regional Administrator, EPA New England, Region 1.

[FR Doc. 2013–01440 Filed 1–24–13; 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–2013–0002; 4500030114]

RIN 1018–AZ23

Endangered and Threatened Wildlife and Plants; Proposed Designation of Critical Habitat for the Zuni Bluehead Sucker

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Proposed rule.

SUMMARY: We, the U.S. Fish and Wildlife Service, propose to designate critical habitat for the Zuni bluehead sucker. If we finalize this rule as proposed, it would extend the Act's protections to this subspecies' critical habitat. The effect of these regulations will be to protect the Zuni bluehead sucker's habitat under the Act.

DATES: We will accept comments received or postmarked on or before March 26, 2013. Comments submitted electronically using the Federal eRulemaking Portal (see **ADDRESSES** section, below) must be received by 11:59 p.m. Eastern Time on the closing date. We must receive requests for public hearings, in writing, at the address shown in **FOR FURTHER INFORMATION CONTACT** by March 11, 2013.

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

(1) *Electronically:* Go to the Federal eRulemaking Portal: *http://www.regulations.gov.* In the Search box, enter FWS–R2–ES–2013–0002, which is the docket number for this rulemaking. Then, in the Search panel on the left side of the screen, under the Document Type heading, click on the Proposed Rules link to locate this document. You may submit a comment by clicking on ''Comment Now!''

(2) *By hard copy:* Submit by U.S. mail or hand-delivery to: Public Comments Processing, Attn: FWS–R2–ES–2013–0002; Division of Policy and Directives Management; U.S. Fish and Wildlife Service; 4401 N. Fairfax Drive, MS 2042–PDM; Arlington, VA 22203.

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

The coordinates or plot points or both from which the critical habitat maps are generated are included in the administrative record for this rulemaking and are available at *http://www.fws.gov/southwest/es/NewMexico/, http://www.regulations.gov* at Docket No. FWS–R2–ES–2013–0002, and at the New Mexico Ecological Services Field Office (see **FOR FURTHER INFORMATION CONTACT**). Any additional tools or supporting information that we may develop for this rulemaking will also be available at the Fish and Wildlife Service Web site and Field Office set out above, and may also be included in the preamble and/or at *www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Wally ''J'' Murphy, Field Supervisor, U.S. Fish and Wildlife Service, New Mexico Ecological Services Field Office, 2105 Osuna NE., Albuquerque, NM 87113, by telephone 505–346–2525 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:

Executive Summary

Why we need to publish a rule. Under the Act, once a species is determined to be an endangered or threatened species throughout all or a significant portion of its range, we are required to promptly publish a proposal in the **Federal Register** and make a determination on our proposal within 1 year. Additionally, critical habitat shall be designated, to the maximum extent prudent and determinable, for any species determined to be an endangered or threatened species under the Act. Designations and revisions of critical habitat can only be completed by issuing a rule. Elsewhere in today's **Federal Register**, we propose to list the Zuni bluehead sucker as an endangered species under the Act.

This rule consists of: A proposed rule for designation of critical habitat for the Zuni bluehead sucker. The Zuni bluehead sucker has been proposed for listing under the Act. This rule proposes designation of critical habitat necessary for the conservation of the species.

The basis for our action. Under the Act, when a species is proposed for listing, to the maximum extent prudent and determinable, we must designate critical habitat for the species. The species has been proposed for listing as endangered, and therefore, we also propose to designate approximately 472 km (293 mi) of stream habitat as critical habitat in Apache County, Arizona, and

Cibola, McKinley, and San Juan Counties, New Mexico, and on the Navajo Indian Reservation.

We will seek peer review. We are seeking comments from knowledgeable individuals with scientific expertise to review our analysis of the best available science and application of that science and to provide any additional scientific information to improve this proposed rule. Because we will consider all comments and information received during the comment period, our final determinations may differ from this proposal.

Information Requested

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 governmental agencies, Native American tribes, the scientific community, industry, or any other interested parties concerning this proposed rule. We particularly seek comments concerning:

(1) The reasons why we should or should not designate habitat as ''critical habitat'' under section 4 of the Act (16 U.S.C. 1531 *et seq.*), including whether there are threats to the species from human activity, the degree of which can be expected to increase due to the designation, and whether that increase in threats outweighs the benefit of designation such that the designation of critical habitat is not prudent.

(2) Specific information on:

(a) The amount and distribution of the Zuni bluehead sucker and its habitat;

(b) What may constitute ''physical or biological features essential to the conservation of the species,'' within the geographical range currently occupied by the species;

(c) Where these features are currently found;

(d) Whether any of these features may require special management considerations or protection;

(e) What areas, that were occupied at the time of listing (or are currently occupied) and that contain features essential to the conservation of the species, should be included in the designation and why; and

(f) What areas not occupied at the time of listing are essential for the conservation of the species and why.

(3) Land use designations and current or planned activities in the areas occupied by the species or proposed to be designated as critical habitat, and possible impacts of these activities on this species and proposed critical habitat.

(4) Information on the projected and reasonably likely impacts of climate change on the Zuni bluehead sucker and proposed critical habitat.

(5) Any foreseeable economic, national security, or other relevant impacts that may result from designating any area that may be included in the final designation. We are particularly interested in any impacts on small entities, and the benefits of including or excluding areas from the proposed designation that are subject to these impacts.

(6) Whether our approach to designating critical habitat could be improved or modified in any way to provide for greater public participation and understanding, or to assist us in accommodating public concerns and comments.

(7) The likelihood of adverse social reactions to the designation of critical habitat and how the consequences of such reactions, if likely to occur, would relate to the conservation and regulatory benefits of the proposed critical habitat designation.

Please include sufficient information with your submission (such as scientific journal articles or other publications) to allow us to verify any scientific or commercial information you include.

Please note that submissions merely stating support for or opposition to the action under consideration without providing supporting information, although noted, will not be considered in making a determination, as section 4(b)(1)(A) of the Act directs that determinations as to whether any species is a threatened or endangered species must be made ''solely on the basis of the best scientific and commercial data available.''

You may submit your comments and materials concerning this proposed rule by one of the methods listed in the **ADDRESSES** section. We request that you send comments only by the methods described in the **ADDRESSES** section.

If you submit information via *http://www.regulations.gov,* your entire submission—including any personal identifying information—will be posted on the Web site. If your submission is made via a hardcopy that includes personal identifying information, you may request at the top of your document that we withhold this information from public review. However, we cannot guarantee that we will be able to do so. We will post all hardcopy submissions on *http://www.regulations.gov.* Please include sufficient information with your comments to allow us to verify any scientific or commercial information you include.

Comments and materials we receive, as well as supporting documentation we used in preparing this proposed rule, will be available for public inspection on *http://www.regulations.gov,* 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**).

Previous Federal Actions

All previous Federal actions are described in the proposal to list the Zuni bluehead sucker as an endangered species under the Act published elsewhere in today's **Federal Register**.

Critical Habitat Designation for the Zuni Bluehead Sucker

Background

Critical habitat is defined in section 3 of the Act as:

(1) The specific areas within the geographical area occupied by the species, at the time it is listed in accordance with the Act, on which are found those physical or biological features:

(a) Essential to the conservation of the species, and

(b) Which may require special management considerations or protection; and

(2) Specific areas outside the geographical area occupied by the species at the time it is listed, upon a determination that such areas are essential for the conservation of the species.

Conservation, as defined under section 3 of the Act, means to use and the use of all methods and procedures that are necessary to bring an endangered or threatened species to the point at which the measures provided pursuant to the Act are no longer necessary. Such methods and procedures include, but are not limited to, all activities associated with scientific resources management such as research, census, law enforcement, habitat acquisition and maintenance, propagation, live trapping, and transplantation, and, in the extraordinary case where population pressures within a given ecosystem cannot be otherwise relieved, may include regulated taking.

Critical habitat receives protection under section 7 of the Act through the requirement that Federal agencies ensure, in consultation with the Service, that any action they authorize, fund, or carry out is not likely to result in the destruction or adverse modification of

critical habitat. The designation of critical habitat does not affect land ownership or establish a refuge, wilderness, reserve, preserve, or other conservation area. Such designation does not allow the government or public to access private lands. Such designation does not require implementation of restoration, recovery, or enhancement measures by non-Federal landowners. Where a landowner requests Federal agency funding or authorization for an action that may affect a listed species or critical habitat, the consultation requirements of section 7(a)(2) of the Act would apply, but even in the event of a destruction or adverse modification finding, the obligation of the Federal action agency and the landowner is not to restore or recover the species, but to implement reasonable and prudent alternatives to avoid destruction or adverse modification of critical habitat.

Under the first prong of the Act's definition of critical habitat, areas within the geographical area occupied by the species at the time it was listed are included in a critical habitat designation if they contain physical or biological features (1) essential to the conservation of the species, and (2) which may require special management considerations or protection. For these areas, critical habitat designations identify, to the extent known using the best scientific and commercial data available, those physical or biological features essential to the conservation of the species (such as space, food, cover, and protected habitat). In identifying those physical or biological features within an area, we focus on the principal biological or physical constituent elements (primary constituent elements such as roost sites, nesting grounds, seasonal wetlands, water quality, tide, soil type) that are essential to the conservation of the species. Primary constituent elements are those specific elements of the physical or biological features that provide for a species' life-history processes and are essential to the conservation of the species.

Under the second prong of the Act's definition of critical habitat, we can designate critical habitat in areas outside the geographic area occupied by the species at the time it is listed, upon a determination that such areas are essential for the conservation of the species. For example, an area currently occupied by the species but that was not occupied at the time of listing may be essential to the conservation of the species and may be included in the critical habitat designation. We designate critical habitat in areas outside the geographic area occupied by a species only when a designation limited to its range would be inadequate to ensure the conservation of the species.

Section 4 of the Act requires that we designate critical habitat on the basis of the best scientific data available. Further, our Policy on Information Standards Under the Endangered Species Act (published in the **Federal Register** on July 1, 1994 (59 FR 34271)), the Information Quality Act (section 515 of the Treasury and General Government Appropriations Act for Fiscal Year 2001 (Pub. L. 106–554; H.R. 5658)), and our associated Information Quality Guidelines, provide criteria, establish procedures, and provide guidance to ensure that our decisions are based on the best scientific data available. They require our biologists, to the extent consistent with the Act and with the use of the best scientific data available, to use primary and original sources of information as the basis for recommendations to designate critical habitat.

When we are determining which areas should be designated as critical habitat, our primary source of information is generally the information developed during the listing process for the species. Additional information sources may include the recovery plan for the species, articles in peer-reviewed journals, conservation plans developed by States and counties, scientific status surveys and studies, biological assessments, other unpublished materials, or experts' opinions or personal knowledge.

Habitat is dynamic, and species may move from one area to another over time. Climate change will be a particular challenge for biodiversity because the interaction of additional stressors associated with climate change and current stressors may push species beyond their ability to survive (Lovejoy 2005, pp. 325–326). The synergistic implications of climate change and habitat fragmentation are the most threatening facet of climate change for biodiversity (Hannah and Lovejoy 2005, p. 4). Current climate change predictions for terrestrial areas in the Northern Hemisphere indicate warmer air temperatures, more intense precipitation events, and increased summer continental drying (Field *et al.* 1999, pp. 1–3; Hayhoe *et al.* 2004, p. 12422; Cayan *et al.* 2005, p. 6; Intergovernmental Panel on Climate Change (IPCC) 2007, p. 1181). Climate change may lead to increased frequency and duration of severe storms and droughts (Golladay *et al.* 2004, p. 504; McLaughlin *et al.* 2002, p. 6074; Cook *et al.* 2004, p. 1015).

We recognize that critical habitat designated at a particular point in time may not include all of the habitat areas that we may later determine are necessary for the recovery of the species. For these reasons, a critical habitat designation does not signal that habitat outside the designated area is unimportant or may not be needed for recovery of the species. Areas that are important to the conservation of the species, both inside and outside the critical habitat designation, will continue to be subject to: (1) Conservation actions implemented under section 7(a)(1) of the Act, (2) regulatory protections afforded by the requirement in section 7(a)(2) of the Act for Federal agencies to ensure their actions are not likely to jeopardize the continued existence of any endangered or threatened species, and (3) section 9 of the Act's prohibitions on taking any individual of the species, including taking caused by actions that affect habitat. Federally funded or permitted projects affecting listed species outside their designated critical habitat areas may still result in jeopardy findings in some cases. These protections and conservation tools will continue to contribute to recovery of this species. Similarly, critical habitat designations made on the basis of the best available information at the time of designation will not control the direction and substance of future recovery plans, habitat conservation plans (HCPs), or other species conservation planning efforts if new information available at the time of these planning efforts calls for a different outcome.

Prudency Determination

Section 4(a)(3) of the Act, as amended, and implementing regulations (50 CFR 424.12), require that, to the maximum extent prudent and determinable, the Secretary designate critical habitat at the time the species is determined to be an endangered or threatened species. Our regulations (50 CFR 424.12(a)(1)) state that the designation of critical habitat is not prudent when one or both of the following situations exist: (1) The species is threatened by taking or other human activity, and identification of critical habitat can be expected to increase the degree of threat to the species, or (2) such designation of critical habitat would not be beneficial to the species.

There is currently no immediate threat of take attributed to collection or vandalism under Factor B for this species, and identification and mapping

of critical habitat is not expected to initiate any such threat. In the absence of finding that the designation of critical habitat would increase threats to a species, if there are any benefits to a critical habitat designation, then a prudent finding is warranted. Here, the potential benefits of designation include: (1) Triggering consultation under section 7 of the Act, in new areas for actions in which there may be a Federal nexus where it would not otherwise occur because, for example, it is or has become unoccupied or the occupancy is in question; (2) focusing conservation activities on the most essential features and areas; (3) providing educational benefits to State or county governments or private entities; and (4) preventing people from causing inadvertent harm to the species. Therefore, because we have determined that the designation of critical habitat will not likely increase the degree of threat to the species and may provide some measure of benefit, we find that designation of critical habitat is prudent for the Zuni bluehead sucker.

Critical Habitat Determinability

Having determined that designation is prudent, under section 4(a)(3) of the Act, we must find whether critical habitat for the Zuni bluehead sucker is determinable. Our regulations at 50 CFR 424.12(a)(2) state that critical habitat is not determinable when one or both of the following situations exist:

(i) Information sufficient to perform required analyses of the impacts of the designation is lacking, or

(ii) The biological needs of the species are not sufficiently well known to permit identification of an area as critical habitat.

When critical habitat is not determinable, the Act allows the Service an additional year to publish a critical habitat designation (16 U.S.C. 1533(b)(6)(C)(ii)).

We reviewed the available information pertaining to the biological needs of the species and habitat characteristics where the species is located. This and other information represent the best scientific data available and led us to conclude that the designation of critical habitat is determinable for the Zuni bluehead sucker.

Physical or Biological Features

In accordance with section 3(5)(A)(i) and 4(b)(1)(A) of the Act and regulations at 50 CFR 424.12, in determining which areas within the geographic area occupied by the species at the time of listing to designate as critical habitat, we consider the physical or biological features that are essential to the conservation of the species and which may require special management considerations or protection. These include, but are not limited to:

(1) Space for individual and population growth and for normal behavior;

(2) Food, water, air, light, minerals, or other nutritional or physiological requirements;

(3) Cover or shelter;

(4) Sites for breeding, reproduction, or rearing (or development) of offspring; and

(5) Habitats that are protected from disturbance or are representative of the historical, geographic, and ecological distributions of a species.

We derive the specific physical or biological features required for the Zuni bluehead sucker from studies of this species' habitat, ecology, and life history as described below. Habitat needs for specific life stages for Zuni bluehead sucker have not been described; therefore, when necessary we will rely on information available for the bluehead sucker, which is closely related to the Zuni bluehead sucker.

Space for Individual and Population Growth and for Normal Behavior

Zuni bluehead sucker occur in stream habitats with abundant shade from overhanging vegetation and boulders, in pools, runs, and riffles with water velocities ranging from 0 to 0.35 m/sec (1.15 ft/sec) or less and ranging in depth from 0.2–2.0 m (7.9–78.7 in) (Hanson 1980, pp. 34, 42; Propst and Hobbes 1996, pp. 13, 16; Gilbert and Carmen 2011, pp. 8–10). Shade provided by the overhanging vegetation curtails water temperature fluctuations in small, headwater streams, such as those occupied by Zuni bluehead sucker (Whitledge *et al.* 2006, p. 1461). Substrate in Zuni bluehead sucker habitat ranges from silt and pebbles to cobbles, boulders, and bedrock (Hanson 1980, pp. 34, 42; Propst and Hobbes 1996, pp. 13, 16; Gilbert and Carmen 2011, pp. 8–10; NMDGF 2012). Clean substrate, such as gravel and coarse sand, free of silt, is necessary for spawning and egg development (Maddux and Kepner 1988, p. 364). Excessive levels of silt can inhibit egg and juvenile fish development through the clogging of the small spaces between substrate particles, which prevents the free flow of oxygenated water. Additionally, siltation can reduce the suitability of the habitat for prey organisms. Juvenile bluehead sucker have been found nearshore in slower and shallower habitats, then moving out into deeper water and faster flowing habitat as they age (Childs *et al.* 1998, p. 624).

Water temperatures in occupied habitats in New Mexico have ranged from 9.9 to 25.2 degrees Celsius (°C) (49.8 to 77.3 degrees Fahrenheit (°F)) during survey efforts (Propst *et al.* 2001, p. 163; Gilbert and Carmen 2011, pp. 8–10). Year-round data loggers have recorded temperatures as low as −3.2°C (24.3 °F) and as high as 24.1°C (75.3 °F) (Gilbert and Carmen 2011, pp. 8–10).

Therefore, based on the information above, we identify the following habitat parameters as the physical or biological features for the Zuni bluehead sucker:

- A variety of stream habitats, including riffles, runs, and pools, with appropriate flows and substrates, with low to moderate amounts of fine sediment and substrate embeddedness, as maintained by natural, unregulated flow that allows for periodic flooding or, if flows are modified or regulated, flow patterns that allow the river to mimic natural functions, such as flows capable of transporting sediment.

Food, Water, Air, Light, Minerals, or Other Nutritional or Physiological Requirements

Food. The Zuni bluehead sucker is a benthic forager (eats food from the stream bottom) that scrapes algae, insects, and other organic and inorganic material from the surface of rocks (NMDGF 2004, p. 8). Stomach content analysis of Zuni bluehead suckers revealed small particulate organic matter, including detritus (nonliving organic material), algae, small midge (two-winged fly) larvae, caddisfly larvae, mayfly larvae, flatworms, and the occasional small terrestrial insects (Smith and Koehn 1979, p. 38). In addition, Smith and Koehn (1979, p. 38) also found fish scales, snails, and insect eggs in Zuni bluehead sucker stomachs.

The primary source of food for Zuni bluehead sucker is periphytic algae (algae attached to rocks), which occurs mainly on cobble, boulder, and bedrock substrates with clean flowing water. Diet preferences have been described for adults, but not for the remaining life stages of Zuni bluehead sucker. Larval bluehead suckers (<25 mm (approx.1 in) total length) feed on diatoms (a type of algae), zooplankton (small floating or swimming organisms that drift with water currents), and dipteran larvae (true fly larvae) in stream areas with low velocity or in backwater habitats (Muth and Snyder 1995, p. 100). Juvenile and adult bluehead sucker are reported primarily to eat a variety of inorganic material, organic material, and bottom-dwelling insects and other small organisms (Childs *et al.* 1998, p. 625;

Osmundson 1999, p. 28; Brooks *et al.* 2000, pp. 66–69).

Aquatic invertebrates are another important component of the Zuni bluehead sucker diet. These aquatic invertebrates have specific habitat requirements of their own. Both caddisflies and mayflies occur primarily in a wide variety of standing and running-water habitats with the greatest diversity being found in rocky-bottom streams with an abundance of oxygen (Merritt and Cummins 1996, pp. 126, 309). Caddisflies and mayflies feed on a variety of detritus, algae, diatoms, and macrophytes (aquatic plants) (Merritt and Cummins 1996, pp. 126, 309). Habitat that consists of rocky bottoms with periphytic algal growth is not only important to sustain aquatic invertebrate populations (a Zuni bluehead sucker food source), but also serves as a primary food resource of the Zuni bluehead sucker.

Water. As a purely aquatic species, Zuni bluehead sucker is entirely dependent on stream habitat for all stages of their life cycle. Therefore, perennial flows are an essential feature with appropriate seasonal flows to maintain habitat conditions that remove excess sediments. Areas with intermittent flows may serve as connective corridors between occupied or seasonally occupied habitat through which the species may move when the habitat is wetted.

There is very little information on water quality requirements for Zuni bluehead sucker. However, excessive sedimentation is the primary threat to water quality for the Zuni bluehead sucker (as discussed above), primarily due to its effects on reproduction and food resources. Turbidity (sediment suspended in the water column) can inhibit algae production through reducing sunlight penetration into the water.

Therefore, based on the information above, we identify the following prey base and water quality characteristics as physical or biological features for the Zuni bluehead sucker:

- An abundant source of algae production and an aquatic insect food base consisting of caddisflies, mayflies, midges, and various terrestrial insects;
- Streams with no harmful levels of pollutants;
- Areas devoid of sediment deposition;
- Perennial flows, or interrupted stream courses that are periodically dewatered but that serve as connective corridors between occupied or seasonally occupied habitat and through which the species may move when the habitat is wetted;
- Dynamic flows that allow for periodic changes in channel morphology.

Cover or Shelter

Cover from predation may be in the form of deep water or physical structure. Very little is known about habitat parameters specifically relating to cover for Zuni bluehead sucker. However, during surveys, Zuni bluehead sucker have been found in shaded pools and near boulder outcrops, which may be used for cover (Kitcheyan 2012, pers. comm.). Additionally, mature bluehead sucker are found in deeper water than larvae and in habitats with less woody cover than younger life stages, which are more vulnerable to predation (Childs *et al.* 1998, p. 624).

Sites for Breeding, Reproduction, or Rearing (or Development) of Offspring

Zuni bluehead sucker spawn from early April to early June when water temperatures are 6 to 15 °C (43 to 59 °F), peaking around 10 °C (50 °F) (Propst 1999, p. 50; Propst *et al.* 2001, p. 164). Zuni bluehead sucker may have two spawning periods, with the majority of the spawning effort expended early in the season (Propst *et al.* 2001, p. 158). Females in spawning condition have been found over gravel beds (Sublette *et al.* 1990, p. 210; Propst *et al.* 2001, p. 158), Clean substrates free of excessive sedimentation are essential for successful breeding (see *Habitat and Life History* section of our proposed listing rule published elsewhere in today's **Federal Register**). Periodic flooding removes excess silt and fine sand from the stream bottom, breaks up embedded bottom materials, and rearranges sediments in ways that promote algae production and create suitable habitats with silt-free substrates.

Therefore, based on the information above, we identify the following parameters for breeding, reproduction, or development of offspring as physical or biological features for the Zuni bluehead sucker:

- Gravel and cobble substrates;
- Pool habitat;
- Slower currents along stream margins with appropriate stream velocities for larvae;
- Instream flow velocities that are less than 35 cm/sec (1.1 ft/sec); and
- Dynamic flows that allow for periodic changes in channel morphology.

Habitats Protected From Disturbance or Representative of the Historical, Geographic, and Ecological Distributions of the Species

The Zuni bluehead sucker has a restricted geographic distribution. Endemic species (species that are exclusively native to a particular location) whose populations exhibit a high degree of isolation are extremely susceptible to extinction from both random and nonrandom catastrophic natural or human-caused events. Therefore, it is essential to maintain both springs and stream systems upon which the Zuni bluehead sucker depends. This means protection from disturbance caused by exposure to land management actions (logging, cattle grazing, and road construction), water contamination, water depletion, beaver dams, or nonnative species. The Zuni bluehead sucker must, at a minimum, sustain its current distribution for the species to continue to persist., Introduced species are a serious threat to native aquatic species (Miller 1961, pp. 365, 397–398; Lachner *et al.* 1970, p. 21; Ono *et al.* 1983, pp. 90–91; Carlson and Muth 1989, pp. 222, 234; Fuller *et al.* 1999, p. 1; Propst *et al.* 2008, pp. 1246–1251; Pilger *et al.* 2010, pp. 300, 311–312; see both *Factor C: Disease and Predation, and Factor E: Other Natural or Manmade Factors Affecting Its Continued Existence* sections of our proposed listing rule published elsewhere in today's **Federal Register**). Because the distribution of the Zuni bluehead sucker is so isolated and its habitat so restricted, introduction of certain nonnative species into its habitat could be devastating. Potentially harmful nonnative species include green sunfish, northern crayfish, fathead minnow, and other nonnative fish-eating fishes.

Zuni bluehead sucker typically inhabit small desert stream systems including isolated headwater springs, small headwater springs, and mainstem river habitats (Gilbert and Carman 2011, p. 2) with clean, hard substrate, flowing water, and abundant riparian vegetation. Degraded habitat consists of silt-laden substrates, high turbidity, and deep, stagnant water (Gilbert and Carman 2011, p. 6). Ponds formed by beaver dams and impoundments as well as pools formed during river intermittency create such degraded habitats. Therefore, based on the information above, we identify the necessary physical or biological features for the Zuni bluehead sucker:

- Nondegraded habitat devoid of nonnative aquatic species, or habitat in

which nonnative aquatic species are at levels that allow persistence of Zuni bluehead sucker.

Primary Constituent Elements for the Zuni Bluehead Sucker

Under the Act and its implementing regulations, we are required to identify the physical or biological features essential to the conservation of the Zuni bluehead sucker in areas occupied at the time of listing, focusing on the features' primary constituent elements. We consider primary constituent elements to be the elements of physical or biological features that provide for a species' life-history processes and are essential to the conservation of the species.

Based on our current knowledge of the physical or biological features and habitat characteristics required to sustain the species' life-history processes, we determine that the primary constituent elements specific to the Zuni bluehead sucker are:

(1) A riverine system with habitat to support all life stages of Zuni bluehead sucker (egg, larval, juvenile, and adult), which includes:

a. Dynamic flows that allow for periodic changes in channel morphology and adequate river functions, such as channel reshaping and delivery of coarse sediments.

b. Stream courses with perennial flows, or areas that may be periodically dewatered but serve as connective corridors between occupied or seasonally occupied habitat and through which the species may move when the habitat is wetted;

c. Stream microhabitat types including runs, riffles, and pools with substrate ranging from gravel, cobble, and bedrock substrates with low or moderate amounts of fine sediment and substrate embeddedness; and

d. Streams with depths generally less than 2 m (3.3 ft), and with slow to swift flow velocities less than 35 cm/sec (1.1 ft/sec);

e. Clear, cool water with low turbidity and temperatures in the general range of 9.0 to 28.0 °C (48.2 to 82.4 °F).

f. No harmful levels of pollutants;

g. Adequate riparian shading to reduce water temperatures when ambient temperatures are high and provide protective cover from predators; and

(2) An abundant aquatic insect food base consisting of fine particulate organic material, filamentous algae, midge larvae, caddisfly larvae, mayfly larvae, flatworms, and small terrestrial insects.

(3) Areas devoid of nonnative aquatic species or areas that are maintained to kept nonnatives at a level that allows the Zuni bluehead sucker to continue to survive and reproduce.

Special Management Considerations or Protection

When designating critical habitat, we assess whether the specific areas within the geographic area occupied by the species at the time of listing contain features which are essential to the conservation of the species and which may require special management considerations or protection. We believe each area included in these designations requires special management and protections as described in our unit descriptions.

We need to consider special management considerations or protection for the features essential to the conservation of the species within each critical habitat area. The special management considerations or protections will depend on the threats to the essential features in that critical habitat area. For example, threats requiring special management considerations or protection include the continued spread of nonnative fish species into Zuni bluehead sucker habitat or increasing number of beavers that reduce habitat quality and foster expansion of nonnative fish and crayfish. Other threats requiring special management considerations or protection include the threat of wildfire and excessive ash and sediment following fire. Improper livestock grazing can be a threat to the remaining populations of Zuni bluehead sucker through trampling of habitat and increasing sedimentation. Inadequate water quantity resulting from drought and water withdrawals affect all life stages of Zuni bluehead sucker. Additionally, the construction of impoundments and water diversions can cause an increase in water depth behind the structure and a reduction or elimination of stream habitat below.

We have included below in our description of each of the critical habitat areas for the Zuni bluehead sucker a discussion of the threats occurring in that area requiring special management considerations or protection.

Criteria Used To Identify Critical Habitat

As required by Section 4(b)(2) of the Act, we use the best scientific data available to designate critical habitat. We review available information pertaining to the habitat requirements of the species. In accordance with the Act and its implementing regulation at 50 CFR 424.12(e), we consider whether designating additional areas—outside those currently occupied as well as those occupied at the time of listing—are necessary to ensure the conservation of the species. We are proposing to designate critical habitat in areas within the geographic area occupied by the species at the time of listing, as described above in the proposed rule to list the Zuni bluehead sucker, and that contain sufficient elements of physical or biological features to support life-history processes essential for the conservation of the species. We are also proposing to designate specific areas outside the geographic area occupied by the species at the time of listing because such areas are essential for the conservation of the species.

Sources of data for this species include multiple databases maintained by universities and State agencies for Arizona and New Mexico, existing State recovery plans, endangered species reports, and numerous survey reports on streams throughout the species' range (Sanchez 1975, pp. 1, 4; Propst *et al.* 1986, pp. 49–51; NMDGF 2003, pp. 6–10; Sponholtz 2003, pp. 18–22; NMDGF 2004, pp. 1–40; Clarkson and Marsh 2006, pp. 1–2; David 2006, pp. 1–40; NMDGF 2007, pp. 1–27; Douglas *et al.* 2009, p. 67; Service 2010, pp. 1–2; NMDGF 2012; Navajo Nation Heritage Program 2012, pp. 1–20). We have also reviewed available information that pertains to the habitat requirements of this species. Sources of information on habitat requirements include existing State recovery plans, endangered species reports, studies conducted at occupied sites and published in peer-reviewed articles, agency reports, and data collected during monitoring efforts (Propst *et al.* 2001, pp. 159–161; NMDGF 2003, pp. 1–14; NMDGF 2004, pp. 4–7).

The current distribution of the Zuni bluehead sucker is much reduced from its historical distribution. We anticipate that recovery will require continued protection of existing populations and habitat, as well as establishing populations in additional streams that more closely approximate its historic distribution in order to ensure there are adequate numbers of fish in stable populations and that these populations occur over a wide geographic area. This will help to ensure that catastrophic events, such as wildfire, cannot simultaneously affect all known populations.

Areas Occupied at the Time of Listing

The proposed critical habitat designation does not include all streams known to have been occupied by the species historically; instead, it focuses on occupied streams within the

historical range that have retained the necessary PCEs that will allow for the maintenance and expansion of existing populations. The following streams meet the definition of areas occupied by the species at the time of listing: Agua Remora, Rio Nutria, Tampico Spring, Tampico Draw, Kinlichee Creek, Black Soil Wash, Scattered Willow Wash, Coyote Wash, Crystal Creek, Sonsela Creek, Tsaile Creek, Wheatfields Creek, and Whiskey Creek. There are no developed areas within the proposed designation except for barriers constructed on streams or road crossings of streams, which do not remove the suitability of these areas for this species.

Areas Outside of the Geographic Range at the Time of Listing

The Zuni River, Rio Pescado, Cebolla Creek, Red Clay Wash, Palisades Creek, and Little Whiskey Creek are within the historical range of the Zuni bluehead sucker but are not within the geographic range currently occupied by the species; the Zuni River and Rio Pescado experience a high degree of river intermittency, and the Zuni bluehead sucker has not been seen in Cebolla Creek, Red Clay Wash, and Little Whiskey Creek in over 30 years, and it has not been observed in the Zuni River or Rio Pescado in approximately 20 years. We consider these sites to be extirpated. For areas not occupied by the species at the time of listing, we must demonstrate that these areas are essential to the conservation of the species in order to include them in our critical habitat designation. To determine if these areas are essential for the conservation of the Zuni bluehead sucker, we considered: (1) The importance of the site to the overall status of the species to prevent extinction and contribute to future recovery of the Zuni bluehead sucker; (2) whether the area could be restored to contain the necessary habitat to support the Zuni bluehead sucker; (3) does the site provide connectivity between occupied sites for genetic exchange: and (4) whether a population of the species could be reestablished in the area.

Of the unoccupied streams, the Zuni River, Rio Pescado, and Palisades Creek exhibit varying degrees of intermittency; the Zuni River and Rio Pescado are generally only continuous after heavy flows in the spring (NMDGF 2004, p. 13; New Mexico Environment Department (NMED) 2004, p. 1), and Palisades Creek has been noted as dry during recent visits (Hobbes 2001, pp. 25–26; Carman 2004, p. 9). However, when the Zuni River, Rio Pescado, and Cebolla Creek do exhibit flow and if suitable habitat were restored, they could allow for important population expansion in this watershed and they are therefore essential for the conservation of the Zuni bluehead sucker. On the other hand, Palisades Creek is a tributary to Whiskey Creek that, when wetted, likely does not provide much benefit to the species. Because this formerly occupied site has been so severely impacted and, as a small tributary, it does not connect occupied sites, it is unlikely to contribute to the recovery of the species and is not considered essential to the conservation of the species. Therefore, it is not included in the proposed designation of critical habitat.

In summary, for areas within the geographic area occupied by the species at the time of listing, we delineated critical habitat unit boundaries using the following criterion:

(1) Evaluate habitat suitability of stream segments within the geographic area occupied at the time of listing, and retain those segments that contain some or all of the PCEs to support life-history functions essential for conservation of the species.

For areas outside the geographic area occupied by the species at the time of listing, we delineated critical habitat unit boundaries using the following steps:

(2) Evaluate stream segments not known to have been occupied at listing but that are within the historical range of the species (outside of the geographic area occupied by the species) to determine if they are essential to the survival and recovery of the species. Essential areas are those that:

(a) Serve as an extension of habitat within the geographic area of an occupied unit;

(b) Expand the geographic distribution within areas not occupied at the time of listing across the historical range of the species; and

(c) Are connected to other occupied areas, which will enhance genetic exchange between populations.

We conclude that the areas proposed for critical habitat provide for the conservation of the Zuni bluehead sucker because they include habitat for all extant populations and include habitat for connectivity and dispersal opportunities within units. Such opportunities for dispersal assist in maintaining the population structure and distribution of the species. The current amount of habitat that is occupied is not sufficient for the recovery of the species; therefore, we included unoccupied habitat in this proposed critical habitat designation.

As a final step, we evaluated those occupied stream segments retained through step 1 of the above analysis and refined the starting and ending points by evaluating the presence or absence of appropriate PCEs. We selected upstream and downstream cutoff points to omit areas that are highly degraded and are not likely restorable. For example, permanently dewatered areas, or areas in which there was a change to unsuitable parameters (*e.g.,* water quality, bedrock substrate) were used to mark the start or endpoint of a stream segment proposed for designation. Critical habitat stream segments were then mapped using ArcMap version 10 (Environmental Systems Research Institute, Inc.), a Geographic Information Systems program.

The areas proposed for designation as critical habitat provide sufficient stream and spring habitat for breeding, nonbreeding, and dispersing adult Zuni bluehead sucker, as well as for the habitat needs for juvenile and larval stages of this fish. In general, the PCEs of critical habitat are contained within the riverine ecosystem formed by the wetted channel and the adjacent floodplains within 91.4 lateral m (300 lateral ft) on either side of bankfull stage, except where bounded by canyon walls. Areas within the lateral extent also contribute to the PCEs, including water quality and intermittent areas through which fish may move when wetted. Zuni bluehead sucker use the riverine ecosystem for feeding, breeding, and sheltering while breeding and migrating.

When determining proposed critical habitat boundaries, we made every effort to avoid including developed areas such as lands covered by bridges, docks, aqueducts, and other structures because such lands lack physical or biological features for the Zuni bluehead sucker. The scale of the maps we prepared under the parameters for publication within the Code of Federal Regulations may not reflect the exclusion of such developed lands. Any such lands inadvertently left inside critical habitat boundaries shown on the maps of this proposed rule have been excluded by text in the proposed rule and are not proposed for designation as critical habitat. Therefore, if the critical habitat is finalized as proposed, a Federal action involving these lands would not trigger section 7 consultation with respect to critical habitat and the requirement of no adverse modification unless the specific action would affect the physical or biological features in the adjacent critical habitat.

We are proposing for designation of critical habitat lands that we have determined are occupied at the time of listing and contain sufficient elements

of physical or biological features to support life-history processes essential for the conservation of the species, and lands outside of the geographic area occupied at the time of listing that we have determined are essential for the conservation of the Zuni bluehead sucker.

Segments were proposed for designation based on sufficient elements of physical or biological features being present to support the Zuni bluehead sucker life-history processes. Some segments contained all of the identified elements of physical or biological features and supported multiple life-history processes. Some segments contained only some elements of the physical or biological features necessary to support the Zuni bluehead sucker's particular use of that habitat.

The critical habitat designation is defined by the map or maps, as modified by any accompanying regulatory text, presented at the end of this document in the rule portion. We include more detailed information on the boundaries of the critical habitat designation in the preamble of this document. We will make the coordinates or plot points or both on which each map is based available to the public on *http://www.regulations.gov* at Docket No. FWS–R2–ES–2012–0101, on our Internet sites *http://www.fws.gov/southwest/es/NewMexico/,* and at the field office responsible for the designation (see **FOR FURTHER INFORMATION CONTACT** above).

Proposed Critical Habitat Designation

We are proposing to designate approximately 472 km (293 mi) in three units as critical habitat for the Zuni bluehead sucker. The critical habitat areas we describe below constitute our current best assessment of areas that meet the definition of critical habitat for Zuni bluehead sucker. The three areas we propose as critical habitat are: (1) Zuni River Unit; (2) Kinlichee Creek Unit; and (3) San Juan River Unit. Table 1 shows the occupancy of the units, the land ownership, and approximate areas of the proposed designated areas for the Zuni bluehead sucker.

TABLE 1—PROPOSED CRITICAL HABITAT UNITS FOR ZUNI BLUEHEAD SUCKER

[Area estimates reflect all land within critical habitat unit boundaries]

Stream segment	Occupied at the time of listing	Land ownership	Length of unit in kilometers (miles)
Unit 1—Zuni River Unit			
Subunit 1a—Zuni River Headwaters			
Agua Remora	Yes	Forest Service	6.6 (4.1)
		Private	2.4 (1.5)
Rio Nutria	Yes	Zuni Pueblo	38.9 (24.2)
		Forest Service	4.1 (2.6)
		State of New Mexico	1.8 (1.1)
		Private	14.2 (8.8)
Tampico Draw	Yes	Forest Service	2.3 (1.4)
		Private	3.7 (2.3)
Tampico Spring	Yes	Private	0.2 (0.1)
Total			74.2 (46.1)
Subunit 1b—Zuni River Mainstem			
Zuni River	No	Zuni Pueblo	7.4 (4.6)
Rio Pescado	No	Zuni Pueblo	47.3 (29.4)
		State of New Mexico	5.8 (3.6)
		Private	15.4 (9.6)
Cebolla Creek	No	Zuni Pueblo	3.7 (2.3)
		State of New Mexico	0.4 (.02)
		Forest Service	6.4 (4.0)
		Private	21.4 (13.3)
Total			107.8 (67.0)
Unit 2—Kinlichee Creek Unit			
Subunit 2a—Kinlichee Creek			
Black Soil Wash	Yes	Navajo Nation	21.6 (13.4)
Kinlichee Creek	Yes	Navajo Nation	47.1 (29.3)
Scattered Willow Wash	Yes	Navajo Nation	18.2 (11.3)
Total			86.9 (54.0)
Subunit 2b—Red Clay Wash			
Red Clay Wash	No	Navajo Nation	9.6 (6.0)
Unit 3—San Juan River Unit			
Subunit 3a—Canyon de Chelly			
Coyote Wash	Yes	Navajo Nation *	6.4 (4.0)

TABLE 1—PROPOSED CRITICAL HABITAT UNITS FOR ZUNI BLUEHEAD SUCKER—Continued

[Area estimates reflect all land within critical habitat unit boundaries]

Stream segment	Occupied at the time of listing	Land ownership	Length of unit in kilometers (miles)
Crystal Creek	Yes	Navajo Nation *	0.5 (0.3)
		Navajo Nation	34.2 (21.2)
Sonsela Creek	Yes	Navajo Nation *	19.5 (12.1)
Tsaile Creek	Yes	Navajo Nation *	23.0 (14.3)
		Navajo Nation	30.6 (19.0)
Wheatfields Creek	Yes	Navajo Nation *	8.5 (5.3)
		Navajo Nation	29.3 (18.2)
Whiskey Creek	Yes	Navajo Nation *	7.5 (4.7)
		Navajo Nation	28.1 (17.5)
Total			187.9 (112.7)
Subunit 3b—Little Whiskey Creek			
Little Whiskey Creek	No	Navajo Nation	8.9 (5.5)
Total			8.9 (5.5)

* These lands are managed by National Park Service in trust for the Navajo Nation.
Note: Area sizes may not sum due to rounding.

We present below brief descriptions of the units and reasons why the units meet the definition of critical habitat for the Zuni bluehead sucker.

Unit 1: Zuni River Unit

Subunit 1a—Zuni River Headwaters: Subunit 1a consists of 74.2 km (46.1 mi) along Agua Remora, Rio Nutria, Tampico Draw, and Tampico Spring in McKinley County, New Mexico. The land in this subunit is primarily owned by Zuni Pueblo, Forest Service, and private landowners with a small amount of State inholdings. The Zuni bluehead sucker occupies all stream reaches in this subunit, and the subunit contains all of the primary constituent elements of the physical or biological features essential to the conservation of the Zuni bluehead sucker. This unit represents the only remaining headwater spring habitats occupied by Zuni bluehead sucker.

Livestock grazing is primarily regulated by the Forest Service and Zuni Pueblo in this subunit; however, trespass livestock grazing may occur. Additional special management considerations or protection may be required within Subunit 1a to address low water levels as a result of water withdrawals and drought, predation from nonnative green sunfish, and the upstream and downstream effects of impoundments. Such special management or protection may include maintaining instream flows, nonnative species removal, and reservoir management that improves up- and downstream habitat to benefit the Zuni bluehead sucker.

Subunit 1b—Zuni River Mainstem: Subunit 1b consists of 107.8 km (67.0 mi) of potential Zuni bluehead sucker habitat along the Zuni River, Rio Pescado, and Cebolla Creek in McKinley and Cibola Counties, New Mexico. Land within this subunit is primarily owned by Zuni Pueblo and private landowners, with a small amount of Forest Service and State land. The Zuni bluehead sucker historically occupied these streams but has not been found in the Zuni River or Rio Pescado since the mid-1990s (NMDGF 2004, p. 5) and has been extirpated from Cebolla Creek since at least 1979 (Hanson 1980, pp. 29, 34). We consider this unit unoccupied. When wetted and if suitable habitat were present, the Zuni River and Rio Pescado could provide important connections between occupied reaches in Subunit 1a and potential future populations in Cebolla Creek, which has been identified as containing suitable habitat in the past and could provide for significant population expansion. Therefore, this subunit is essential for the conservation of the Zuni bluehead sucker because it provides for connection between populations and also provides space for the growth and expansion of the species in this portion of its historical range.

Unit 2: Kinlichee Creek Unit

Subunit 2a—Kinlichee Creek: Subunit 2a consists of 86.9 km (54.0 mi) along Kinlichee Creek and two tributaries (Black Soil Wash and Scattered Willow Wash) in Apache County, Arizona. This entire subunit is located within the Navajo Indian Reservation. The Zuni bluehead sucker occupies all stream reaches in this subunit, and the subunit contains all of the primary constituent elements of the physical or biological features essential to the conservation of the Zuni bluehead sucker.

Special management considerations or protection may be required within Subunit 2a to address low water levels as a result of water withdrawals and drought, sedimentation and riparian vegetation destruction from road development and livestock grazing, and predation from nonnative species. Such special management considerations or protection may include instream flows, stream fencing, erosion control structures along roads and during construction, reservoir management that improves up- and downstream habitat to benefit the Zuni bluehead sucker and nonnative species removal.

Subunit 2b—Red Clay Wash: Subunit 2b consists of 9.6 km (6.0 mi) of potential Zuni bluehead sucker habitat along Red Clay Wash, in Apache County, Arizona, on the Navajo Indian Reservation. The Zuni bluehead sucker historically occupied this stream but does not currently occur there. Inclusion of Red Clay Wash expands the recovery potential of the Zuni bluehead sucker in the lower Kinlichee watershed by increasing population redundancy within the species' historical range and is therefore essential to the conservation of the species.

Unit 3: San Juan River Unit

Subunit 3a—Canyon de Chelly: Subunit 3a consists of 187.9 km (112.7 mi) along Tsaile Creek, Wheatfields Creek, Whiskey Creek, Coyote Wash, Crystal Creek, and Sonsela Creek in

Apache County, Arizona, and San Juan County, New Mexico. This unit is located within the Navajo Indian Reservation, portions of which are managed by the National Park Service as Canyon de Chelly National Monument in trust for the Navajo Nation. The Zuni bluehead sucker occupies all stream reaches in this subunit, and the subunit contains all of the primary constituent elements of the physical or biological features essential to the conservation of the Zuni bluehead sucker.

Special management considerations or protection may be required within Subunit 3a to address low water levels as a result of water withdrawals and drought, sedimentation and riparian vegetation destruction from road development and livestock grazing, and predation from nonnative species. Such special management considerations or protection may include instream flows stream fencing, erosion control structures along roads and during construction, reservoir management that improves up- and downstream habitat to benefit the Zuni bluehead sucker, and nonnative species removal.

Subunit 3b—Little Whiskey Creek: Subunit 3b consists of 8.9 km (5.5 mi) of potential Zuni bluehead sucker habitat along Little Whiskey Creek in San Juan County, New Mexico, on the Navajo Indian Reservation. The Zuni bluehead sucker does not currently occur in Little Whiskey Creek, but suitable habitat is present and it is reasonable to conclude the species occurred there historically. Inclusion of Little Whiskey Creek expands the recovery potential of the Zuni bluehead sucker in the upper Whiskey Creek watershed by increasing population redundancy within the species' historical range and is therefore essential to the conservation of the species.

Effects of Critical Habitat Designation

Section 7 Consultation

Section 7(a)(2) of the Act requires Federal agencies, including the Service, to ensure that any action they fund, authorize, or carry out is not likely to jeopardize the continued existence of any endangered species or threatened species or result in the destruction or adverse modification of designated critical habitat of such species. In addition, section 7(a)(4) of the Act requires Federal agencies to confer with the Service on any agency action which is likely to jeopardize the continued existence of any species proposed to be listed under the Act or result in the destruction or adverse modification of proposed critical habitat.

Decisions by the 5th and 9th Circuit Courts of Appeals have invalidated our regulatory definition of ''destruction or adverse modification'' (50 CFR 402.02) (see *Gifford Pinchot Task Force* v. *U.S. Fish and Wildlife Service,* 378 F. 3d 1059 (9th Cir. 2004) and *Sierra Club* v. *U.S. Fish and Wildlife Service et al.,* 245 F.3d 434, 442 (5th Cir. 2001)), and we do not rely on this regulatory definition when analyzing whether an action is likely to destroy or adversely modify critical habitat. Under the statutory provisions of the Act, we determine destruction or adverse modification on the basis of whether, with implementation of the proposed Federal action, the affected critical habitat would continue to serve its intended conservation role for the species.

If a Federal action may affect a listed species or its critical habitat, the responsible Federal agency (action agency) must enter into consultation with us. Examples of actions that are subject to the section 7 consultation process are actions on State, tribal, local, or private lands that require a Federal permit (such as a permit from the U.S. Army Corps of Engineers under section 404 of the Clean Water Act (33 U.S.C. 1251 *et seq.*) or a permit from the Service under section 10 of the Act) or that involve some other Federal action (such as funding from the Federal Highway Administration, Federal Aviation Administration, or the Federal Emergency Management Agency). Federal actions not affecting listed species or critical habitat, and actions on State, tribal, local, or private lands that are not federally funded or authorized, do not require section 7 consultation.

As a result of section 7 consultation, we document compliance with the requirements of section 7(a)(2) through our issuance of:

(1) A concurrence letter for Federal actions that may affect, but are not likely to adversely affect, listed species or critical habitat; or

(2) A biological opinion for Federal actions that may affect and are likely to adversely affect listed species or critical habitat.

When we issue a biological opinion concluding that a project is likely to jeopardize the continued existence of a listed species and/or destroy or adversely modify critical habitat, we provide reasonable and prudent alternatives to the project, if any are identifiable, that would avoid the likelihood of jeopardy and/or destruction or adverse modification of critical habitat. We define ''reasonable and prudent alternatives'' (at 50 CFR 402.02) as alternative actions identified during consultation that:

(1) Can be implemented in a manner consistent with the intended purpose of the action,

(2) Can be implemented consistent with the scope of the Federal agency's legal authority and jurisdiction,

(3) Are economically and technologically feasible, and

(4) Would, in the Director's opinion, avoid the likelihood of jeopardizing the continued existence of the listed species and/or avoid the likelihood of destroying or adversely modifying critical habitat.

Reasonable and prudent alternatives can vary from slight project modifications to extensive redesign or relocation of the project. Costs associated with implementing a reasonable and prudent alternative are similarly variable.

Regulations at 50 CFR 402.16 require Federal agencies to reinitiate consultation on previously reviewed actions in instances where we have listed a new species or subsequently designated critical habitat that may be affected and the Federal agency has retained discretionary involvement or control over the action (or the agency's discretionary involvement or control is authorized by law). Consequently, Federal agencies sometimes may need to request reinitiation of consultation with us on actions for which formal consultation has been completed, if those actions with discretionary involvement or control may affect subsequently listed species or designated critical habitat.

Application of the ''Adverse Modification'' Standard

The key factor related to the adverse modification determination is whether, with implementation of the proposed Federal action, the affected critical habitat would continue to serve its intended conservation role for the species. Activities that may destroy or adversely modify critical habitat are those that alter the physical or biological features to an extent that appreciably reduces the conservation value of critical habitat for the Zuni bluehead sucker. As discussed above, the role of critical habitat is to support life-history needs of the species and provide for the conservation of the species.

Section 4(b)(8) of the Act requires us to briefly evaluate and describe, in any proposed or final regulation that designates critical habitat, activities involving a Federal action that may destroy or adversely modify such

habitat, or that may be affected by such designation.

Activities that may affect critical habitat, when carried out, funded, or authorized by a Federal agency, should result in consultation for the Zuni bluehead sucker. These activities include, but are not limited to:

(1) Actions that would diminish flows within the active stream channel. Such activities could include, but are not limited to: Water diversion, water withdrawal, channelization, construction of any barriers or impediments within the active stream channel, construction of permanent or temporary diversion structures, and groundwater pumping within aquifers associated with the stream or springs. These activities could affect water depth, velocity, and flow patterns, all of which are essential to the different life stages of Zuni bluehead sucker.

(2) Actions that would significantly increase sediment deposition within a stream channel. Such activities could include, but are not limited to: Excessive sedimentation from livestock grazing, road construction, commercial or urban development, channel alteration, timber harvest, or other watershed and floodplain disturbances. These activities could adversely affect reproduction of the species by preventing hatching of eggs through suffocation, or by eliminating suitable habitat for egg placement by Zuni bluehead sucker. In addition, excessive levels of sedimentation reduce or eliminate algae production and can make it difficult for the Zuni bluehead sucker to locate prey.

(3) Actions that result in the introduction, spread, or augmentation of nonnative aquatic species in occupied stream segments, or in stream segments that are hydrologically connected to occupied stream segments, even if those segments are occasionally intermittent, or introduction of other species that compete with or prey on Zuni bluehead sucker. Possible actions could include, but are not limited to: Stocking of nonnative fishes, stocking of sport fish, or other related actions. These activities can introduce parasites or disease, or affect the growth, reproduction, and survival of Zuni bluehead sucker.

(4) Actions that would significantly alter channel morphology. Such activities could include, but are not limited to: Channelization, impoundment, road and bridge construction, mining, dredging, and destruction of riparian vegetation. These activities may lead to changes in water flows and levels that would degrade or eliminate the Zuni bluehead, their habitats, or both. These actions can also lead to increased sedimentation and degradation of the water.

(5) Actions that significantly alter the water chemistry of the active channel. Such activities could include release of chemicals, biological pollutants, or other substances into the surface water or connected groundwater at a point source or by dispersed release (nonpoint source), and storage of chemicals or pollutants that can be transmitted, via surface water, groundwater, or air, into critical habitat. These actions can affect water chemistry and the prey base of the Zuni bluehead sucker.

Exemptions

Application of Section 4(a)(3) of the Act

The Sikes Act Improvement Act of 1997 (Sikes Act) (16 U.S.C. 670a) required each military installation that includes land and water suitable for the conservation and management of natural resources to complete an integrated natural resources management plan (INRMP) by November 17, 2001. An INRMP integrates implementation of the military mission of the installation with stewardship of the natural resources found on the base. Each INRMP includes:

(1) An assessment of the ecological needs on the installation, including the need to provide for the conservation of listed species;

(2) A statement of goals and priorities;

(3) A detailed description of management actions to be implemented to provide for these ecological needs; and

(4) A monitoring and adaptive management plan.

Among other things, each INRMP must, to the extent appropriate and applicable, provide for fish and wildlife management; fish and wildlife habitat enhancement or modification; wetland protection, enhancement, and restoration where necessary to support fish and wildlife; and enforcement of applicable natural resource laws.

The National Defense Authorization Act for Fiscal Year 2004 (Pub. L. 108–136) amended the Act to limit areas eligible for designation as critical habitat. Specifically, section 4(a)(3)(B)(i) of the Act (16 U.S.C. 1533(a)(3)(B)(i)) now provides: ''The Secretary shall not designate as critical habitat any lands or other geographic areas owned or controlled by the Department of Defense, or designated for its use, that are subject to an integrated natural resources management plan prepared under section 101 of the Sikes Act (16 U.S.C. 670a), if the Secretary determines in writing that such plan provides a benefit to the species for which critical habitat is proposed for designation.''

There are no Department of Defense lands within the proposed critical habitat designation for Zuni bluehead sucker.

Exclusions

Application of Section 4(b)(2) of the Act

Section 4(b)(2) of the Act states that the Secretary shall designate and make revisions to critical habitat on the basis of the best available scientific data after taking into consideration the economic impact, national security impact, and any other relevant impact of specifying any particular area as critical habitat. The Secretary may exclude an area from critical habitat if he determines that the benefits of such exclusion outweigh the benefits of specifying such area as part of the critical habitat, unless he determines, based on the best scientific data available, that the failure to designate such area as critical habitat will result in the extinction of the species. In making that determination, the statute on its face, as well as the legislative history, are clear that the Secretary has broad discretion regarding which factor(s) to use and how much weight to give to any factor.

Under section 4(b)(2) of the Act, we may exclude an area from designated critical habitat based on economic impacts, impacts on national security, or any other relevant impacts. In considering whether to exclude a particular area from the designation, we identify the benefits of including the area in the designation, identify the benefits of excluding the area from the designation, and evaluate whether the benefits of exclusion outweigh the benefits of inclusion. If the analysis indicates that the benefits of exclusion outweigh the benefits of inclusion, the Secretary may exercise his discretion to exclude the area only if such exclusion would not result in the extinction of the species.

Exclusions Based on Economic Impacts

Under section 4(b)(2) of the Act, we consider the economic impacts of specifying any particular area as critical habitat. In order to consider economic impacts, we are preparing an analysis of the economic impacts of the proposed critical habitat designation and related factors. Potential land use sectors that may be affected by the Zuni bluehead sucker critical habitat designation include water diversion or impoundment repairs, forest management (silvicultural practices), fire suppression activities, road development, grazing, groundwater

withdrawals, and subdivision development. We also consider any social impacts that might occur because of the designation.

During the development of a final designation, we will consider economic impacts based on information in our economic analysis, public comments, and other new information, and areas may be excluded from the final critical habitat designation under section 4(b)(2) of the Act and our implementing regulations at 50 CFR 424.19.

Exclusions Based on National Security Impacts

Under section 4(b)(2) of the Act, we consider whether there are lands where a national security impact might exist. In preparing this proposal, we have determined that the lands within the proposed designation of critical habitat for the Zuni bluehead sucker are not owned or managed by the Department of Defense, and, therefore, we anticipate no impact on national security. Consequently, the Secretary is not intending to exercise his discretion to exclude any areas from the final designation based on impacts on national security.

Exclusions Based on Other Relevant Impacts

Under section 4(b)(2) of the Act, we consider any other relevant impacts, in addition to economic impacts and impacts on national security. We consider a number of factors including whether the landowners have developed any HCPs or other management plans for the area, or whether there are conservation partnerships that would be encouraged by designation of, or exclusion from, critical habitat. In addition, we look at any tribal issues, and consider the government-to-government relationship of the United States with tribal entities. We also consider any social impacts that might occur because of the designation.

When we evaluate the existence of a conservation plan when considering the benefits of exclusion, we consider a variety of factors, including but not limited to, whether the plan is finalized; how it provides for the conservation of the essential physical or biological features; whether there is a reasonable expectation that the conservation management strategies and actions contained in a management plan will be implemented into the future; whether the conservation strategies in the plan are likely to be effective; and whether the plan contains a monitoring program or adaptive management to ensure that the conservation measures are effective and can be adapted in the future in response to new information.

There are tribal lands included in the proposed designation of critical habitat for the Zuni bluehead sucker. Using the criteria found in the *Criteria Used To Identify Critical Habitat* section, we have determined that tribal lands that are occupied by the Zuni bluehead sucker contain the features essential for the conservation the species, as well as tribal lands unoccupied by the Zuni bluehead sucker that are essential for the conservation of the species. We have begun government-to-government consultation with these tribes, and will continue to do so throughout the public comment period and during development of the final designation of critical habitat for the Zuni bluehead sucker. We will consider these areas for exclusion from the final critical habitat designation to the extent consistent with the requirements of section 4(b)(2) of the Act. The Navajo Nation and Zuni Pueblo are the main tribes affected by this proposed rule. We sent notification letters in July 2012 to both tribes describing the exclusion process under section 4(b)(2) of the Act, and we have engaged in conversations with both tribes about the proposal to the extent possible without disclosing predecisional information. We coordinated with the Navajo Nation in May 2012, to coordinate surveys on Navajo lands. Additionally, we are working with Zuni Pueblo to develop a management plan for their lands. We will schedule a meeting with the tribes and any other interested tribes shortly after publication of this proposed rule so that we can give them as much time as possible to comment.

A final determination on whether the Secretary will exercise his discretion to exclude any of these areas from critical habitat for the Zuni bluehead sucker will be made when we publish the final rule designating critical habitat. We will take into account public comments and carefully weigh the benefits of exclusion versus inclusion of these areas. We may also consider areas not identified above for exclusion from the final critical habitat designation based on information we may receive during the preparation of the final rule (*e.g.,* management plans for additional areas).

Peer Review

In accordance with our joint policy on peer review published in the **Federal Register** on July 1, 1994 (59 FR 34270), we will seek the expert opinions of at least three appropriate and independent specialists regarding this proposed rule. The purpose of peer review is to ensure that our listing determination and critical habitat designation are based on scientifically sound data, assumptions, and analyses. We have invited these peer reviewers to comment during this public comment period.

We will consider all comments and information received during this comment period on this proposed rule during our preparation of a final determination. Accordingly, the final decision may differ from this proposal.

Public Hearings

Section 4(b)(5) of the Act provides for one or more public hearings on this proposal, if requested. Requests must be received within 45 days after the date of publication of this proposed rule in the **Federal Register**. Such requests must be sent to the address shown in the **FOR FURTHER INFORMATION CONTACT** section. We will schedule public hearings on this proposal, if any are requested, and announce the dates, times, and places of those hearings, as well as how to obtain reasonable accommodations, in the **Federal Register** and local newspapers at least 15 days before the hearing.

Required Determinations

Regulatory Planning and Review—Executive Orders 12866 and 13563

Executive Order 12866 provides that the Office of Information and Regulatory Affairs will review all significant rules. The Office of Information and Regulatory Affairs has determined that this rule is not significant.

Executive Order 13563 reaffirms the principles of Executive Order 12866 while calling for improvements in the nation's regulatory system to promote predictability, to reduce uncertainty, and to use the best, most innovative, and least burdensome tools for achieving regulatory ends. The executive order directs agencies to consider regulatory approaches that reduce burdens and maintain flexibility and freedom of choice for the public where these approaches are relevant, feasible, and consistent with regulatory objectives. Executive Order 13563 emphasizes further that regulations must be based on the best available science and that the rulemaking process must allow for public participation and an open exchange of ideas. We have developed this rule in a manner consistent with these requirements.

Regulatory Flexibility Act (5 U.S.C. 601 et seq.)

Under the Regulatory Flexibility Act (RFA; 5 U.S.C. 601 *et seq.*) as amended by the Small Business Regulatory Enforcement Fairness Act (SBREFA) of 1996 (5 U.S.C 801 *et seq.*), whenever an

agency must publish a notice of rulemaking for any proposed or final rule, it must prepare and make available for public comment a regulatory flexibility analysis that describes the effects of the rule on small entities (small businesses, small organizations, and small government jurisdictions). However, no regulatory flexibility analysis is required if the head of the agency certifies the rule will not have a significant economic impact on a substantial number of small entities. The SBREFA amended the RFA to require Federal agencies to provide a certification statement of the factual basis for certifying that the rule will not have a significant economic impact on a substantial number of small entities.

According to the Small Business Administration, small entities include small organizations such as independent nonprofit organizations; small governmental jurisdictions, including school boards and city and town governments that serve fewer than 50,000 residents; and small businesses (13 CFR 121.201). Small businesses include such businesses as manufacturing and mining concerns with fewer than 500 employees, wholesale trade entities with fewer than 100 employees, retail and service businesses with less than $5 million in annual sales, general and heavy construction businesses with less than $27.5 million in annual business, special trade contractors doing less than $11.5 million in annual business, and forestry and logging operations with fewer than 500 employees and annual business less than $7 million. To determine whether small entities may be affected, we will consider the types of activities that might trigger regulatory impacts under this designation as well as types of project modifications that may result. In general, the term ''significant economic impact'' is meant to apply to a typical small business firm's business operations.

Importantly, the incremental impacts of a rule must be *both* significant and substantial to prevent certification of the rule under the RFA and to require the preparation of an initial regulatory flexibility analysis. If a substantial number of small entities are affected by the proposed critical habitat designation, but the per-entity economic impact is not significant, the Service may certify. Likewise, if the per-entity economic impact is likely to be significant, but the number of affected entities is not substantial, the Service may also certify.

The Service's current understanding of recent case law is that Federal agencies are only required to evaluate the potential impacts of rulemaking on those entities directly regulated by the rulemaking; therefore, they are not required to evaluate the potential impacts to those entities not directly regulated. The designation of critical habitat for an endangered or threatened species only has a regulatory effect where a Federal action agency is involved in a particular action that may affect the designated critical habitat. Under these circumstances, only the Federal action agency is directly regulated by the designation, and, therefore, consistent with the Service's current interpretation of RFA and recent case law, the Service may limit its evaluation of the potential impacts to those identified for Federal action agencies. Under this interpretation, there is no requirement under the RFA to evaluate the potential impacts to entities not directly regulated, such as small businesses. However, Executive Orders 12866 and 13563 direct Federal agencies to assess costs and benefits of available regulatory alternatives in quantitative (to the extent feasible) and qualitative terms. Consequently, it is the current practice of the Service to assess to the extent practicable these potential impacts if sufficient data are available, whether or not this analysis is believed by the Service to be strictly required by the RFA. In other words, while the effects analysis required under the RFA is limited to entities directly regulated by the rulemaking, the effects analysis under the Act, consistent with the EO regulatory analysis requirements, can take into consideration impacts to both directly and indirectly impacted entities, where practicable and reasonable.

In conclusion, we believe that, based on our interpretation of directly regulated entities under the RFA and relevant case law, this designation of critical habitat will only directly regulate Federal agencies which are not by definition small business entities. And as such, we certify that, if promulgated, this designation of critical habitat would not have a significant economic impact on a substantial number of small business entities. Therefore, an initial regulatory flexibility analysis is not required. However, though not necessarily required by the RFA, in our draft economic analysis for this proposal we will consider and evaluate the potential effects to third parties that may be involved with consultations with Federal action agencies related to this action.

Energy Supply, Distribution, or Use—Executive Order 13211

Executive Order 13211 (Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use) requires agencies to prepare Statements of Energy Effects when undertaking certain actions. We do not expect the designation of this proposed critical habitat to significantly affect energy supplies, distribution, or use. Therefore, this action is not a significant energy action, and no Statement of Energy Effects is required. However, we will further evaluate this issue as we conduct our economic analysis, and review and revise this assessment as warranted.

Unfunded Mandates Reform Act (2 U.S.C. 1501 et seq.)

In accordance with the Unfunded Mandates Reform Act (2 U.S.C. 1501 *et seq.*), we make the following findings:

(1) This proposed rule will not produce a Federal mandate. In general, a Federal mandate is a provision in legislation, statute, or regulation that would impose an enforceable duty upon State, local, or tribal governments, or the private sector, and includes both ''Federal intergovernmental mandates'' and ''Federal private sector mandates.'' These terms are defined in 2 U.S.C. 658(5)–(7). ''Federal intergovernmental mandate'' includes a regulation that ''would impose an enforceable duty upon State, local, or tribal governments'' with two exceptions. It excludes ''a condition of Federal assistance.'' It also excludes ''a duty arising from participation in a voluntary Federal program,'' unless the regulation ''relates to a then-existing Federal program under which $500,000,000 or more is provided annually to State, local, and tribal governments under entitlement authority,'' if the provision would ''increase the stringency of conditions of assistance'' or ''place caps upon, or otherwise decrease, the Federal Government's responsibility to provide funding,'' and the State, local, or tribal governments ''lack authority'' to adjust accordingly. At the time of enactment, these entitlement programs were: Medicaid; Aid to Families with Dependent Children work programs; Child Nutrition; Food Stamps; Social Services Block Grants; Vocational Rehabilitation State Grants; Foster Care, Adoption Assistance, and Independent Living; Family Support Welfare Services; and Child Support Enforcement. ''Federal private sector mandate'' includes a regulation that ''would impose an enforceable duty upon the private sector, except (i) a

condition of Federal assistance or (ii) a duty arising from participation in a voluntary Federal program.''

The designation of critical habitat does not impose a legally binding duty on non-Federal Government entities or private parties. Under the Act, the only regulatory effect is that Federal agencies must ensure that their actions do not destroy or adversely modify critical habitat under section 7. While non-Federal entities that receive Federal funding, assistance, or permits, or that otherwise require approval or authorization from a Federal agency for an action, may be indirectly impacted by the designation of critical habitat, the legally binding duty to avoid destruction or adverse modification of critical habitat rests squarely on the Federal agency. Furthermore, to the extent that non-Federal entities are indirectly impacted because they receive Federal assistance or participate in a voluntary Federal aid program, the Unfunded Mandates Reform Act would not apply, nor would critical habitat shift the costs of the large entitlement programs listed above onto State governments.

(2) We lack the available economic information to determine if a Small Government Agency Plan is required. Therefore, we defer this finding until completion of the draft economic analysis is prepared under section 4(b)(2) of the Act.

Takings—Executive Order 12630

In accordance with Executive Order 12630 (Government Actions and Interference with Constitutionally Protected Private Property Rights), we will analyze the potential takings implications of designating critical habitat for the Zuni bluehead sucker in a takings implications assessment. The draft economic analysis will provide the foundation for us to use in preparing a takings implication assessment. Critical habitat designation does not affect landowner actions that do not require Federal funding or permits, nor does it preclude development of habitat conservation programs or issuance of incidental take permits to permit actions that do require Federal funding or permits to go forward.

Federalism—Executive Order 13132

In accordance with Executive Order 13132 (Federalism), this proposed rule does not have significant Federalism effects. A Federalism assessment is not required. In keeping with Department of the Interior and Department of Commerce policy, we requested information from, and coordinated development of, this proposed critical habitat designation with appropriate State resource agencies in New Mexico and Arizona. The designation of critical habitat in areas currently occupied by the Zuni bluehead sucker imposes no additional restrictions to those currently in place and, therefore, has little incremental impact on State and local governments and their activities. The designation may have some benefit to these governments because the areas that contain the physical or biological features essential to the conservation of the species are more clearly defined, and the elements of the features of the habitat necessary to the conservation of the species are specifically identified. This information does not alter where and what federally sponsored activities may occur. However, it may assist local governments in long-range planning (rather than having them wait for case-by-case section 7 consultations to occur).

Where State and local governments require approval or authorization from a Federal agency for actions that may affect critical habitat, consultation under section 7(a)(2) would be required. While non-Federal entities that receive Federal funding, assistance, or permits, or that otherwise require approval or authorization from a Federal agency for an action, may be indirectly impacted by the designation of critical habitat, the legally binding duty to avoid destruction or adverse modification of critical habitat rests squarely on the Federal agency.

Civil Justice Reform—Executive Order 12988

In accordance with Executive Order 12988 (Civil Justice Reform), the Office of the Solicitor has determined that the rule does not unduly burden the judicial system and that it meets the requirements of sections 3(a) and 3(b)(2) of the Order. We are designating critical habitat in accordance with the provisions of the Act. To assist the public in understanding the habitat needs of the species, the rule identifies the elements of physical or biological features essential to the conservation of the species. The designated areas of critical habitat are presented on maps, and the rule provides several options for the interested public to obtain more detailed location information, if desired.

Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.)

This rule does not contain any new collections of information that require approval by OMB under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). This rule will not impose recordkeeping or reporting requirements on State or local governments, individuals, businesses, or organizations. 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.

National Environmental Policy Act (42 U.S.C. 4321 et seq.)

It is our position that, outside the jurisdiction of the U.S. Court of Appeals for the Tenth Circuit, we do not need to prepare environmental analyses pursuant to NEPA in connection with designating critical habitat under the Endangered Species Act. We published a notice outlining our reasons for this determination in the **Federal Register** on October 25, 1983 (48 FR 49244). This position was upheld by the U.S. Court of Appeals for the Ninth Circuit (*Douglas County* v. *Babbitt,* 48 F.3d 1495 (9th Cir. 1995), cert. denied 516 U.S. 1042 (1996)). However, when the range of the species includes States within the Tenth Circuit, such as that of the Zuni bluehead sucker, under the Tenth Circuit ruling in *Catron County Board of Commissioners* v. *U.S. Fish and Wildlife Service,* 75 F.3d 1429 (10th Cir. 1996), we will undertake a NEPA analysis for critical habitat designation and notify the public of the availability of the draft environmental assessment for this proposal when it is finished.

Government-to-Government Relationship With Tribes

In accordance with the President's memorandum of April 29, 1994 (Government-to-Government Relations with Native American Tribal Governments; 59 FR 22951), Executive Order 13175 (Consultation and Coordination With Indian Tribal Governments), and the Department of the Interior's manual at 512 DM 2, we readily acknowledge our responsibility to communicate meaningfully with recognized Federal Tribes on a government-to-government basis. In accordance with Secretarial Order 3206 of June 5, 1997 (American Indian Tribal Rights, Federal-Tribal Trust Responsibilities, and the Endangered Species Act), we readily acknowledge our responsibilities to work directly with tribes in developing programs for healthy ecosystems, to acknowledge that tribal lands are not subject to the same controls as Federal public lands, to remain sensitive to Indian culture, and to make information available to tribes.

There are tribal lands in Arizona and New Mexico included in this proposed designation of critical habitat. Using the criteria found in the *Criteria Used To Identify Critical Habitat* section, we

have determined that there are tribal lands that are occupied by the Zuni bluehead sucker that contain the features essential for the conservation of the species, as well as tribal lands unoccupied by the species at the time of listing that are essential for the conservation of the Zuni bluehead sucker. We have begun government-to-government consultation with these tribes throughout the public comment period and during development of the final designation of Zuni bluehead sucker critical habitat. We will consider these areas for exclusion from the final critical habitat designation to the extent consistent with the requirements of section 4(b)(2) of the Act. The Navajo Nation and Zuni Pueblo are the main tribes affected by this proposed rule. We sent notification letters in July 2012 to each tribe describing the exclusion process under section 4(b)(2) of the Act, and we have engaged in conversations with both tribes about the proposal to the extent possible without disclosing predecisional information. We coordinated with the Navajo Nation in May 2012 to coordinate surveys on Navajo lands. Additionally, we are working with Zuni Pueblo to develop a management plan for their lands. We will schedule meetings with these tribes and any other interested tribes shortly after publication of this proposed rule so that we can give them as much time as possible to comment.

Clarity of the Rule

We are required by Executive Orders 12866 and 12988 and by the Presidential Memorandum of June 1, 1998, to write all rules in plain language. This means that each rule we publish must:

(1) Be logically organized;

(2) Use the active voice to address readers directly;

(3) Use clear language rather than jargon;

(4) Be divided into short sections and sentences; and

(5) Use lists and tables wherever possible.

If you feel that we have not met these requirements, send us comments by one of the methods listed in the **ADDRESSES** section. To better help us revise the rule, your comments should be as specific as possible. For example, you should tell us the numbers of the sections or paragraphs that are unclearly written, which sections or sentences are too long, the sections where you feel lists or tables would be useful, etc.

References Cited

A complete list of references cited in this rulemaking is available on the Internet at *http://www.regulations.gov* and upon request from the New Mexico Ecological Services Field Office (see **FOR FURTHER INFORMATION CONTACT**).

Authors

The primary authors of this proposed rule are the staff members of the New Mexico Ecological Services Field Office.

List of Subjects in 50 CFR Part 17

Endangered and threatened species, Exports, Imports, Reporting and recordkeeping requirements, Transportation.

Proposed Regulation Promulgation

Accordingly, we propose to amend part 17, subchapter B of chapter I, title 50 of the Code of Federal Regulations, as set forth below:

PART 17—[AMENDED]

■ 1. The authority citation for part 17 continues to read as follows:

Authority: 16 U.S.C. 1361–1407; 1531–1544; and 4201–4245, unless otherwise noted.

■ 2. In § 17.95, amend paragraph (e) by adding an entry for ''Zuni bluehead sucker (*Catostomus discobolus yarrowi*),'' after the entry for ''Warner Sucker (*Catostomus warnerensis*)'' to read as follows:

§ 17.95 Critical habitat—fish and wildlife.

* * * * *

(e) *Fishes.*

* * * * *

Zuni bluehead sucker (*Catostomus discobolus yarrowi*)

(1) Critical habitat units are depicted for Apache County, Arizona, and Cibola, McKinley, and San Juan Counties, New Mexico, on the maps below.

(2) Within these areas, the primary constituent elements of the physical or biological features essential to the conservation of the Zuni bluehead sucker consist of three components:

(i) A riverine system with habitat to support all life stages of Zuni bluehead sucker, which includes:

(A) Dynamic flows that allow for periodic changes in channel morphology and adequate river functions, such as channel reshaping and delivery of coarse sediments.

(B) Stream courses with perennial flows, or areas that may be periodically dewatered but serve as connective corridors between occupied or seasonally occupied habitat and through which the species may move when the habitat is wetted.

(C) Stream microhabitat types including runs, riffles, and pools with substrate ranging from gravel, cobble and bedrock substrates with low or moderate amounts of fine sediment and substrate embeddedness.

(D) Streams with depths generally less than 2 m (3.3 ft), and with slow to swift flow velocities less than 35 cm/sec (1.1 ft/sec).

(E) Clear, cool water with low turbidity and temperatures in the general range of 9.0 to 28.0 °C (48.2 to 82.4 °F).

(F) No harmful levels of pollutants.

(G) Adequate riparian shading to reduce water temperatures when ambient temperatures are high and provide protective cover from predators.

(ii) An abundant aquatic insect food base consisting of fine particulate organic material, filamentous algae, midge larvae, caddisfly larvae, mayfly larvae, flatworms, and small terrestrial insects.

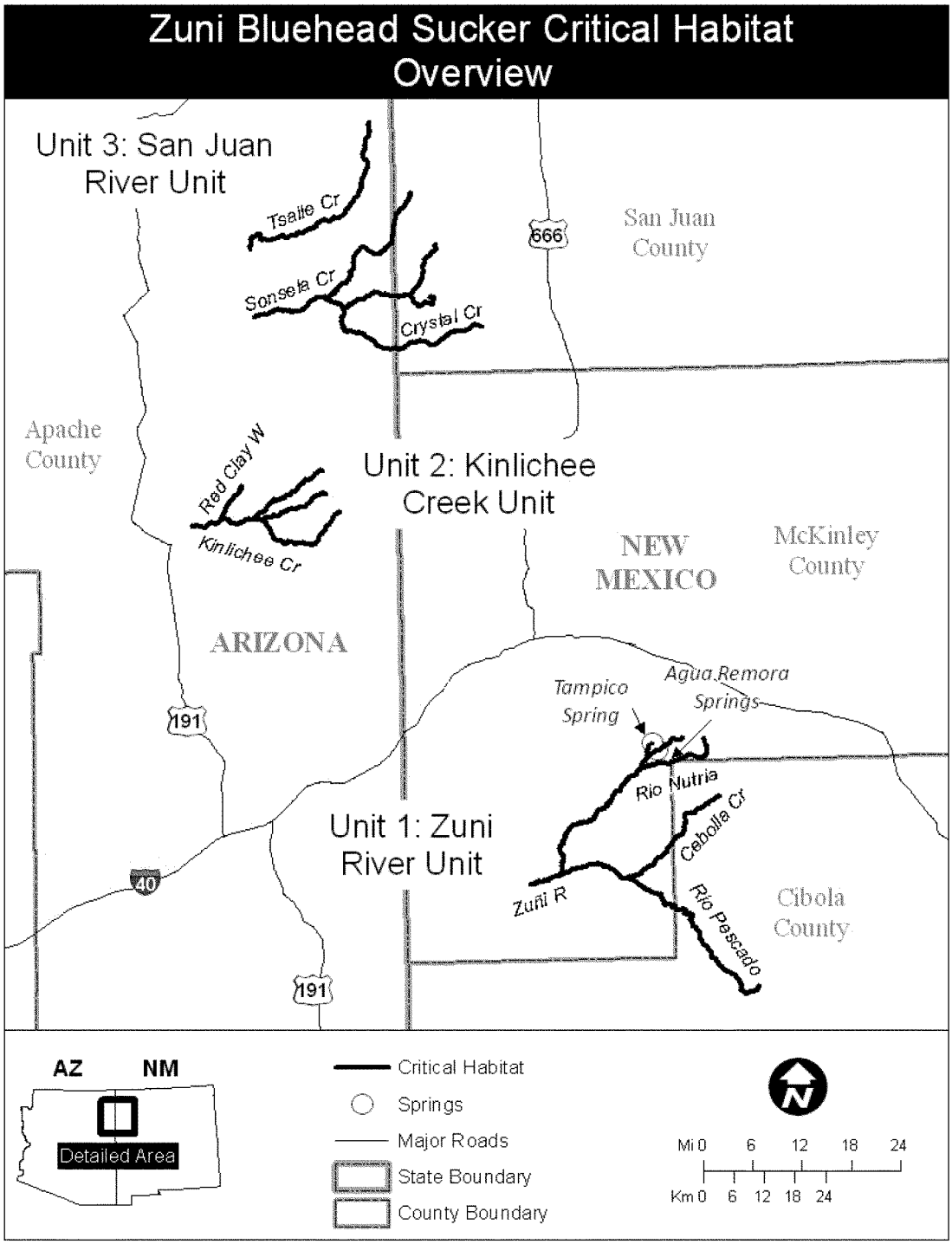
(iii) Areas devoid of nonnative aquatic species or areas that are maintained to kept nonnatives at a level that allows the Zuni bluehead sucker to continue to survive and reproduce.

(3) Critical habitat does not include manmade structures (such as bridges, docks, and aqueducts) and the land on which they are located existing within the legal boundaries on [DATE 30 DAYS AFTER THE DATE OF PUBLICATION OF THE FINAL RULE IN THE **Federal Register**].

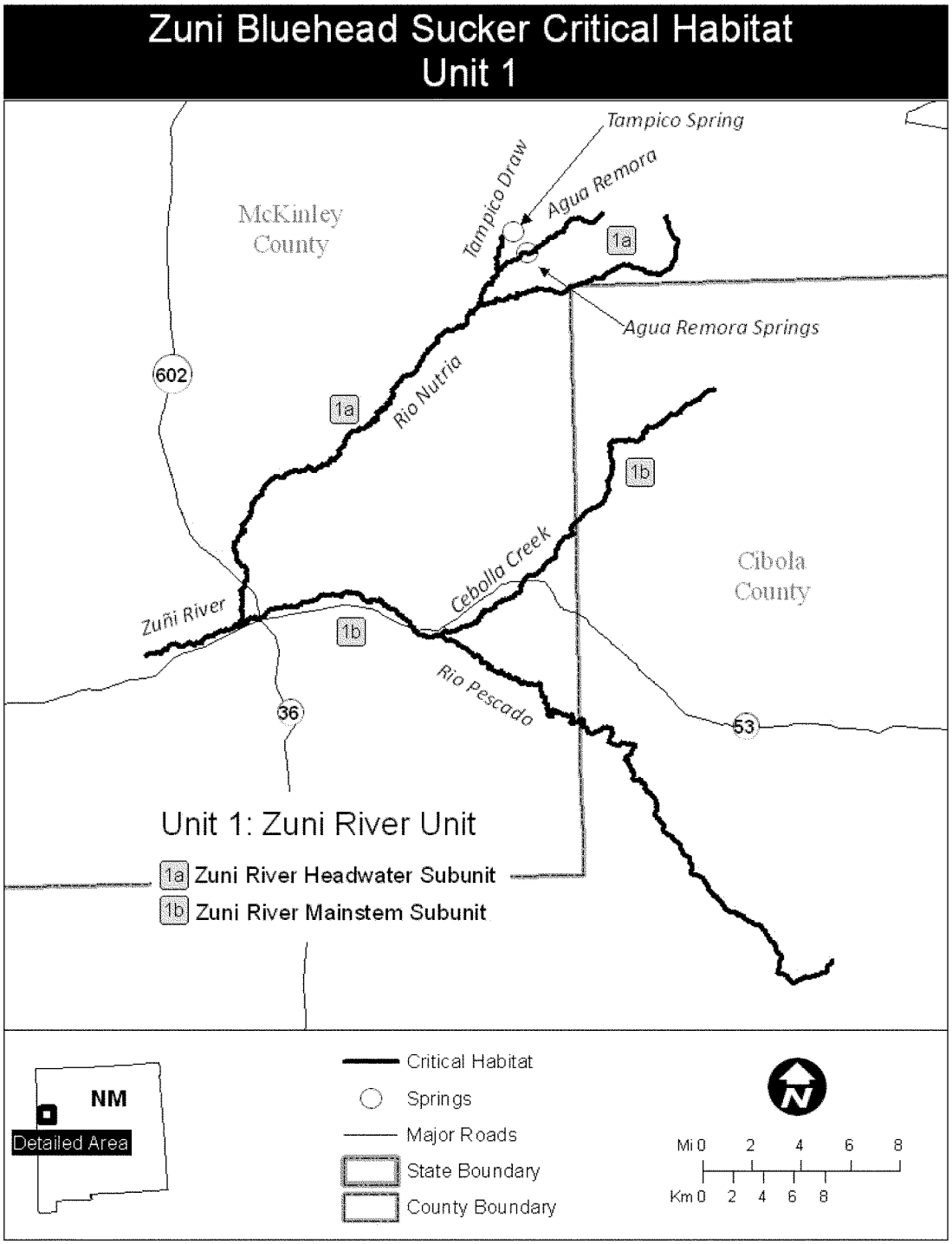
(4) *Critical habitat map units.* Data layers defining map units were created on a base of USGS digital ortho-photo quarter-quadrangles, and critical habitat units were then mapped using Universal Transverse Mercator (UTM) Zone 15N coordinates. The maps in this entry, as modified by any accompanying regulatory text, establish the boundaries of the critical habitat designation. The coordinates or plot points or both on which each map is based are available to the public at the Service's Internet site, (*http://www.fws.gov/southwest/es/NewMexico/*), (*http://www.regulations.gov* at Docket No. FWS–R2–ES–2013–002 and at the New Mexico Ecological Services Field Office. You may obtain field office location information by contacting one of the Service regional offices, the addresses of which are listed at 50 CFR part 22.

(5) *Note:* Index of critical habitat units for the Zuni bluehead sucker follows:

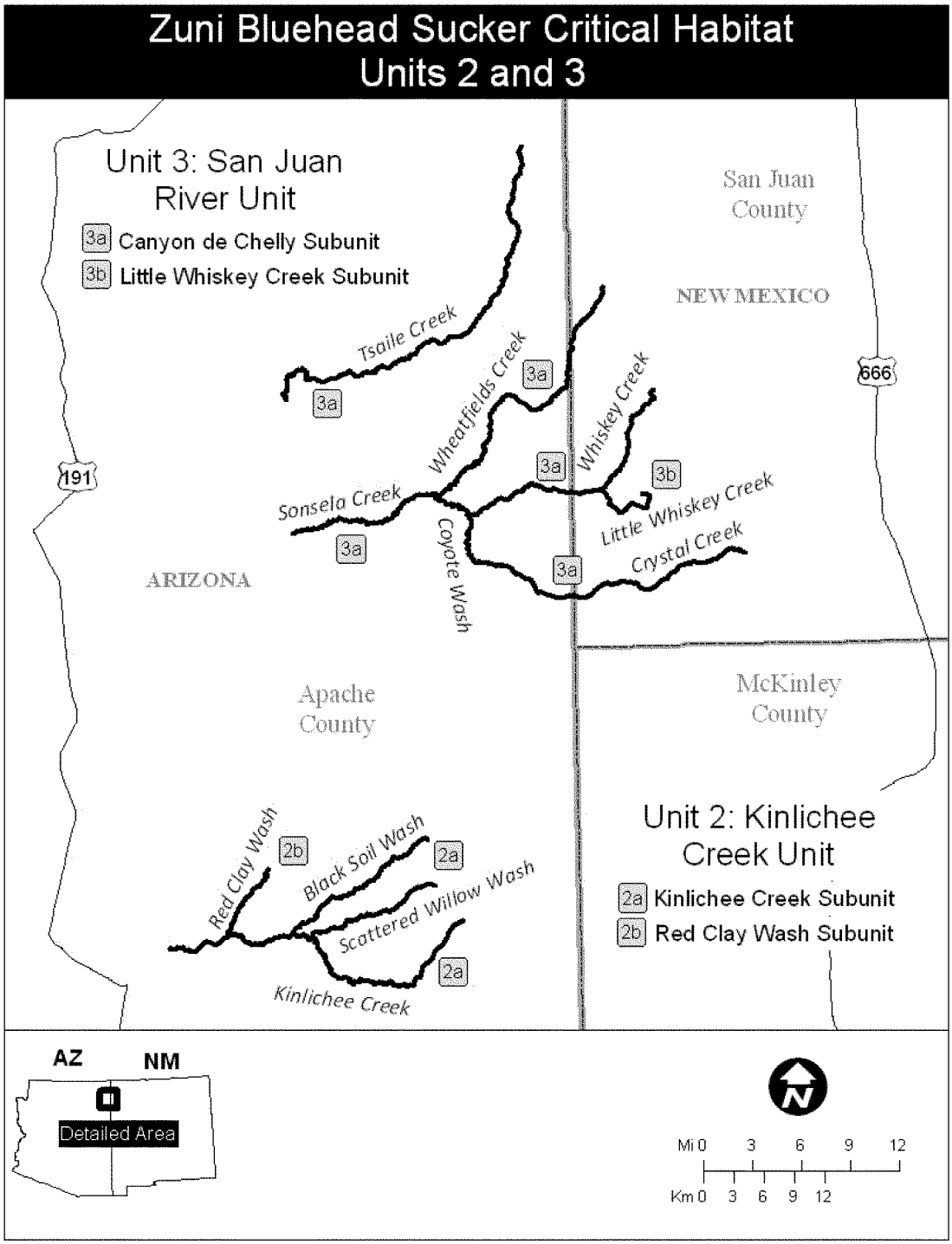
BILLING CODE 4310–55–P



(6) Unit 1: Zuni River Unit, McKinley and Cibola Counties, New Mexico. Map of Unit 1 follows:



(7) Unit 2: Kinlichee Creek Unit, Apache County, Arizona, and McKinley and San Juan Counties, New Mexico. Map of Unit 2 follows:


Zuni Bluehead Sucker Critical Habitat
Units 2 and 3
Unit 3: San Juan River Unit
3a Canyon de Chelly Subunit
3b Little Whiskey Creek Subunit
San Juan County
NEW MEXICO
Tsaile Creek
Wheatfields Creek
Whiskey Creek
Sonsela Creek
Coyote Wash
Little Whiskey Creek
Crystal Creek
666
191
ARIZONA
Apache County
McKinley County
Red Clay Wash
Black Soil Wash
Scattered Willow Wash
Kinlichee Creek
Unit 2: Kinlichee Creek Unit
2a Kinlichee Creek Subunit
2b Red Clay Wash Subunit
AZ
NM
Detailed Area
Mi 0 3 6 9 12
Km 0 3 6 9 12

(8) Unit 3: San Juan River Unit, Apache County, Arizona, and San Juan County, New Mexico. Map of Unit 3 is provided at paragraph (7) of this entry.

* * * * *

Dated: January 15, 2013.

Michael Bean,

Acting Principal Deputy Assistant Secretary for Fish Wildlife and Parks.

[FR Doc. 2013–01302 Filed 1–24–13; 8:45 am]

BILLING CODE 4310–55–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

[Docket No. FWS–R2–ES–2012–0101; 4500030113]

RIN 1018–AY25

Endangered and Threatened Wildlife and Plants; Proposed Endangered Status for the Zuni Bluehead Sucker

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Proposed rule.

SUMMARY: We, the U.S. Fish and Wildlife Service, propose to list the Zuni bluehead sucker as an endangered species under the Endangered Species Act and propose to designate critical habitat for the species. If we finalize this rule as proposed, it would extend the Act's protections to this subspecies and its critical habitat. The effect of these regulations will be to conserve the Zuni bluehead sucker and protect its habitat under the Act.

DATES: We will accept comments received or postmarked on or before March 26, 2013. Comments submitted electronically using the Federal eRulemaking Portal (see **ADDRESSES** section, below) must be received by 11:59 p.m. Eastern Time on the closing date. We must receive requests for public hearings, in writing, at the address shown in **FOR FURTHER INFORMATION CONTACT** by March 11, 2013.

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

(1) *Electronically:* Go to the Federal eRulemaking Portal: *http://www.regulations.gov.* In the Search box, enter FWS–R2–ES–2012–0101, which is the docket number for this rulemaking. Then, in the Search panel on the left side of the screen, under the Document Type heading, click on the Proposed Rules link to locate this document. You may submit a comment by clicking on ''Comment Now!''

(2) *By hard copy:* Submit by U.S. mail or hand-delivery to: Public Comments Processing, Attn: FWS–R2–ES–2012–0101; Division of Policy and Directives Management; U.S. Fish and Wildlife Service; 4401 N. Fairfax Drive, MS 2042–PDM; Arlington, VA 22203.

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

FOR FURTHER INFORMATION CONTACT: Wally ''J'' Murphy, Field Supervisor, U.S. Fish and Wildlife Service, New Mexico Ecological Services Field Office, 2105 Osuna NE., Albuquerque, NM 87113, by telephone 505–346–2525 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:

Executive Summary

Why we need to publish a rule. Under the Act, if a species is determined to be an endangered or threatened species throughout all or a significant portion of its range, we are required to promptly publish a proposal in the **Federal Register** and make a determination on our proposal within 1 year. Critical habitat shall be designated, to the maximum extent prudent and determinable, for any species determined to be an endangered or threatened species under the Act. Listing a species as an endangered or threatened species and designations and revisions of critical habitat can only be completed by issuing a rule. Elsewhere in today's **Federal Register**, we propose to designate critical habitat for the Zuni bluehead sucker under the Act.

This rule consists of: (1) A proposed rule to list the Zuni bluehead sucker (*Catostomus discobolus yarrowi*) as an endangered species; and (2) a proposed rule for designation of critical habitat for the Zuni bluehead sucker. The Zuni bluehead sucker is a candidate species for which we have on file sufficient information on biological vulnerability and threats to support preparation of a listing proposal, but for which development of a listing regulation has been precluded by other higher priority listing activities. This rule reassesses all available information regarding status of and threats to the Zuni bluehead sucker.

The basis for our action. Under the Act, we can determine that a species is an endangered or threatened species based on any of five factors: (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.

We have determined that the Zuni bluehead sucker is threatened by Factors A, C, D, and E.

We will seek peer review. We are seeking comments from knowledgeable individuals with scientific expertise to review our analysis of the best available science and application of that science and to provide any additional scientific information to improve this proposed rule. Because we will consider all comments and information received during the comment period, our final determinations may differ from this proposal.

Information Requested

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 governmental agencies, Native American tribes, the scientific community, industry, or any other interested parties concerning this proposed rule. We particularly seek comments concerning:

(1) The Zuni bluehead sucker's biology, range, and population trends, including:

(a) Habitat requirements for feeding, breeding, and sheltering;

(b) Genetics and taxonomy;

(c) Historical and current range including distribution patterns;

(d) Historical and current population levels, and current and projected trends; and

(e) Past and ongoing conservation measures for the species, its habitat or both.

(2) The factors that are the basis for making a listing determination for a species under section 4(a) of the Act (16 U.S.C. 1531 *et seq.*), which are:

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

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

(c) Disease or predation;

(d) The inadequacy of existing regulatory mechanisms; or

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

(3) Biological, commercial trade, or other relevant data concerning any threats (or lack thereof) to this species and existing regulations that may be addressing those threats.

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

(5) Any information on the biological or ecological requirements of the species, and ongoing conservation measures for the species and its habitat.

Please include sufficient information with your submission (such as scientific journal articles or other publications) to allow us to verify any scientific or commercial information you include.

Please note that submissions merely stating support for or opposition to the action under consideration without providing supporting information, although noted, will not be considered in making a determination, as section 4(b)(1)(A) of the Act directs that determinations as to whether any species is a threatened or endangered species must be made ''solely on the basis of the best scientific and commercial data available.''

You may submit your comments and materials concerning this proposed rule by one of the methods listed in the **ADDRESSES** section. We request that you send comments only by the methods described in the **ADDRESSES** section.

If you submit information via *http://www.regulations.gov,* your entire submission—including any personal identifying information—will be posted on the Web site. If your submission is made via a hardcopy that includes personal identifying information, you may request at the top of your document that we withhold this information from public review. However, we cannot guarantee that we will be able to do so. We will post all hardcopy submissions on *http://www.regulations.gov.* Please include sufficient information with your comments to allow us to verify any scientific or commercial information you include.

Comments and materials we receive, as well as supporting documentation we used in preparing this proposed rule, will be available for public inspection on *http://www.regulations.gov,* 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**).

Previous Federal Actions

We identified the Zuni bluehead sucker as a Category 2 species in the September 18, 1985, Review of Vertebrate Wildlife; Notice of Review (50 FR 37958). Category 2 Candidates were defined as species for which we had information that proposed listing was possibly appropriate, but conclusive data on biological vulnerability and threats were not available to support a proposed rule at the time. The species remained so designated in subsequent annual Candidate Notices of Review (CNOR) (54 FR 554, January 6, 1989; 56 FR 58804, November 21, 1991; and 59 FR 58982, November 15, 1994). In the February 28, 1996, CNOR (61 FR 7596), we discontinued the designation of Category 2 species as candidates; therefore, the Zuni bluehead sucker was no longer a candidate species.

Subsequently, in 2001, the Zuni bluehead sucker was added to the candidate list (66 FR 54807, October 30, 2001). Candidates are those fish, wildlife, and plants for which we have on file sufficient information on biological vulnerability and threats to support preparation of a listing proposal, but for which development of a listing regulation is precluded by other higher priority listing activities. The Zuni bluehead sucker was included in all of our subsequent annual CNORs (67 FR 40657, June 13, 2002; 69 FR 24875, May 4, 2004; 70 FR 24869, May 11, 2005; 71 FR 53756, September 12, 2006; 72 FR 69033, December 6, 2007; 73 FR 75175, December 10, 2008; 74 FR 57803, November 9, 2009; 75 FR 69221, November 10, 2010; and 76 FR 66370, October 26, 2011). On May 11, 2004, we were petitioned to list Zuni bluehead sucker, although no new information was provided in the petition. Because we had already found the species warranted proposed listing, no further action was taken on the petition. Zuni bluehead sucker has a listing priority number of 3, which reflects a subspecies with threats that are both imminent and high in magnitude.

Elsewhere in today's **Federal Register**, we propose to designate critical habitat for the Zuni bluehead sucker under the Act.

Status Assessment for the Zuni Bluehead Sucker

Background

Species Information

Species Information and Taxonomy

The Zuni bluehead sucker has a fusiform (torpedo-shaped), slender body with a subterminal mouth (mouth posterior to the tip of the snout) (Propst 1999, p. 49). Most individuals do not exceed 203 centimeters (cm) (8 inches (in)) in total length, although the species has been known to exceed 25 cm (9 in) in total length (Propst and Hobbes 1996, pp. 22–34). The Zuni bluehead sucker has a bluish head, silvery-tan to dark green back, and yellowish to silvery-white sides and abdomen. Adults are mottled slate-gray to almost black dorsally (upper part of the body) and cream-white ventrally (toward the abdomen). During the spawning season, males may be differentiated by coarse tubercles (wart-like projections) on the rear fins and the caudal peduncle (the narrow part of the fish's body to which the tail fin is attached). Males also have distinctive breeding coloration, becoming intensely black dorsally with a bright red horizontal band and a white abdomen (Propst 1999, p. 49; Propst *et al.* 2001, p. 163).

There is some ambiguity regarding early specimen collections of Zuni bluehead sucker; however, it is believed that the first specimen of the Zuni bluehead sucker was collected from the Zuni River near Zuni Pueblo in McKinley County, New Mexico in 1873 (Cope 1874, p. 138). The next collection was made in 1926 from the Zuni River, near Zuni Pueblo (Propst *et al.* 2001, p. 159). It was not subsequently collected in New Mexico until W. J. Koster (University of New Mexico, Museum of Southwestern Biology) collected the species in the Rio Pescado in 1948 and the Rio Nutria in 1960 (Propst 1999, p. 49; Propst *et al.* 2001, p. 159).

Smith (1966, pp. 87–90) and Smith *et al.* (1983, pp. 37–38) postulated that the Zuni bluehead sucker subspecies is a result of an event in which two species of sucker that were formerly geographically separated came into contact with one another in the late Pleistocene and exchanged genes. The Zuni bluehead sucker shares traits with the Rio Grande sucker (*Catostomus plebeius*) and the Little Colorado River bluehead sucker (bluehead sucker) (*C. discobolus*). Analysis of morphological (pertaining to the form and structure of the fish) and genetic information support the recognition of the Zuni bluehead sucker as distinct from both the Rio Grande sucker and the bluehead sucker (Smith 1966, pp. 87–90; Smith *et al.* 1983, pp. 37–38; Crabtree and Buth 1987, p. 843; Propst 1999, p. 49; Sublette *et al.* 1990, pp. 209, 211). Based on our review of the best available scientific information, we conclude that the Zuni bluehead sucker is a valid subspecies.

Habitat and Life History

Carman (2008, p. 2) described Zuni bluehead sucker habitat as stream reaches with clean, perennial water flowing over hard substrate (material on

the stream bottom), such as bedrock. Silt-laden habitat, such as beaver ponds, is not suitable habitat for the species. Propst and Hobbes (1996, pp. 13, 16) reported that Zuni bluehead suckers were collected mainly in pool and pool-run habitats. These habitat areas were shaded with water velocities of less than 0.1 meter per second (m/s) (0.3 feet per second (ft/s)) (Propst and Hobbes 1996, p. 13). Most specimens were found in water that was 30 to 50 cm (12 to 20 in) deep, cobble, boulders, and bedrock substrate (Propst and Hobbes 1996, pp. 13, 16). Pools were often edged by emergent aquatic vascular plants and riparian vegetation (mainly willows (*Salix* spp.)) (Propst and Hobbes 1996, p. 16).

Zuni bluehead suckers feed primarily on algae scraped from rocks, rubble, and gravel substrates (Winter 1979, p. 4; Sublette *et al.* 1990, p. 211). Algae attached to rocks and plants are generally abundant in reaches where Zuni bluehead suckers are common (New Mexico Department of Game and Fish (NMDGF) 2004, p. 8). Bluehead suckers, including Zuni bluehead sucker, require clean gravel substrate with minimal silt for spawning (Maddux and Kepner 1988, p. 364) because silt covers eggs and leads to suffocation.

Distribution

The Zuni bluehead sucker has been found in the Zuni River watershed in New Mexico. Recent genetic testing of bluehead suckers in the Little Colorado River watershed in eastern Arizona and from streams in or near Canyon De Chelly in northeastern Arizona suggest that members of the Zuni bluehead sucker subspecies are located there as well. Zuni bluehead sucker were once common in the Little Colorado and Zuni River drainages, but its distribution rangewide has been reduced by over 90 percent in the last 20 years (Propst 1999, p. 51; NMDGF 2004, p. 15). The Zuni bluehead sucker is now found in low numbers in the Kinlichee Creek and Canyon de Chelly areas in Arizona (Hobbes 2000, pp. 9–16; Albert 2001, pp. 10–14; David 2006, p. 35) and is restricted to three isolated populations in the upper Rio Nutria drainage in the Zuni River watershed in west-central New Mexico (Carman 2008, pp. 2–3). The Kinlichee Creek, Canyon de Chelly, and Rio Nutria areas are completely isolated and separate from one another.

New Mexico Distribution

The Zuni bluehead sucker was first found in the Zuni River watershed in west-central New Mexico (Smith 1966, p. 83; Smith *et al.* 1983, p. 37; Crabtree and Buth 1987, p. 843; Propst and Hobbes 1996, p. 7; Propst 1999, p. 49). The Zuni River watershed extends west from the continental divide, and across the Pueblo of Zuni tribal lands. The Zuni River then drains into the Little Colorado River in Arizona west of the Zuni reservation. Within the Zuni River watershed, Zuni bluehead sucker have been known to occur in the Zuni River, in the Rio Pescado and Rio Nutria (from the mouth of Rio Nutria Box Canyon near the eastern boundary of the Zuni Indian Reservation upstream), and in some of their tributaries (the headwaters in the Zuni mountains) that include Tampico Spring and Agua Remora (formerly known as Radosevich Creek) (Hanson 1980, p. 1; Propst *et al.* 2001, p. 161). Elsewhere in the Zuni River drainage, the Zuni bluehead sucker is rare or absent. Flow is intermittent in the Zuni River, Rio Pescado, and Rio Nutria.

Zuni bluehead sucker numbers have been starkly reduced in the Zuni River watershed in New Mexico, largely due to 27 chemical treatments during the 1960s to remove green sunfish *(Lepomis cyanellus*) and fathead minnow (*Pimephales promelas*) from the Rio Nutria to aid in the establishment of a rainbow trout (*Oncorhynchus mykiss*) sport fishery in reservoirs on Zuni Pueblo (Winter 1979, p. 4). These treatments eliminated the Zuni bluehead sucker from most of the Zuni River drainage (Winter 1979, p. 4). As a result, by the late 1970s, the Zuni bluehead sucker's range in New Mexico had been reduced. While records are largely incomplete, it is known that a population of Zuni bluehead suckers near the mouth of the Rio Nutria Box Canyon was extirpated and that substantial numbers were also eliminated in other reaches of the Rio Nutria and Pescado drainages (NMDGF 2004, p. 16).

The Zuni bluehead sucker has not been collected from the mainstem Zuni River since 1978 or from the Rio Pescado since 1993. Currently, much of the lower portions of historical habitat in the Zuni River and Rio Pescado are dry during certain times of the year. Continued monitoring of these streams since 2004 has confirmed the extirpation of the Zuni bluehead sucker from these rivers (NMDGF 2004, p. 4; Carman 2007, p. 1; 2008, p. 1; 2009, p. 1). Additionally, Cebolla Creek, a Zuni River tributary, was surveyed in 1979, and no Zuni bluehead suckers were found, although habitat appeared suitable (Hanson 1980, pp. 29, 34).

The population of Zuni bluehead suckers in the Rio Nutria was maintained by dispersal of individuals from upstream untreated reaches, such as Agua Remora (Winter 1979, p. 4; Propst 1999, pp. 49–50), and so the Zuni bluehead sucker currently persists in three semi-isolated populations over 4.8 kilometers (km) (3 miles (mi)), mainly upstream of the mouth of the Rio Nutria Box Canyon (Propst 1999, pp. 49–50; Propst *et al.* 2001, p. 168; Carman 2008, pp. 2–3). Within this area, it is most common near the Rio Nutria Box Canyon mouth, the confluence of the Rio Nutria and Tampico Draw, and headwater springs such as Agua Remora and Tampico Springs (Stroh and Propst 1993, p. 34; Propst and Hobbes 1996, p. 10; Propst 1999, p. 50; Propst *et al.* 2001, p. 162; Carman 2007, p. 1; 2008, p. 1; 2009, p. 2; 2010, p. 1; Gilbert and Carman 2011, p. 1). Within the 4.8-km (3-mi) occupied reach, the largest extent of perennial stream with limited levels of siltation is currently found in the Rio Nutria Box Canyon, from the confluence with Tampico Draw downstream to the canyon mouth.

Recently, bluehead suckers were found in Bowl Canyon Creek (also known as Asaayi Creek) in New Mexico (Sponholtz *et al.* 2003, p. 20; David 2006, p. 2), which were initially reported as *C. discobolus* (Sponholtz *et al.* 2003, pp. 18–22; Clarkson and Marsh 2006, pp. 1–3), but their proximity to Crystal Creek, part of the Canyon de Chelly National Monument complex, indicates they may also be members of the Zuni bluehead sucker subspecies. However, there are no direct stream connections and they have not yet been genetically analyzed (Service 2012a, pers. comm.). Therefore, at this time we are not currently considering bluehead suckers in Bowl Canyon Creek to be Zuni bluehead sucker.

Population Status of the Species in New Mexico

The results from numerous survey efforts confirm that Zuni bluehead sucker populations in New Mexico are fragmented and low in numbers. Fish surveys have been conducted within the Zuni River watershed from 1977 to 1979, 1984, 1990 to 1993, 2000 to 2001, and every year since 2004 (Winter 1977, p. 1; Hanson 1980, p. 29; Stefferud 1985, p. 1; Propst and Hobbes 1996, p. 14, Carman 2010, pp. 13–15, Gilbert and Carman 2011, p. 23). No information on catch and effort is available prior to 1991; therefore, we may only make qualitative comparisons of the number of Zuni bluehead sucker collected over time for data prior to 1991. The number of fish over time is not a reliable method to evaluate population trends due to variability in sampling effort. Instead, catch per unit effort, or catch rates (i.e.,

number of fish per second of electrofishing) is a better metric for evaluating population trends and is how we assess the species' status after 1991 in this proposed rule. While catch per unit effort is valuable for assessing trends over time, it does not allow us to develop overall population estimates for the species.

In Tampico Draw, a tributary to Rio Nutria, Zuni bluehead sucker numbers declined dramatically, presumably due to beaver (*Castor canadensis*) dams (Gilbert and Carman 2011, p. 20), in 2006 from as high as 0.12 suckers per second (Carman 2006, p. 8) to 0.004 suckers per second (Carman 2007, p. 9) but appeared to rebound somewhat in 2009 (0.07 suckers per second) (Carman 2010, p. 15), after high spring flows washed out the beaver dams, creating more suitable habitat for Zuni bluehead sucker (Gilbert and Carman 2011, p. 5). Larval Zuni bluehead suckers have been confirmed in the Rio Nutria and its headwater springs, including Tampico Draw, each year between 2007 and 2010, indicating successful spawning (Carman 2008, p. 1; Carman 2009, p. 18; Carman 2010, p. 15; Gilbert and Carman 2011, p. 1).

Although we cannot make statistical comparisons due to the lack of quantitative data prior to 1991, the number of Zuni bluehead suckers collected from Agua Remora in the Rio Nutria drainage on the Cibola National Forest has declined since 1977. The number of Zuni bluehead suckers captured declined from 150 in 1977 (Winter 1977, p. 1) to 16 individuals in 2010 (Gilbert and Carman 2011, p. 23). Although the numbers are extremely low, Zuni bluehead suckers have persisted at Agua Remora, with fish catch rates ranging from 0.02 Zuni bluehead suckers per second to 0.12 fish per second (Carman 2010, p. 15). Young (less than 5 cm (2 in) total length) Zuni bluehead suckers have not been observed in the Agua Remora headwater spring habitat, and only mature adults were present there in 2005, 2006, and 2008 (Carman 2006, p. 8; Carman 2007, p. 13; Carman 2009, p. 14).

In 2007, permission to sample Tampico Springs, within the Rio Nutria drainage, was granted for the first time since 1994 (Carman 2008, p. 11); it has been sampled annually since. The spring consists of a series of semi-isolated pools occupied only by Zuni bluehead sucker. Zuni bluehead suckers at the headwater spring are smaller than at other sites, ranging 2.2–12.8 cm (0.9–5.0 in) total length (Carman 2009, p. 12). Tampico Springs catch rates have been declining consistently in recent years; while this site once exhibited the highest catch rates for the species, at 0.60 suckers per second in 2007 (Carman 2008, p. 10), numbers have since declined, with 0.22 fish caught per second in 2008 (Carman 2009, p. 12), 0.15 fish per second in 2009 (Carman 2010, p. 15), and 0.16 fish per second in 2010 (Gilbert and Carman 2011, p. 23). Despite the declines at Tampico Spring, this site maintains the highest catch rates among sites within the Rio Nutria and its headwaters (Gilbert and Carman 2011, p. 20).

In summary, the Zuni bluehead sucker currently persists in three semi-isolated populations over 4.8 km (3 mi), and fish surveys from 1990 to 2009 show that Zuni bluehead sucker populations in headwater springs like Aqua Remora and upper Rio Nutria have declined significantly from numbers seen in the 1970s. In the 1990s, the population at the Zuni River confluence with Rio Nutria and Rio Pescado was declining, and the populations in the Rio Pescado and lower Zuni River were almost depleted (Stroh and Propst 1993, p. 1). The Zuni bluehead sucker has not been collected from the Zuni River or Rio Pescado since 1993 (Gilbert and Carman 2011, p. 1). In occupied areas, dispersal from upstream populations (i.e., Rio Nutria) may augment downstream populations, but both downstream and upstream movement is generally blocked by physical obstructions, such as natural waterfalls, irrigation diversions, and impoundments (Propst *et al.* 2001, p. 168). The irregular occurrence of the Zuni bluehead sucker in reaches downstream from the mouth of Rio Nutria Canyon (Rio Nutria, Zuni, and Pescado Rivers) indicates limited downstream dispersal from currently occupied stream reaches. No Zuni bluehead suckers were found in the Rio Nutria between the canyon mouth and the confluence of the Rio Pescado.

Arizona Distribution

In Arizona, Zuni bluehead suckers are found on the Navajo Indian Reservation in two areas. First we will discuss the Kinlichee Creek area, which includes an area of the Little Colorado watershed west of Ft. Defiance, Arizona, in several locations over a 47-km (29-mi) area (Smith *et al.* 1983, p. 39; Crabtree and Buth 1987, p. 843; Hobbes 2000, pp. 9–16) and which includes Kinlichee Creek, Red Clay Wash, Black Soil Wash, and Scattered Willow Wash. Next we will discuss the Canyon de Chelly area, which includes Wheatfields, Whiskey, Tsaile, Sonsela, and Crystal Creeks.

Results from genetic analyses of the bluehead sucker indicate that samples from Kinlichee Creek (Black Soil Wash) share genetic markers (markers identify the place of genes that are located at specific positions on specific chromosomes that are used in genetic analyses) with Zuni bluehead sucker from New Mexico (Service 2012a, pers. comm.). The available genetic information indicates that bluehead suckers from the Kinlichee Creek area (see further discussion below) are Zuni bluehead sucker (Dowling 2011, p. 1). Therefore, based on our review of the genetic information above, we consider the bluehead suckers in Kinlichee Creek and its tributaries to be Zuni bluehead suckers. We are aware that this information is being prepared for publication (Dowling 2012, p. 1). Because the genetic information has not yet been published, the Navajo Nation still considers these fish to be bluehead suckers (*C. discobolus*).

Zuni bluehead sucker survey efforts have been more irregular in Arizona than in New Mexico. Populations of Zuni bluehead sucker are currently found in several locations over approximately 47 km (29 mi) of Kinlichee Creek (Smith *et al.* 1983, p. 39; Crabtree and Buth 1987, p. 843; Hobbes 2000, pp. 9–16). It is unlikely that the whole length of Kinlichee Creek is occupied, because the streams are susceptible to drying during drought. In addition, no comprehensive surveys have been done along this stream reach. Within the watershed, the species occurs in Kinlichee Creek, Black Soil Wash, Red Clay Wash, and Scattered Willow Wash based on collections made in 2000, 2001, 2004, and 2010 (Hobbes 2000, pp. 9–16; Hobbes 2001a, pp. 38, 43; Hobbes 2001b, entire; Carman 2004, pp. 1–8; Johnson 2010a, p. 1).

Near Canyon de Chelly in northeast Arizona and northwest New Mexico, Zuni bluehead sucker occur in the Chinle watershed, which flows into the San Juan River; we will refer to fish from this area as Canyon de Chelly fish. Zuni bluehead sucker occur in Coyote Wash, Sonsela (= Canyon de Chelly Creek), Crystal, Whiskey, and Wheatfields creeks on the Navajo Indian Reservation (Sponholtz *et al.* 2003, p. 4; David 2006, pp. 2–3, 12, 34), and in Tsaile Creek downstream of Tsaile Dam within Canyon de Chelly National Monument (Clarkson and Marsh 2006, p. 1; David 2006, p. 2). Sonsela and Whiskey Creek flow into Canyon de Chelly, and Wheatfields Creek flows into Wheatfields Lake (Sponholtz *et al.* 2003, p. 4). These streams originate along the western slope of the Chuska Mountains, New Mexico, and eventually drain into the San Juan River.

The presence of bluehead suckers in Tsaile and Wheatfields creeks in

Canyon de Chelly National Monument was known prior to 1966, when Smith (1966, p. 77) included specimens from those creeks in his analysis of suckers, determining these suckers were bluehead suckers. He called out the Zuni River specimens of bluehead suckers as being different from the standard *C. discobolus* that included the Canyon de Chelly specimens (Smith 1966, p. 83). Subsequently, Smith *et al.* (1983, pp. 38–39) looked more closely at the Zuni bluehead sucker and included specimens from Whiskey Creek in Canyon de Chelly. After evaluation, those specimens were not considered at the time to be Zuni bluehead suckers (Smith *et al.* 1983, p. 39). Outside of Canyon de Chelly but within close proximity, Wheatfields Creek is the only stream known to contain fish with Zuni bluehead sucker genes (Service 2012a, pers. comm.); however, because of habitat connectivity and potential for genetic interchange, it is likely that bluehead suckers within Tsaile, Sonsela, Crystal, and Whiskey creeks also contain Zuni bluehead sucker genes based on collections between 2001 and 2010 (see genetic discussion above) (Service 1982, pp. 2–3; Hobbes 2001a, pp. 24, 29, 31, 34; Sponholtz *et al.* 2003, pp. 18–22; Carman 2004, pp. 9–18; Clarkson and Marsh 2006, p. 3; David 2006, p. 3; Johnson 2010b, p. 1; Johnson 2010c, p. 1). Therefore, we consider bluehead suckers in these creeks also to be Zuni bluehead sucker because they are within reasonable distance of each other and are likely exchanging genes (Service 2012a, pers. comm.). We presume Zuni bluehead sucker once occurred in Palisades and Little Whiskey Creeks, both tributaries to Whiskey Creek, but impoundments and other barriers eliminated the entire fish community in both streams prior to 1980 (Service 1982, p. 4). Palisades Creek has been documented to be dry in recent years (Carman 2004, p. 9).

Population Status of the Species in Arizona

For several years (2000, 2001, and 2004), Zuni bluehead sucker surveys were conducted in the Kinlichee Creek watershed in Arizona on the Navajo Indian Reservation (Hobbes 2001a, entire; Carman 2004, entire). These were historical collection sites that had not been sampled since 1987 when the Zuni bluehead sucker was last documented by Crabtree and Buth (1987, p. 851). The species was collected in low numbers in Kinlichee Creek, Red Clay Wash, Black Soil Wash, and Scattered Willow Wash. More recently, collections occurred in Black Soil Wash and Kinlichee Creek, with 184 Zuni bluehead sucker collected from Black Soil Wash and 21 from Kinlichee Creek (Kitcheyan and Mata 2012, p. 6), indicating the species' continued presence in these streams. Additionally, in the Canyon de Chelly area, recent collections have occurred in Wheatfields, Whiskey, Tsaile, Sonsela, and Crystal Creeks. Because these were only presence/absence surveys, we have no population information for the Arizona stream reaches.

Summary of Zuni Bluehead Sucker Distribution

Zuni bluehead sucker rangewide distribution has been reduced by over 90 percent in the last 20 years (Propst 1999, p. 51, NMDGF 2004, p. 15). The Zuni bluehead sucker is now found in low numbers in the Kinlichee Creek and Canyon de Chelly areas in Arizona (Hobbes 2000, pp. 9–16; Albert 2001, pp. 10–14; David 2006, p. 35) and is restricted to three isolated populations in the upper Rio Nutria drainage in west-central New Mexico (Carman 2008, pp. 2–3).

Summary of Factors Affecting the Species

Section 4 of the Act (16 U.S.C. 1533), and its implementing regulations at 50 CFR part 424, set forth the procedures for adding species to the Federal Lists of Endangered and Threatened Wildlife and Plants. Under section 4(a)(1) of the Act, we may list a species based on any of the following five factors: (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; and (E) other natural or manmade factors affecting its continued existence. Listing actions may be warranted based on any of the above threat factors, singly or in combination. Each of these factors is discussed below.

Factor A. The Present or Threatened Destruction, Modification, or Curtailment of Its Habitat or Range

The principal threats to Zuni bluehead sucker habitat include water withdrawal, sedimentation, impoundments, housing development, wildfire, and climate change. These threats are intensified by the species' small range. Severe degradation to watersheds occupied by Zuni bluehead sucker has occurred through excessive timber harvest, overgrazing, and road construction. Although most of these activities occurred in the late 1800s and early 1900s, the subsequent erosion, gullying, headcutting, and loss of water have continued to degrade habitat for the Zuni bluehead sucker (NMDGF 2004, p. 18).

Water Withdrawal

Surface and groundwater withdrawal result in the direct loss of habitat as well as fragmentation of Zuni bluehead sucker habitat by reducing stream flow and/or water depth. Reduced stream velocities result in increased sedimentation, while overall loss of wetted habitat strands Zuni bluehead suckers in isolated shallow pools that may not provide suitable hard substrates for feeding and reproduction. Loss of appropriate habitat may decrease the reproductive success of Zuni bluehead sucker and result in mortality of individuals. Historically, water withdrawals led to the conversion of large portions of flowing streams to intermittent streams or dewatered channels, thus eliminating suitable Zuni bluehead sucker habitat in affected areas (NMDGF 2004, p. 12). Water withdrawals that lead to dewatering or reduced river flows or pool levels reduce the available habitat for the species.

Groundwater withdrawal can cause reduction or loss of spring flow (Brune 2002, p. 356). Currently, the Zuni River, the Rio Pescado, and the Rio Nutria flow intermittently, except for short reaches that flow perennially in response to discharge from springs. These streams are dependent on spring discharges, and the drainages contain various springs across the Zuni tribal lands (Orr 1987, p. 37; Drakos and Riesterer 2009, p. 96). Since spring ecosystems rely on water discharged to the surface from underground aquifers, groundwater depletion can result in the destruction of riverine habitat through spring drying (Scudday 1977, pp. 515–516). Spring drying or flow reduction resulting from groundwater pumping has also been documented in the Roswell (August 9, 2005; 70 FR 46304) and Mimbres Basins (Summers 1976, pp. 62, 65) of New Mexico. In addition, there has been a general declining trend in spring flow found on Zuni Tribal lands between 1972 and 2009 (Drakos and Riesterer 2009, p. 96). The lowermost pool in Agua Remora had reduced water depths in 2005 and nearly dried in 2007 and 2009; Zuni bluehead suckers were salvaged from this area and moved upstream to the middle pool or taken to the Albuquerque BioPark for a rearing program (Carman 2008, p. 17; Carman 2009, p. 24).

Groundwater use in the range of the Zuni bluehead sucker is expected to increase due to human population expansion. In early 2007, a development

company (Tampico Springs 3000, LLC), presented a preliminary plat to McKinley County, New Mexico, for Tampico Springs Ranch Subdivision. The subdivision is located just northeast of currently occupied Zuni bluehead sucker habitat. The subdivision would have a total of 490 lots, varying from 1.2 to 4.8 hectares (ha) (3 to 11.9 acres (ac)), each with an individual well and septic system. An increase in the number of wells would affect aquifer drawdowns, and individual septic tanks could potentially lead to water quality concerns. The geohydrologic investigation report, prepared for Phase I of the subdivision, states that water withdrawal is likely to affect flow at Brennan and Tampico Springs (MJDarrconsult, Inc. 2007, p. 26). In January 2008, the plat for Phase I of the subdivision was approved by McKinley County with conditions, including metering of water wells to enforce the 0.3 acre-ft per year per household restriction (Carman 2008, p. 17). Construction of Phase I has begun, with 17 of 45 lots sold (First United Realty 2012, p. 1).

In Arizona, existing water withdrawals throughout the Navajo Indian Reservation are generally for water haulers (people who collect water in tanks and transport it to another location for use); domestic and municipal use; water storage facilities; commercial, agricultural, mining and industry uses;, recreation and wildlife; and wastewater management. Water withdrawals have been documented on the Navajo Indian Reservation for many years. Water levels in wells in the Black Mesa area have declined as much as 70 ft (21.3 m) since 1963 (Littin 1992, p. 1). As of 2003, there were 75 livestock wells on the Navajo Indian Reservation, in both alluvial (connected to the river) and deep water aquifers (Navajo Nation Department of Water Resources 2003, p. 40). Currently, near Tsaile Creek, over 600 ac (242 ha) are developed for irrigation, but only 100 ac (40 ha) are irrigated due to water shortages; most of this water is diverted from Tsaile Creek (Natural Resources Conservation Service (NRCS) 2000, p. 37). Additionally, water in Kinlichee Creek has been noted as very low in recent years (Kitcheyan and Mata 2012, p. 3), and Palisades Creek, Scattered Willow Wash, Black Soil Wash, and Kinlichee Creek have been intermittent several years in a row (Carman 2004, pp. 2, 8; Kitcheyan and Mata 2012, p. 3). These low water events are exacerbated by continued water withdrawal in the region. Given past groundwater use and the likelihood of continued drought (see *Climate Change,* below), groundwater declines will likely continue into the future.

In summary, water withdrawals have affected the Zuni bluehead sucker rangewide in the past, resulting in dry streambeds or very low water levels in the lower Rio Nutria, Rio Pescado, Zuni River, and Agua Remora in New Mexico and in Palisades Creek, Scattered Willow Wash, and Kinlichee Creek in Arizona. Based on our review of the available information, we conclude that the effects of water withdrawal are a continuing threat to the Zuni bluehead sucker habitat across its range and as a result are negatively impacting the species.

Sedimentation

Sedimentation occurs when particles suspended in the water column fall out of suspension and cover the streambed, filling in spaces between substrate particles. Sedimentation results in the loss of suitable habitat and available food resources for Zuni bluehead sucker. Fine sediments, in particular, reduce or prevent production of algae, the Zuni bluehead sucker's primary food. Research has shown that heavy sediment loads have the potential to limit algae production by restricting light penetration or smothering (Graham 1990, pp. 107–109, 113–114). If mobilized during the spawning season, fine sediments may also smother and suffocate recently spawned eggs (Propst and Hobbes 1996, p. 39). The reproductive successes of fishes that require clean gravel substrate have been reduced by increased sedimentation due to smothering of eggs, which may be the case for Zuni bluehead sucker (Berkman and Rabeni 1987, p. 285; Propst and Hobbes 1996, p. 38). Increasing sedimentation in Agua Remora and Rio Nutria has led to the loss of optimal Zuni bluehead sucker habitat (permanent, clear flowing water over hard substrate). Sedimentation throughout the range of Zuni bluehead sucker is primarily caused by logging, livestock grazing, and road construction; these are discussed in detail below.

Logging

Logging activities in the early to mid-1800s likely caused major changes in watershed characteristics and stream morphology (Chamberlin *et al.* 1991, pp. 181–205; Ohmart 1996, p. 259). Early logging efforts were often concentrated along canyon bottoms with perennial streams. Tree removal along perennial streams within the historical range of Zuni bluehead sucker likely altered water temperature regimes, sediment loading, bank stability, and availability of large woody debris (Chamberlin *et al.* 1991, pp. 181–205). Soil surface erosion from logging or logging activities is directly related to the amount of bare compacted areas exposed to rainfall and runoff, which then contributes large quantities of fine sediments to stream channels (Chamberlin *et al.* 1991, p. 193). For example, in the early 1890s, logging and presence of logging railroads were widespread within the Zuni Mountains, which supported several lumber towns (NRCS) 1998, p. 17). Extensive clearcutting and overgrazing were the primary contributors to the reduction of the original riparian vegetation by 70 to 90 percent in the Zuni Mountains (Ohmart 1996, p. 259). Logging is actively practiced on both private and public lands within the Zuni watershed (NRCS 1998, p. 17). For example, in 2012, the Forest Service funded the Zuni Mountain Collaborative Forest Landscape Restoration project, which will increase logging to reduce fire risk in the Rio Puerco and Rio Nutria watersheds over the next 10 years (Forest Service 2012, pp. 1–2). Ultimately, the reduction in fire risk in these watersheds is likely to benefit the Zuni bluehead sucker; however, the short-term increase in logging is likely to increase sedimentation in these watersheds.

In Arizona, on the Navajo Indian Reservation, timber operations began in the 1880s (Einbender-Velez 2010, p. 2). In the 1980s, cutting increased significantly to about 36 million board-feet per year (Atencio 1994, p. 2). In 1990, Tsaile Canyon, which encompasses a Zuni bluehead sucker population, was heavily logged, with all of the old growth forest and many of the saplings removed (Atencio 1994, p. 2). However, the Navajo Forest Products Industry shut down in 1994, and timber harvesting has been much reduced.

In summary, sedimentation from logging has historically affected Zuni bluehead sucker habitat rangewide, resulting in unsuitable habitat. Logging rates have reduced in recent years but will continue into the future, particularly in the Rio Puerco and Rio Nutria watersheds over the next decade, which will likely impact Zuni bluehead sucker habitat.

Livestock Grazing

Livestock grazing has been one of the most widespread and long-term causes of adverse impacts to native fishes and their habitat (Miller 1961, pp. 394–395, 399; Armour *et al.* 1991; pp. 7–10; Fleischner 1994, pp. 629–635; Larsen *et al.* 1998, pp. 161, 164). Widespread livestock grazing and logging likely contributed to habitat modifications,

resulting in severe degradation of the Zuni watershed (Hanson 1982, p. 14; NRCS 1998, p. 1; NMDGF 2004, p. 12). Livestock grazing has been shown to increase soil compaction, decrease water infiltration rates, increase runoff, change vegetative species composition, decrease riparian vegetation, increase stream sedimentation, increase stream water temperature, decrease fish populations, and change channel form (Meehan and Platts 1978, pp. 275–276; Kauffman and Krueger 1984, pp. 430–435; Schulz and Leininger 1990, p. 295; Platts 1991, pp. 393–403; Fleischner 1994, pp. 629–635; Ohmart 1996, pp. 246–274). Although direct impacts to the riparian zone and stream can be the most obvious sign of livestock grazing, upland watershed condition influences the timing and amount of water delivered to stream channels (Ohmart 1996, pp. 260, 268). Increased soil compaction and decreased vegetative cover lead to faster delivery of water to stream channels, increased peak flows, and lower summer base flow (Platts 1991, p. 390; Ohmart 1996, p. 255; Belsky and Blumenthal 1997, pp. 321, 324). As a consequence, streams are more likely to experience flood events during monsoonlike weather in summer (water runs off quickly instead of soaking into the ground) that negatively affects the riparian and aquatic habitats. Therefore, heavily grazed streams are more likely to become intermittent or dry in September and October, when groundwater recharge is reduced because water runs off quickly, rather than being absorbed by the soil (Ohmart 1996, p. 268).

Improper livestock grazing increases sedimentation through trampling of the stream banks and compacting soil, both of which can result in a reduction or elimination of riparian vegetation, which can be detrimental to stream habitat. Riparian vegetation insulates streams from temperature extremes in both summer and winter. Further, it filters sediment so that it does not enter the stream; sediment can lead to reduction or prevention of algal growth and smothering of newly spawned eggs (Propst and Hobbes 1996, p. 38). Riparian vegetation also provides a source of nutrients to the stream from leaf litter, which increases stream productivity, and it contributes root wads and large and small woody debris to the stream, which provide cover for the fish (Kauffman and Krueger 1984, pp. 430–431; Platts 1991, pp. 395–400; Ohmart 1996, pp. 247–249).

The Cibola National Forest (Forest) commissioned the Zuni Mountain Sucker Habitat Management Plan ''to protect, and to enhance, where possible, habitat of threatened and endangered species within the confines of the Forest'' (Winter 1979, p. 3). In 1978 and 1979, the Forest fenced off Agua Remora from grazing, which resulted in marked regrowth of the riparian area (Merkel 1979, p. 15; Stefferud 1985, p. 1). In 1988, the NMDGF Share with Wildlife program partnered with the Forest to increase the fenced area, doubling the amount of protected habitat. However, the fence is occasionally in disrepair leading to unauthorized grazing in Agua Remora, and the fence is only checked if there is evidence of grazing within Agua Remora. A recent field trip to Agua Remora identified that the fence was in disrepair, and five cows were on the site; the riparian area had lost vegetative cover (Gilbert 2012, p. 1). Additionally, there are several active grazing allotments north of Agua Remora, with the closest being 2.4 km (1.5 mi) away; livestock grazing also occurs on nearby private land.

During the 1930s, in Arizona, on the Navajo Indian Reservation, nearly one million livestock (sheep, goats, horses, or cattle) ranged across the landscape, exposing soil and increasing erosion (Weisiger 2007, p. 440). Grazing continues today throughout the entire Navajo Indian Reservation, although herd numbers are much lower than in the early 1900s. Although grazing has been reduced, the continuing drought has exacerbated effects of depleted forage, and the livestock numbers are considered to be overpopulated, (Davis 2012, p. 1). Additionally, cultural resistance to fencing on the Navajo Indian Reservation (Beatty Davis 1997, p. 49) creates a challenge for range management and stream protection. Direct access to streams and overgrazing by livestock on the Navajo Indian Reservation has been documented repeatedly (Sanchez 1975, p. 1, Service 1982, pp. 3–4; U.S. Army Corps of Engineers 1995, p. 3; Hobbes 2000, p. 14; NMDGF 2003, pp. 6, 13; Sponholtz *et al.* 2003, pp. 25–26; David 2006, pp. 4, 20; Kitcheyan and Mata 2012, p. 3). Overall, both historic and current livestock grazing within the riparian zone and upland slopes has reduced vegetative cover and accelerated storm runoff and sediment into reservoirs and increased erosion in areas such as Tsaile Creek (Bureau of Reclamation (BOR) 2011, p. 22).

In summary, Zuni bluehead sucker habitat near or adjacent to areas where livestock grazing occurs is significantly impacted. The resulting habitat degradation is a threat to the remaining Zuni bluehead sucker populations in New Mexico and Arizona. The available information indicates that these activities likely contributed to the reduction in riparian habitat, channel incision, and increased soil compaction, which resulted in unfavorable habitat conditions for Zuni bluehead sucker foraging or reproduction. Such unfavorable habitat conditions affect populations by reducing their viability. Based on our review of the available information we conclude that the effects of livestock grazing are a threat to Zuni bluehead sucker habitat, and the species, throughout its entire range.

Road Construction

Roads have adversely affected Zuni bluehead sucker habitat by increasing surface runoff and sedimentation, which can increase turbidity, reduce primary production, and reduce numbers of aquatic insects (Burns 1972, p. 1; Eaglin and Hubert 1993, pp. 844–845). Roads require instream structures, such as culverts and bridges that remove aquatic habitat and can act as barriers to fish movement (Warren and Pardew 1998, p. 637). All of these activities negatively impact Zuni bluehead suckers and their habitat by lowering water quality, reducing the quality and quantity of pools by filling them with sediments, reducing the quantity of large woody debris necessary to form pools, and by imposing barriers to movement. The end result is deterioration of habitat for the Zuni bluehead sucker (Burns 1972, p. 1; Eaglin and Hubert 1993, pp. 844–845).

Vehicular use of roads in creek bottoms can degrade Zuni bluehead sucker habitat. Such use inhibits riparian plant growth, breaks down banks, causes erosion, causes sedimentation, and increases turbidity in the stream, particularly where vehicles drive through the stream (especially immediately downstream of the vehicular activity). These effects are likely to result in wider and shallower stream channels (Furniss *et al.* 1991, pp. 297–301). This change causes progressive adjustments in other variables of hydraulic geometry and results in changes to the configuration of pools, runs, riffles, and backwaters; levels of fine sediments and substrate embeddedness (the degree to which rocks and cobble are stuck in the streambed); availability of instream cover; and other fish habitat requirements in the vicinity of vehicle crossings (Sullivan *et al.* 1987, pp. 67, 69–70; Rosgen 1994, p. 185). It also changes the way in which flood flows interact with the stream channel and may exacerbate flood damage to banks, channel bottoms, and riparian vegetation.

Road construction activities may have direct adverse effects on the watershed

from soil erosion and sedimentation to the streams. Aerial photographs from 1935 and 1991 showed road density in the Cebolla and Rio Nutria watersheds rose 138 and 47 percent, respectively (NMDGF 2004, p. 12). Forest Road 50, which is in the upper watershed of Zuni bluehead sucker habitat (approximately 5 km (3 mi) away from the closest occupied habitat), was upgraded in 1999, and several roads were developed in 2007 for the Tampico Springs Subdivision. Currently, the US Forest Service proposes to allow McKinley County to upgrade Forest Road 191D with gravel surface material (Forest Service 2011, p. i), which may increase vehicle traffic and surface runoff. This road is approximately 3 km (2 mi) from Agua Remora and 1.6 km (1 mi) from Tampico Springs (Forest Service 2011, p. 44).

On the Navajo Indian Reservation, past road construction continues to affect stream habitat. On Kinlichee Creek, for example, Bridge BR 280 constricts the channel considerably, which increases flow rates, channel scouring, and downstream deposition of sediment (U.S. Army Corps of Engineers 1995, p. 3). Sedimentation from road construction has occurred throughout the range of Zuni bluehead sucker in the past and is likely to continue in the future.

In summary, historical logging, overgrazing by livestock, and road construction have destroyed much of the groundcover across the Zuni bluehead sucker's range (Sanchez 1975, pp. 1, 4; Beatty Davis 1997, pp. 3, 7; NMDGF 2004, p. 12; BOR 2011, p. 22), resulting in increased erosion, increased stream flow fluctuation, and the accumulation of large quantities of sediment throughout Zuni bluehead sucker habitat (Merkel 1979, p. 4). Livestock grazing and road construction are likely to continue at present rates throughout the species' range, and logging is likely to continue at reduced rates. Sedimentation results in depressed reproductive rates and inhibition of algal growth for food. Therefore, based on our review of the available information, we conclude that the effects of sedimentation are a threat to the Zuni bluehead sucker and its habitat rangewide.

Dams/Impoundments

Much of the primary water use from the Zuni River watershed is for irrigation of agriculture, livestock grazing, and human consumption. Many small impoundments, built primarily for watering livestock, partially prevent flows from reaching the mainstem rivers. According to Merkel (1979, p. 1), the lower Rio Nutria, Rio Pescado, and Zuni River drainages have been drastically altered by human activities, such as the construction of many small impoundments for livestock watering. Reservoirs and diversion dams for irrigation have depleted stream flows below the dams and inundated stream reaches above the dams (Merkel 1979, p. 1; Hanson 1982, p. 4). Degradation of the upper watershed has led to increased sedimentation and many of the reservoirs are now only shallow, eutrophic (nutrient rich) ponds or wetlands with little or no storage capacity (NMDGF 2004, p. 20). Sediment trapping by these impoundments has also changed the character of the streams by altering channel morphology and substrate composition. The lower Rio Nutria was once a perennial stream with wide meanders bordered by willow and cottonwood (*Populus* spp.). After construction of impoundments in the Rio Nutria below the box canyon meanders, the channel became deeply incised with predominantly silt or silt-sand substrate, which is unsuitable for Zuni bluehead sucker. Flow is intermittent between the ephemeral pools and impoundments. Current habitat conditions are not favorable for Zuni bluehead sucker in much of the watershed downstream from the mouth of Rio Nutria Box Canyon, primarily due to impoundments, dams, and sedimentation from logging and grazing.

On the Navajo Indian Reservation, many small impoundments exist throughout Zuni bluehead sucker historic habitat, primarily for irrigation (U.S. Army Corps of Engineers 1995, p. 3). Additionally, large impoundments have been built on Tsaile and Wheatfields Creeks (NRCS 2000, pp. 20, 23; BOR 2002, p. 12), which have largely fragmented Zuni bluehead sucker habitat for miles up and downstream of the impoundments. Zuni bluehead suckers currently occur downstream of Tsaile Dam and upstream of Wheatfields Dam (Sponholtz *et al.* 2003, p. 4).

Additionally, beaver dams affect Zuni bluehead sucker habitat, particularly in New Mexico. In 2006, beaver activity in Tampico Draw and Rio Nutria increased greatly, fragmenting much Zuni bluehead sucker habitat (Carman 2007, p. 1). A marked decrease in captured Zuni bluehead sucker in Tampico Draw was attributed to increased siltation and water ponding due to beaver activity (Carman 2007, p. 1). In 2010, spring flows washed out the beaver dams in Tampico Draw, creating more suitable habitat for Zuni bluehead sucker (Gilbert and Carman 2011, p. 6). The best available information does not indicate beaver activity is affecting Zuni bluehead sucker populations in Arizona.

In summary, Zuni bluehead sucker habitat has been reduced rangewide due to impoundment construction. Impoundments have lasting effects on stream habitat both up and downstream, subsequently fragmenting fish populations and decreasing their resiliency and long-term persistence. Based on our review of the available information, we conclude that the effects of impoundments are a current threat to Zuni bluehead sucker and are having rangewide impacts on their habitat.

Housing Developments

Subdivision developments within the range of Zuni bluehead sucker would increase the amount of impervious surfaces in this watershed. Impervious surfaces include buildings, roads, and parking lots (Brabec *et al.* 2002, p. 499). An increase in the amount of impervious surfaces could increase the amount of runoff and decrease infiltration rates. Impacts of urbanization on stormwater runoff can cause changes in land or stream corridor use, land formations, hydrology, stream hydraulics, habitat, and sediment transport and storage. Urbanization can cause changes in fish population composition and distribution due to habitat changes and lower water table elevations due to groundwater use.

In 2007, the Forest granted an easement to McKinley County for access across Forest Service land via Forest Road 191D (Forest Service 2010 pp. 1–2). The granting of the right-of-way allows McKinley County to upgrade and assume maintenance of this road, which provides access to the upper Rio Nutria watershed. This road may facilitate the development of the Tampico Springs Ranch subdivision, resulting in additional sedimentation and potential groundwater loss in the watershed (Forest Service 2010, p. 17).

In summary, the increases in sedimentation and water withdrawals that could result from the development of additional phases of the subdivision are a threat to the Zuni bluehead sucker habitat in Rio Nutria and Tampico Springs, which constitutes the bulk of the species' distribution and habitat in New Mexico. As a result, these effects to habitat are negatively impacting the species.

Wildfires

Wildfires can destroy vegetation along slopes and stream channels altering the physical properties of the soil. The lack

of ground cover increases the amount of potential runoff, thereby increasing the amount of woody debris, sedimentation, and ash entering the stream (Swanston 1991, pp. 141, 175–177). Indirect effects, such as ash flow events that follow wildfire during monsoonal seasons can inundate Zuni bluehead sucker habitat and smother and destroy eggs. Severe wildfires that extirpate fish populations are a relatively recent phenomenon and result from the cumulative effects of historical or ongoing overgrazing by domestic livestock, fire suppression, and climate change (Madany and West 1983, p. 666; Swetnam 1990, pp. 6–17; Touchan *et al.* 1995, p. 272 Swetnam and Baisan 1996, p. 28; Belsky and Blumenthal 1997, p. 318; Gresswell 1999, p. 212; Brown *et al.* 2004, p. 366; McKenzie *et al.* 2004, p. 898; Westerling *et al.* 2006, p. 943).

Historically, wildfires in the region were primarily cool-burning understory fires with fire return intervals of 4 to 8 years (Swetnam and Dieterich 1985, p. 395). Cooper (1960, p. 137) found that, prior to the 1950s, crown fires (intense fires that completely consume trees and move forward through tree canopies) were extremely rare or nonexistent in the region. Since the mid-1980s, wildfire frequency in western forests is nearly four times the average of 1970 to 1986, and the total area burned is more than 6.5 times the previous level (Westerling *et al.* 2006, p. 941). The average length of fire season increased by 78 days from the 1970 to 1986 period to the 1987 to 2003 period, and the average time between discovery and control increased from 7.5 days to 37.1 days for the same timeframes (Westerling *et al.* 2006, p. 941). McKenzie *et al.* (2004, p. 893) suggested, based on models, that the length of the fire season will likely increase further and that fires in the western United States will be more frequent and more severe. In particular, they found that fire in New Mexico appears to be acutely sensitive to summer climate and temperature changes and may respond dramatically to climate warming.

Changes in relative humidity, especially drying over the western United States, are also projected to increase the number of days of high fire danger (Brown *et al.* 2004, p. 365). Because Zuni bluehead sucker are found primarily in isolated, small headwater streams, they are unable to swim away from ash flows, and opportunities for natural recolonization are unlikely, due to the highly fragmented nature of Zuni bluehead sucker populations. Persistence of Zuni bluehead sucker in streams affected by fire and subsequent ash flows is unlikely in the Zuni watershed. The recently funded Zuni Mountain Collaborative Forest Landscape Restoration project is expected to reduce wildfire risk over 22,662 ha (56,000 ac) in the Rio Puerco and Rio Nutria watersheds (Forest Service 2012, p. 1). Currently, wildfire risk in this area is considered high (class III), but over the next decade this risk is expected to be reduced. The available information does not indicate that wildfire is a threat to populations in Arizona. Therefore, based on the likelihood that fire risk will be reduced in New Mexico, we do not consider wildfire to be a threat to Zuni bluehead sucker habitat rangewide.

Climate Change

Our analyses under the Endangered Species Act include consideration of ongoing and projected changes in climate. The terms ''climate'' and ''climate change'' are defined by the Intergovernmental Panel on Climate Change (IPCC). The term ''climate'' refers to the mean and variability of different types of weather conditions over time, with 30 years being a typical period for such measurements, although shorter or longer periods also may be used (IPCC 2007a, p. 78). The term ''climate change'' thus refers to a change in the mean or variability of one or more measures of climate (e.g., temperature or precipitation) that persists for an extended period, typically decades or longer, whether the change is due to natural variability, human activity, or both (IPCC 2007a, p. 78).

Scientific measurements spanning several decades demonstrate that changes in climate are occurring, and that the rate of change has been faster since the 1950s. Examples include warming of the global climate system, and substantial increases in precipitation in some regions of the world and decreases in other regions. (For these and other examples, see IPCC 2007a, p. 30; and Solomon *et al.* 2007, pp. 35–54, 82–85). Results of scientific analyses presented by the IPCC show that most of the observed increase in global average temperature since the mid-20th century cannot be explained by natural variability in climate, and is ''very likely'' (defined by the IPCC as 90 percent or higher probability) due to the observed increase in greenhouse gas (GHG) concentrations in the atmosphere as a result of human activities, particularly carbon dioxide emissions from use of fossil fuels (IPCC 2007a, pp. 5–6 and figures SPM.3 and SPM.4; Solomon *et al.* 2007, pp. 21–35). Further confirmation of the role of GHGs comes from analyses by Huber and Knutti (2011, p. 4), who concluded it is extremely likely that approximately 75 percent of global warming since 1950 has been caused by human activities.

Scientists use a variety of climate models, which include consideration of natural processes and variability, as well as various scenarios of potential levels and timing of GHG emissions, to evaluate the causes of changes already observed and to project future changes in temperature and other climate conditions (e.g., Meehl *et al.* 2007, entire; Ganguly *et al.* 2009, pp. 11555, 15558; Prinn *et al.* 2011, pp. 527, 529). All combinations of models and emissions scenarios yield very similar projections of increases in the most common measure of climate change, average global surface temperature (commonly known as global warming), until about 2030. Although projections of the magnitude and rate of warming differ after about 2030, the overall trajectory of all the projections is one of increased global warming through the end of this century, even for the projections based on scenarios that assume that GHG emissions will stabilize or decline. Thus, there is strong scientific support for projections that warming will continue through the 21st century, and that the magnitude and rate of change will be influenced substantially by the extent of GHG emissions (IPCC 2007a, pp. 44–45; Meehl *et al.* 2007, pp. 760–764 and 797–811; Ganguly *et al.* 2009, pp. 15555–15558; Prinn *et al.* 2011, pp. 527, 529). (See IPCC 2007b, p. 8, for a summary of other global projections of climate-related changes, such as frequency of heat waves and changes in precipitation. Also see IPCC 2011(entire) for a summary of observations and projections of extreme climate events.)

Various changes in climate may have direct or indirect effects on species. These effects may be positive, neutral, or negative, and they may change over time, depending on the species and other relevant considerations, such as interactions of climate with other variables (e.g., habitat fragmentation) (IPCC 2007b, pp. 8–14, 18–19). Identifying likely effects often involves aspects of climate change vulnerability analysis. Vulnerability refers to the degree to which a species (or system) is susceptible to, and unable to cope with, adverse effects of climate change, including climate variability and extremes. Vulnerability is a function of the type, magnitude, and rate of climate change and variation to which a species is exposed, its sensitivity, and its adaptive capacity (IPCC 2007a, p. 89; see also Glick *et al.* 2011, pp. 19–22).

There is no single method for conducting such analyses that applies to all situations (Glick *et al.* 2011, p. 3). We use our expert judgment and appropriate analytical approaches to weigh relevant information, including uncertainty, in our consideration of various aspects of climate change.

As is the case with all stressors that we assess, even if we conclude that a species is currently affected or is likely to be affected in a negative way by one or more climate-related impacts, it does not necessarily follow that the species meets the definition of an ''endangered species'' or a ''threatened species'' under the Act. If a species is listed as endangered or threatened, knowledge regarding the vulnerability of the species to, and known or anticipated impacts from, climate-associated changes in environmental conditions can be used to help devise appropriate strategies for its recovery.

Global climate projections are informative, and, in some cases, the only or the best scientific information available for us to use. However, projected changes in climate and related impacts can vary substantially across and within different regions of the world (e.g., IPCC 2007a, pp. 8–12). Therefore, we use ''downscaled'' projections when they are available and have been developed through appropriate scientific procedures, because such projections provide higher resolution information that is more relevant to spatial scales used for analyses of a given species (see Glick *et al.* 2011, pp. 58–61, for a discussion of downscaling). With regard to our analysis for the Zuni bluehead sucker, downscaled projections are available.

Climate simulations of Palmer Drought Severity Index (PSDI) (a calculation of the cumulative effects of precipitation and temperature on surface moisture balance) for the Southwest for the periods of 2006–2030 and 2035–2060 predict an increase in drought severity with surface warming. Additionally, drought still increases during wetter simulations because of the effect of heat-related moisture loss (Hoerling and Eischeid 2007, p. 19). Annual mean precipitation is likely to decrease in the Southwest as well as the length of snow season and snow depth (IPCC 2007b, p. 887). Most models project a widespread decrease in snow depth in the Rocky Mountains and earlier snowmelt (IPCC 2007b, p. 891). Exactly how climate change will affect precipitation is less certain, because precipitation predictions are based on continental-scale general circulation models that do not yet account for land use and land cover change effects on climate or regional phenomena. Consistent with recent observations in changes from climate, the outlook presented for the Southwest predicts warmer, drier, drought-like conditions (Seager *et al.* 2007, p. 1181; Hoerling and Eischeid 2007, p. 19). A decline in water resources will be a significant factor in the compromised watersheds of the desert southwest.

Climate change could affect the Zuni bluehead sucker through increased temperatures, evaporation, and probability of long-term drought. However, we are not able to predict with certainty how the indirect effects of climate change will affect Zuni bluehead sucker habitats due to a lack of information on the groundwater system that provides water to the species' spring-fed habitat and large-scale projections of precipitation that contribute to stream flow. We conclude that climate change may be a significant stressor that indirectly exacerbates existing threats by increasing the likelihood of prolonged drought that would reduce water availability for streamflow or spring flow and incur future habitat loss. The National Integrated Drought Information System (2012) classifies drought in increasing severity categories from abnormally dry, to moderate, severe, extreme, and, most severe, exceptional. The southwestern United States is currently experiencing drought conditions classified as moderate to exceptional. Drought conditions are reported as severe to extreme for areas occupied by Zuni bluehead sucker in Arizona and New Mexico (National Integrated Drought Information System 2012).

While Zuni bluehead sucker have survived many droughts in its evolutionary history, the present status of this species and its habitat is so degraded that the effects of the drought may be more difficult for the species to withstand. In some areas of Zuni bluehead sucker habitat, drought results in lower streamflow or pool habitat, with consequently warmer water temperatures and more crowded habitats with potentially higher levels of predation and competition. In other areas drought reduces flooding, which would normally rejuvenate habitat and tend to reduce populations of some nonnative species, which are less adapted to the large floods of Southwest streams (Minckley and Meffe 1987, pp. 93–104; Stefferud and Rinne 1996, p. 93). As such, long-term and recurrent drought, as a result of climate change, may affect Zuni bluehead sucker habitat, but the severity of the threat and impacts remains uncertain. Therefore, we conclude that long-term drought, as a result of climate change, is currently a threat to the Zuni bluehead sucker, and will likely be a threat in the future. In addition, the impacts from climate change will likely exacerbate the current and ongoing threat of habitat loss caused by other factors, as discussed above.

Summary of Factor A

The Zuni bluehead sucker faces a variety of threats throughout its range in Arizona and New Mexico, including water withdrawals, logging, livestock grazing, water impoundments, road construction, subdivision development, and long-term drought. In New Mexico, water withdrawals, subdivision development, livestock grazing, road construction, logging, and drought threaten Zuni bluehead suckers and their habitat. In Arizona, water withdrawals, livestock grazing, road construction, and drought have affected the Zuni bluehead sucker. These activities, alone and in combination, contribute to the substantial loss and degradation of habitat in Arizona and New Mexico.

The changes in the flow regimes and loss of habitat from water withdrawals, sedimentation, and impoundments have reduced and eliminated populations of Zuni bluehead sucker in both New Mexico and Arizona. These conditions, in combination with the predicted worsening drought conditions due to climate change, will continue to degrade and eliminate Zuni bluehead sucker habitat.

Factor B. Overutilization for Commercial, Recreational, Scientific, or Educational Purposes

The Zuni bluehead sucker is not a game fish and does not have recreational or commercial value. Both the Arizona Game and Fish Department (AGFD) and NMDGF prohibit collection of the species (NMDGF 1998, p. 11; AGFD 2011, p. 6), although collection of Zuni bluehead sucker may be authorized by either State by special permit. A limited amount of scientific collection occurs but does not pose a threat to Zuni bluehead sucker because it is regulated appropriately by the States. Recreational angling may occur within occupied Zuni bluehead sucker habitats, as nonnative crayfish are commonly fished for and used for bait. Zuni bluehead sucker may be incidentally caught by anglers targeting other fish, whereby Zuni bluehead suckers can be injured or killed. However, we do not have any evidence suggesting that the occasional removal of Zuni bluehead sucker in this manner is a threat to the species.

Factor C. Disease or Predation

Disease

In general, fish species are susceptible to a spectrum of diseases, and the Zuni bluehead sucker is no exception. Diseases could potentially impact the reproduction, growth, and survival of the Zuni bluehead sucker. In addition, drought conditions (discussed above) may cause physiological stress on Zuni bluehead sucker making them more susceptible to disease.

Black grub, also called black spot (*Neascus* spp.) is a parasitic larval fluke that appears as black spots on the body of a fish. Adult black grub trematodes live in a bird's mouth and produce eggs, which are swallowed unharmed and released into the water in the bird's feces. Eggs mature in the water, hatch, and infest mollusks as an intermediate host. They then migrate into the tissues of a second intermediate host, which is typically a fish. When the larvae penetrate and migrate into the tissues of a fish, they cause damage and possibly hemorrhaging. The larvae then become encapsulated by host tissue and appear as black spots. The damage caused by one individual black grub is negligible, but in great numbers they may kill a fish (Lane and Morris 2000, pp. 2–3; Quist *et al.* 2007, p. 130). Black grub was found on several Zuni bluehead suckers in 2005 in the Rio Nutria Box Canyon area (Carman 2006, p. 8). None were seen on fish caught in 2006 or 2007, but black grub was observed again in the Rio Nutria Box Canyon in 2008 and Agua Remora in 2008 through 2010 (Carman 2009, p. 9; Gilbert and Carman 2011, p. 17). Because surveys have been intermittent in recent years, there is no information on whether black grub is present within occupied habitats of Zuni bluehead sucker in Arizona on the Navajo Indian Reservation, but black grub does occur within the Little Colorado River and San Juan River drainages (Hobbes 2001a, pp. 38–39). Results from investigations on the effects of black grub on other species of fish have varied; effects have ranged from none, to slowing growth, to mortality (Hunter and Hunter 1938, pp. 480–481; Vinikour 1977, pp. 83, 88; Lemly and Esch 1984, pp. 475, 488–490; Quist *et al.* 2007, p. 130). Vinikour (1977, pp. 83, 88) found no effect on longnose dace (*Rhinichthys cataractae*) between populations that were infested with black grub and noninfested population. However, Hunter and Hunter (1938, pp. 480–481) showed that young black bass (*Micropterus dolomieu*) with heavy infestation of black grub lost weight. Young bluegill (*Lepomis macrochirus*) died due to black grub infestation (Lemly and Esch 1984, pp. 475, 488–490). The effects of black grub on the Zuni bluehead sucker are unknown.

There is no published information on other diseases of the Zuni bluehead sucker, although information is available from the Little Colorado River and San Juan River watershed for similar species. Asian tapeworm (*Bothriocephalus acheilognathi*) and anchor worm (*Lernaea*) have been found in the San Juan River system, but neither was found to infest bluehead suckers (Landye *et al.* 1999, p. 6). In addition, Landye *et al.* (1999, p. 7) also detected the protozoan *Ichthyophthirius,* but it was not found to affect bluehead suckers.

The available information does not indicate disease is a threat to the Zuni bluehead sucker rangewide. However, black grub may be a threat to the species; this parasite has profound effects on many other species of fish and it has been detected in Zuni bluehead sucker. Currently, the best available information indicates that it could be a threat and additional sampling and studies are needed. We request information on any potential threat posed by black grub or other disease to the Zuni bluehead sucker.

Predation

The introduction and spread of nonnative species has been identified as one of the primary factors in the continuing decline of native fishes throughout North America and particularly in the southwestern United States (Miller 1961, pp. 365, 397–398; Lachner *et al.* 1970, p. 21; Ono *et al.* 1983, pp. 90–91; Carlson and Muth 1989, pp. 222, 234; Fuller *et al.* 1999, p. 1; Propst *et al.* 2008, pp. 1246–1251; Pilger *et al.* 2010, pp. 300, 311–312). Nonnative fish and crayfish are found throughout the range of the Zuni bluehead sucker.

Nonnative fishes known to occur within the historical range of the Zuni bluehead sucker include channel catfish (*Ictalurus punctatus*), fathead minnow, green sunfish, plains killifish (*Fundulus zebrinus*), largemouth bass (*Micropterus salmoides*), rainbow trout, cutthroat trout (*Oncorhynchus clarkii*), northern pike (*Esox lucius*) brown trout (*Salmo trutta*), grass carp (*Ctenopharyngodon idella*), and goldfish (*Carassius auratus*) (NMDGF 2003, pp. 2–14; NMDGF 2005, p. 10; David 2006, pp. 7–15). In particular, nonnative predatory fishes (primarily green sunfish) have contributed to the displacement or elimination of the species from portions of its historical range (NMDGF 2004, p. 24). Predation by green sunfish upon native fishes with the Colorado River drainage has been well documented (Marsh and Langhorst 1988, p. 65; Lohr and Fausch 1996, p. 155; Dudley and Matter 2000, pp. 24, 27–28; Tyus and Saunders 2000, p. 19). Propst *et al.* (2001, p. 162) documented few or no Zuni bluehead suckers in areas occupied by green sunfish. The rarity of small Zuni bluehead suckers in Agua Remora may be due to green sunfish predation on young Zuni bluehead sucker, limiting recruitment (Marsh and Langhorst 1988, p. 65; Carman 2008, p. 17). In 2006, green sunfish dominated the catch in Agua Remora (Carman 2007, p. 7), but since that time, dedicated eradication efforts have led to a significant decline in green sunfish numbers, and larval Zuni bluehead suckers were observed in 2009 (Gilbert and Carman 2011, p. 17), indicating the population was responding positively to the reduced numbers of green sunfish. The Zuni bluehead sucker occurs only in stream habitats that are comparatively free of nonnative fishes (Propst and Hobbes 1996, p. 37; Carman 2009, p. 20). In Arizona, many of these nonnative predatory fishes occur on the Navajo Indian Reservation within occupied sites, including Whiskey Creek (Hobbes 2001a, p. 27; Carman 2004, p. 9), Wheatfields Creek (Hobbes 2001a, p. 32; Carman 2004, p. 15), and Tsaile Creek (Hobbes 2001a, pp. 35–37; Carman 2004, p. 17), and it is likely that predation of Zuni bluehead sucker is occurring at these sites.

Other nonnative predatory fish are found within the range of Zuni bluehead sucker, including fathead minnow, brown trout, rainbow trout, northern pike, and channel catfish. Predation by these species on native suckers has been documented in the San Juan River, New Mexico, and Yampa and Green Rivers, Colorado (Marsh and Brooks 1989, pp. 188, 191; Johnson *et al.* 1993, p. 1139; Brooks *et al.* 2000, pp. 75–76, 80; Ward and Bonar 2003, p. 43).

Two species of nonnative crayfish have been documented in the lower Colorado River drainage: The northern crayfish (*Orconectes virilis*) and red swamp crayfish (*Procambarus clarkii*) (Childs 1999, p. 5). Crayfish can impact aquatic systems because they are opportunistic omnivores (eating both animals and plants) (Carpenter 2005, p. 335). Many studies have demonstrated that introduced crayfish prey upon native fishes and compete with them for shelter (Rahel and Stein 1988, p. 94; Rahel 1989, p. 301; Bryan *et al.* 2002, pp. 49, 55–56; Carpenter 2005, pp. 5, 339). Crayfish are known to eat fish eggs, especially those bound to the substrate (Dorn and Mittelbach 2004, p.

2135), like those of the Zuni bluehead sucker.

The northern crayfish was detected in the Zuni River confluence with the Rio Pescado, in the Rio Pescado itself, and in the lower end of Rio Nutria in 2000, 2001, and 2004, respectively (NMDGF 2004, p. 5; Carman 2009, p. 20). The northern crayfish is also present at occupied sites of Zuni bluehead sucker on the Navajo Indian Reservation in Arizona, including Whiskey Creek (Carman 2004, p. 9), Wheatfields Creek (Hobbes 2001a, p. 30; Carman 2004, p. 12), Black Soil Wash (Carman 2004, p. 4; Kitcheyan and Mata 2012, p. 2), Kinlichee Creek (Kitcheyan and Mata 2012, p. 2), and Tsaile Creek (Hobbes 2001a, p. 36; Carman 2004, p. 17). The northern crayfish is tolerant of a wide range of habitats and may be a threat to Zuni bluehead sucker through competition or predation.

Nonnative fish and crayfish occur throughout the range of the Zuni bluehead sucker, and in Agua Remora the dominance of green sunfish appears to be the cause of limited recruitment and population decline. Given the widespread occurrence of green sunfish and other nonnative predators across the range of the Zuni bluehead sucker and the low Zuni bluehead sucker population numbers rangewide, we conclude that predation is a threat to the Zuni bluehead sucker.

Conservation Efforts To Reduce Disease or Predation

As stated above, NMDGF has begun a green sunfish eradication effort at Agua Remora, which has significantly lowered the green sunfish population there, such that larval Zuni bluehead sucker were observed after implementation of this program, after several years of absence.

Summary of Factor C

In summary, black grub has been documented throughout the range of the species and is known to adversely affect or kill fish. In addition, nonnative predatory fish, particularly green sunfish, have contributed to the displacement or elimination of the species throughout its range, and nonnative crayfish are likely preying upon Zuni bluehead sucker eggs. Therefore, we conclude that disease may be a threat to the Zuni bluehead sucker and predation is a documented threat to the species. These threats are already occurring, they affect the species throughout its range, and they result in the reduced viability of the species because of the reduced range and low population numbers rangewide.

Factor D. The Inadequacy of Existing Regulatory Mechanisms

Under this factor, we examine whether existing regulatory mechanisms are inadequate to address the threats to the Zuni bluehead sucker discussed under other factors. Section 4(b)(1)(A) of the Act requires the Service to take into account ''those efforts, if any, being made by any State or foreign nation, or any political subdivision of a State or foreign nation, to protect such species * * *.'' In relation to Factor D under the Act, we interpret this language to require the Service to consider relevant Federal, State, and Tribal laws, regulations, and other such mechanisms that may minimize any of the threats we describe in threat analyses under the other four factors, or otherwise enhance conservation of the species. We give strongest weight to statutes and their implementing regulations and to management direction that stems from those laws and regulations. An example would be State governmental actions enforced under a State statute or constitution, or Federal action under statute.

Having evaluated the significance of the threat as mitigated by any such conservation efforts, we analyze under Factor D the extent to which existing regulatory mechanisms are inadequate to address the specific threats to the species. Regulatory mechanisms, if they exist, may reduce or eliminate the impacts from one or more identified threats. In this section, we review existing State and Federal regulatory mechanisms to determine whether they effectively reduce or remove threats to the Zuni bluehead sucker.

Existing regulatory mechanisms that could provide some protection for the Zuni bluehead sucker include: (1) New Mexico Wildlife Conservation Act; (2) Wildlife of Special Concern Act in Arizona; (3) National Environmental Policy Act (NEPA); (4) National Forest Management Act; and (5) Zuni Pueblo Law and Order Code.

State Regulations

New Mexico State law provides limited protection to the Zuni bluehead sucker. The species is listed in New Mexico as endangered, Group 2, which are those species ''whose prospects of survival or recruitment within the state are likely to become jeopardized in the near future'' (NMDGF 1988, p. 1; Bison-M 2012). This designation provides protection under the New Mexico Wildlife Conservation Act of 1974 (the State's endangered species act) (19 NMAC 33.6.8), but it only prohibits direct take of this species, except under issuance of a scientific collecting permit. A limited amount of scientific collection occurs but does not pose a threat to Zuni bluehead sucker because it is regulated appropriately by the State. The New Mexico Wildlife Conservation Act defines ''take'' or ''taking'' as ''harass, hunt, capture, or kill any wildlife or attempt to do so'' (17 NMAC 17.2.38). In other words, New Mexico State status as an endangered species conveys protection from collection or intentional harm to the animals themselves but does not provide habitat protection. Penalties for violations may result in fines up to $1,000 and imprisonment up to 1 year.

The Wildlife of Special Concern Act in Arizona lists the Zuni bluehead sucker as a candidate species (AGFD 1996, p. 8). Candidate species are those species or subspecies for which threats are known or suspected but for which substantial population declines from historical levels have not been documented (though they appear likely to have occurred) (AGFD 1996, p. 8). The listing under the State of Arizona law does not provide protection to the species or their habitats. However, in 2007, AGFD identified the Zuni bluehead sucker in fishing regulations as a State-protected native fish that may not be possessed; however this status still lacks habitat protection (AGFD 2007, p. 1). Penalties for violations result in a fine.

In Arizona and New Mexico the Zuni bluehead sucker is classified as a Species of Greatest Conservation Need (SCGN) (AGFD 2006, p. 154; NMDGF 2006, p. 54). New Mexico's SGCN are associated with key habitats and include low and declining populations and species of high recreational, economic, or charismatic value (NMDGF 2006, p. 8). No regulatory protections are afforded based on this designation. Because there are no provisions for habitat conservation in either State's law, the existing New Mexico Wildlife Conservation Act and the Arizona Wildlife of Special Concern Act do not address the threat of nonnative species in the habitat of the Zuni bluehead sucker.

As discussed above (see Factor C. Disease or Predation), the introduction and spread of nonnative aquatic species is a threat to Zuni bluehead sucker. The existing regulatory mechanisms in Arizona and New Mexico do not protect the Zuni bluehead sucker from nonnative aquatic predators. Regulation of programs to introduce, augment, spread, or permit such actions do not address the spread of nonnative species, as many nonnative species

introductions are conducted through incidental or unregulated actions.

We also searched for State laws or local ordinances that would include provisions for instream water rights to protect fish and wildlife and their habitat. New Mexico water rights are regulated by the Interstate Stream Commission and the Office of State Engineer for surface and groundwater; New Mexico State law does not allow for instream flows for fish and wildlife. Instream flows for fish and wildlife (*i.e.,* water is not diverted for irrigation but remains in the river to ensure permanent flows) are allowed under Arizona water law; however, this is a relatively recent provision, and instream water rights have low priority and are often overcome by more senior diversion rights. Arizona State law also allows groundwater pumping via a permit process administered by the Arizona Department of Water Resources. As discussed above (see the above discussion on water withdrawals under *Factor A*), despite this regulation, groundwater withdrawals have resulted in reduced surface flow in Zuni bluehead sucker habitat. Therefore, it seems that the Arizona State law does not adequately protect Zuni bluehead sucker habitat.

Federal Regulations

Many Federal statutes potentially afford protection to Zuni bluehead sucker. A few of these are the Federal Land Policy and Management Act (43 U.S.C. 1701–1782) the National Forest Management Act (16 U.S.C. 1600 *et seq.*), and the Clean Water Act (33 U.S.C. 1251 *et seq.*). However, in practice, the provisions of these statutes that require consideration of rare species have not been able to address the threats to the Zuni bluehead sucker.

The Federal Land Policy and Management Act and National Forest Management Act provide mechanisms for protection and enhancement of Zuni bluehead sucker and its habitat on Federal lands. The only Zuni bluehead sucker population on Federal land is in Agua Remora, on the Cibola National Forest. The National Forest Management Act requires the Forest Service to prepare management plans for each National Forest; a plan has been completed for the Cibola National Forest (Forest Service 1985, pp. 17–18). Forest plans must meet the requirements of the Natural Resources Multiple-Use Act to address such issues as recreation, range, timber, biological diversity, and economic and social factors in agency decision making. The 1985 Cibola National Forest Plan includes a discussion of protection of the Zuni bluehead sucker. The plan indicated that fencing would protect Zuni bluehead sucker riparian habitat, but improved range management was needed to restore the entire watershed. The Forest Service has made minor progress in protecting the habitat at Agua Remora by fencing the area to prevent grazing, but as discussed above, fencing has not been completely effective due to inadequate maintenance of the fences. Continued monitoring and maintenance of this fence is necessary to provide sufficient protection to the Zuni bluehead sucker population in Agua Remora from the effects of livestock grazing.

In addition, the Zuni bluehead sucker is listed as a sensitive species for the Forest Service's Southwestern Region, which includes Arizona and New Mexico (USFS 2007, p. 22). The Forest Service intends to develop and implement management practices to ensure that designated sensitive species do not become threatened or endangered because of Forest Service actions. Essentially, sensitive species must receive special management considerations or protection by the Forest Service to ensure their viability to preclude trends toward endangerment that would result in the need for Federal listing. While the Forest Service has attempted fencing at Agua Remora to eliminate the threat of livestock grazing, there are a number of other threats to the population at Agua Remora that are beyond the Forest Service's control; namely, water levels have been extremely low in recent years, and in the absence of removals by NMDGF, green sunfish affect Zuni bluehead sucker recruitment.

Section 404 of the Clean Water Act regulates placement of fill into waters of the United States, including most of Zuni bluehead sucker habitat. However, many actions highly detrimental to Zuni bluehead sucker and its habitat, such as irrigation diversion, structure construction and maintenance, and livestock grazing are often exempted from the Clean Water Act or do not apply for protection under the Clean Water Act. Other detrimental actions, such as bank stabilization and road crossings, are covered under nationwide permits that receive little or no Service review. A lack of thorough, site-specific analyses for projects can allow substantial adverse effects to Zuni bluehead sucker and its habitat.

Tribal Regulations

Zuni Pueblo—The Zuni bluehead sucker, speckled dace, and grass carp are protected from fishing in Zuni Pueblo lakes (Zuni Pueblo Law and Order Code S7–5–3 paragraph 36). In addition, stream fishing is prohibited on the Pueblo. These regulations protect the species from take by fishing but do not protect Zuni bluehead sucker habitat or prevent take from sources other than fishing, such as water withdrawals and livestock grazing.

Navajo Nation—The Zuni bluehead sucker is currently not protected within the Navajo Indian Reservation. The Navajo Nation Endangered Species List classifies the bluehead sucker as a whole as a G4 species. G4 species are candidates and include those species or subspecies that may be endangered but for which they lack sufficient information to support listing (Navajo Nation Heritage Program 2008, pp. i, iv, vi, 84).

Summary of Factor D

In summary, the States' endangered species and water withdrawal regulations, as well as the Federal Land Policy and Management Act and the National Forest Management Act are not adequate to protect the Zuni bluehead sucker or its habitat. State regulations prohibiting take of the species have been in place for decades; however, these regulations are not adequate to address the threats to habitat, particularly water withdrawals, impoundments, and the distribution and abundance of nonnative fishes. Because most of the threats to the Zuni bluehead sucker are from effects to its habitat and the introduction of nonnative, invasive species, in order to protect individuals and ensure the species' long-term conservation and survival, its habitat must be protected. Therefore, we conclude these existing regulations are inadequate to mitigate the impacts of identified threats to the species.

Factor E. Other Natural or Manmade Factors Affecting Its Continued Existence

Other natural or manmade factors affecting the continued existence of the Zuni bluehead sucker include habitat fragmentation, which is intensified by the small sizes of the remaining populations.

Habitat Fragmentation

Zuni bluehead sucker populations appear to have always been relatively isolated from one another, as evidenced by the genetic lineages that have been observed (Service 2012a, pers. comm.). The further fragmentation of habitat and resulting increased isolation of Zuni bluehead sucker populations affects the species rangewide, by increasing the risk of population loss and subsequent

loss of genetic lineages. Dewatering and drought conditions have resulted in fragmentation of Zuni bluehead sucker populations, and continued water demands are expected to further reduce habitat available to the Zuni bluehead sucker and will likely further fragment and isolate populations. Fragmentation of Zuni bluehead sucker habitat increases the species' vulnerability from threats of further habitat loss and competition from nonnative fish because immigration and recolonization from adjacent populations is less likely. In-depth analyses of southwestern fish occurrence patterns (including Zuni bluehead sucker) led Fagan *et al.* (2002, p. 3254) to conclude that the number of occurrences or populations of a species is far less significant in determining extinction risk than is fragmentation of the species. Another source of habitat fragmentation is the construction of dams. Dams are known to change the hydraulics of the streams in the system, converting many formerly perennial streams into semiperennial or ephemeral streams that prevent movement of fish between populations and dramatically alter the flow regime of streams through the impoundment of water (Ligon *et al.* 1995, pp. 184–189).

Small, isolated populations are subject to genetic threats, such as inbreeding depression (reduced health due to elevated levels of inbreeding) and to genetic drift (a reduction in gene flow within the species that can increase the probability of unhealthy traits; Meffe and Carroll 1994). Facial deformities have been seen in approximately 5 percent of the populations at Agua Remora and Tampico Springs; these deformities have been attributed to the genetic effects of small populations (Carman 2009, p. 13), although the rate of deformity declined over time, such that no captured fish exhibited deformities in 2010 (Gilbert and Carman 2011, p. 17). External deformities such as these have been linked to a low survival rate in other small, isolated fish populations (Sato 2006, p. 598); a lowered survival rate could reduce the Zuni bluehead sucker population sizes at Aqua Remora and Tampico Springs over time.

Due to the small reaches of remaining habitat where Zuni bluehead suckers occur in relatively low numbers, single populations of Zuni bluehead sucker are at high risk of extirpation due to stochastic events from other known threats, such as wildfire or episodic drought (see Factor A discussion). Zuni bluehead sucker have experienced and withstood a number of droughts over time, but given the anticipated increased frequency and duration of drought, combined with the reduced population size and occupied habitat, the species is at a higher risk of extirpation and the species has a reduced resiliency to stochastic events.

Summary of Factor E

Currently, Zuni bluehead sucker populations are highly fragmented within small, isolated springs and stream segments, causing them to be vulnerable to stochastic events, such as wildfire and episodic drought. In addition, detrimental genetic effects have already been observed within two populations. All known Zuni bluehead sucker populations are small and isolated, increasing their vulnerability. Due to the reduction in their range, and small population size, the remaining populations of Zuni bluehead experience reduced viability; therefore, we conclude that habitat fragmentation is a threat to Zuni bluehead sucker.

Cumulative Effects: Factors A Through E

Many of the threats discussed above act in concert, and the resulting effects to Zuni bluehead sucker are amplified. For example, the reduction of water quantity restricts the geographic size of the population, which causes the species to be more vulnerable to other threats, such as beaver dams modifying habitat, an increase in nonnative predators, or ash flows from wildfire that may further reduce or eliminate the population. The ability of a population to be resilient to threats depends on the robustness of the population. For Zuni bluehead sucker, the remaining populations are likely not robust. They are reduced in size and their habitat has been reduced to a fraction of their historic range. Given these circumstances, the combined effects of current threats to the populations puts the species at risk rangewide. The combined effects of drought and nonnative predatory fish may reduce habitat, fragment the remaining habitat, and reduce reproductive potential, resulting in fewer fish. The remaining populations become less resilient and are not capable of recovering from the threats. Reproductive efforts from the Zuni bluehead sucker populations will be affected by the threats to their habitat, resulting in populations with reduced viabilities.

Determination

We have carefully assessed the best scientific and commercial information available regarding the past, present, and future threats to Zuni bluehead suckers. Habitat loss from water withdrawals, sedimentation, and impoundments is occurring rangewide, has resulted in extirpation of the species from all but headwater habitats, and is not likely to be reduced in the future (Factor A). The species' range has been reduced by 90 percent in New Mexico, and current distribution is limited to three populations in 4.8 km (3 mi) of streams. Drought frequency and water withdrawals are likely to increase, further restricting habitat and fragmenting or eliminating populations. Predation from nonnative fish is occurring rangewide and has been shown to reduce recruitment and population size at one location; this situation is likely impacting other populations, as well (Factor C). State wildlife laws and Federal regulations such as the National Forest Management Act are not adequate to address the threats to the species (Factor D). Additionally, the Zuni bluehead sucker is not able to naturally recolonize unoccupied areas (Factor E). There is virtually no redundancy of populations within each occupied watershed, further increasing the risk of loss of representation of existing genetic lineages and, ultimately, extinction. These threats have already resulted in the extirpation of Zuni bluehead sucker throughout an estimated 90 percent of its range and are only likely to increase in severity. Although there is less information available on threats occurring on the Navajo Indian Reservation, the information we do have is similar in kind and intensity to that for New Mexico. These threats are ongoing, are rangewide, are expected to increase in the future, and are significant because they further restrict limited available habitat and decrease the resiliency of the Zuni bluehead sucker within those habitats.

The Act defines an endangered species as any species that is ''in danger of extinction throughout all or a significant portion of its range'' and a threatened species as any species ''that is likely to become endangered throughout all or a significant portion of its range within the foreseeable future.'' We find that the Zuni bluehead sucker is presently in danger of extinction throughout its entire range based on the severity and immediacy of threats currently impacting the species. The overall range has been significantly reduced, the remaining habitat and populations are threatened by a variety of factors acting in combination to reduce the overall viability of the species. The risk of extinction is high because the remaining populations are small, isolated, and have limited potential for recolonization. Therefore,

on the basis of the best available scientific and commercial information, we propose listing the Zuni bluehead sucker as endangered in accordance with sections 3(6) and 4(a)(1) of the Act. We find that a threatened species status is not appropriate for the Zuni bluehead sucker because of the contracted range (loss of 90 percent of its historic range), because the threats are occurring rangewide and are not localized, and because the threats are ongoing and expected to continue into the future.

Under the Act and our implementing regulations, a species may warrant listing if it is threatened or endangered throughout all or a significant portion of its range. The Zuni bluehead sucker proposed for listing in this rule is highly restricted in its range and the threats occur throughout its range. Therefore, we assessed the status of the species throughout its entire range. The threats to the survival of the species occur throughout the species' range and are not restricted to any particular significant portion of that range. Accordingly, our assessment and proposed determination applies to the species throughout its entire range.

Available Conservation Measures

Conservation measures provided to species listed as endangered or threatened under the Act include recognition, recovery actions, requirements for Federal protection, and prohibitions against certain practices. Recognition through listing results in public awareness and conservation by Federal, State, Tribal, and local agencies, private organizations, and individuals. The Act encourages cooperation with the States and requires that recovery actions be carried out for all listed species. The protection required by Federal agencies and the prohibitions against certain activities are discussed, in part, below.

The primary purpose of the Act is the conservation of endangered and threatened species and the ecosystems upon which they depend. The ultimate goal of such conservation efforts is the recovery of these listed species, so that they no longer need the protective measures of the Act. Subsection 4(f) of the Act requires the Service to develop and implement recovery plans for the conservation of endangered and threatened species. The recovery planning process involves the identification of actions that are necessary to halt or reverse the species' decline by addressing the threats to its survival and recovery. The goal of this process is to restore listed species to a point where they are secure, self-sustaining, and functioning components of their ecosystems.

Recovery planning includes the development of a recovery outline shortly after a species is listed and preparation of a draft and final recovery plan. The recovery outline guides the immediate implementation of urgent recovery actions and describes the process to be used to develop a recovery plan. Revisions of the plan may be done to address continuing or new threats to the species, as new substantive information becomes available. The recovery plan identifies site-specific management actions that set a trigger for review of the five factors that control whether a species remains endangered or may be downlisted or delisted, and methods for monitoring recovery progress. Recovery plans also establish a framework for agencies to coordinate their recovery efforts and provide estimates of the cost of implementing recovery tasks. Recovery teams (composed of species experts, Federal and State agencies, nongovernmental organizations, and stakeholders) are often established to develop recovery plans. When completed, the recovery outline, draft recovery plan, and the final recovery plan will be available on our Web site (*http://www.fws.gov/endangered*), or from our New Mexico Ecological Services Field Office (see **FOR FURTHER INFORMATION CONTACT**).

Implementation of recovery actions generally requires the participation of a broad range of partners, including other Federal agencies, States, Tribal, nongovernmental organizations, businesses, and private landowners. Examples of recovery actions include habitat restoration (e.g., restoration of native vegetation), research, captive propagation and reintroduction, and outreach and education. The recovery of many listed species cannot be accomplished solely on Federal lands because their range may occur primarily or solely on non-Federal lands. To achieve recovery of these species requires cooperative conservation efforts on private, State, and Tribal lands.

If this species is listed, funding for recovery actions will be available from a variety of sources, including Federal budgets, State programs, and cost share grants for non-Federal landowners, the academic community, and nongovernmental organizations. In addition, pursuant to section 6 of the Act, the States of Arizona and New Mexico would be eligible for Federal funds to implement management actions that promote the protection or recovery of the Zuni bluehead sucker. Information on our grant programs that are available to aid species recovery can be found at: *http://www.fws.gov/grants.*

Although the Zuni bluehead sucker is only proposed for listing under the Act at this time, please let us know if you are interested in participating in recovery efforts for this species. Additionally, we invite you to submit any new information on this species whenever it becomes available and any information you may have for recovery planning purposes (see **FOR FURTHER INFORMATION CONTACT**).

Section 7(a) of the Act requires Federal agencies to evaluate their actions with respect to any species that is proposed or listed as an endangered or threatened species and with respect to its critical habitat, if any is designated. Regulations implementing this interagency cooperation provision of the Act are codified at 50 CFR part 402. Section 7(a)(4) of the Act requires Federal agencies to confer with the Service on any action that is likely to jeopardize the continued existence of a species proposed for listing or result in destruction or adverse modification of proposed critical habitat. If a species is listed subsequently, section 7(a)(2) of the Act requires Federal agencies to ensure that activities they authorize, fund, or carry out are not likely to jeopardize the continued existence of the species or destroy or adversely modify its critical habitat. If a Federal action may affect a listed species or its critical habitat, the responsible Federal agency must enter into formal consultation with the Service.

Federal agency actions within the species' habitat that may require conference or consultation or both as described in the preceding paragraph include management and any other landscape-altering activities on Federal lands administered by the U.S. Fish and Wildlife Service, U.S. Forest Service, and National Park Service (Canyon De Chelly National Monument); issuance of section 404 Clean Water Act permits by the Army Corps of Engineers; and construction and maintenance of roads or highways by the Federal Highway Administration.

The Act and its implementing regulations set forth a series of general prohibitions and exceptions that apply to all endangered wildlife. The prohibitions of section 9(a)(2) of the Act, codified at 50 CFR 17.21 for endangered wildlife, in part, make it illegal for any person subject to the jurisdiction of the United States to take (includes harass, harm, pursue, hunt, shoot, wound, kill, trap, capture, or collect; or to attempt any of these), import, export, ship in interstate commerce in the course of commercial activity, or sell or offer for

sale in interstate or foreign commerce any listed species. Under the Lacey Act (18 U.S.C. 42–43; 16 U.S.C. 3371–3378), it is also illegal to possess, sell, deliver, carry, transport, or ship any such wildlife that has been taken illegally. Certain exceptions apply to agents of the Service and State conservation agencies.

We may issue permits to carry out otherwise prohibited activities involving endangered and threatened wildlife species under certain circumstances. Regulations governing permits are codified at 50 CFR 17.22 for endangered species, and at 17.32 for threatened species. With regard to endangered wildlife, a permit must be issued for the following purposes: for scientific purposes, to enhance the propagation or survival of the species, and for incidental take in connection with otherwise lawful activities.

It is our policy, as published in the **Federal Register** on July 1, 1994 (59 FR 34272), to identify to the maximum extent practicable at the time a species is listed, those activities that would or would not constitute a violation of section 9 of the Act. The intent of this policy is to increase public awareness of the effect of a proposed listing on proposed and ongoing activities within the range of species proposed for listing. The following activities could potentially result in a violation of section 9 of the Act; this list is not comprehensive:

(1) Unauthorized collecting, handling, possessing, selling, delivering, carrying, or transporting of the species, including import or export across State lines and international boundaries, except for properly documented antique specimens of these taxa at least 100 years old, as defined by section 10(h)(1) of the Act;

(2) Introduction of nonnative species that compete with or prey upon the Zuni bluehead sucker, such as the introduction of nonnative green sunfish to the States of Arizona and New Mexico;

(3) The unauthorized release of biological control agents that attack any life stage of this species;

(4) Unauthorized modification of the channel or water flow of any stream or removal or destruction of emergent aquatic vegetation in any body of water in which the Zuni bluehead sucker is known to occur; and

(5) Unauthorized discharge of chemicals or fill material into any waters in which the Zuni bluehead sucker is known to occur.

Questions regarding whether specific activities would constitute a violation of section 9 of the Act should be directed to the New Mexico Ecological Services Field Office (see **FOR FURTHER INFORMATION CONTACT**).

Peer Review

In accordance with our joint policy on peer review published in the **Federal Register** on July 1, 1994 (59 FR 34270), we will seek the expert opinions of at least three appropriate and independent specialists regarding this proposed rule. The purpose of peer review is to ensure that our listing determination and critical habitat designation are based on scientifically sound data, assumptions, and analyses. We have invited these peer reviewers to comment during this public comment period.

We will consider all comments and information received during this comment period on this proposed rule during our preparation of a final determination. Accordingly, the final decision may differ from this proposal.

Public Hearings

Section 4(b)(5) of the Act provides for one or more public hearings on this proposal, if requested. Requests must be received within 45 days after the date of publication of this proposed rule in the **Federal Register**. Such requests must be sent to the address shown in the **FOR FURTHER INFORMATION CONTACT** section. We will schedule public hearings on this proposal, if any are requested, and announce the dates, times, and places of those hearings, as well as how to obtain reasonable accommodations, in the **Federal Register** and local newspapers at least 15 days before the hearing.

Required Determinations

Clarity of the Rule

We are required by Executive Orders 12866 and 12988 and by the Presidential Memorandum of June 1, 1998, to write all rules in plain language. This means that each rule we publish must:

(1) Be logically organized;

(2) Use the active voice to address readers directly;

(3) Use clear language rather than jargon;

(4) Be divided into short sections and sentences; and

(5) Use lists and tables wherever possible.

If you feel that we have not met these requirements, send us comments by one of the methods listed in the **ADDRESSES** section. To better help us revise the rule, your comments should be as specific as possible. For example, you should tell us the numbers of the sections or paragraphs that are unclearly written, which sections or sentences are too long, the sections where you feel lists or tables would be useful, etc.

Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.)

This rule does not contain any new collections of information that require approval by OMB under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). This rule will not impose recordkeeping or reporting requirements on State or local governments, individuals, businesses, or organizations. 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.

National Environmental Policy Act (42 U.S.C. 4321 et seq.)

We have determined that environmental assessments and environmental impact statements, as defined under the authority of the National Environmental Policy Act (NEPA; 42 U.S.C. 4321 *et seq.*), need not be prepared in connection with listing a species as an endangered or threatened species under the Endangered Species Act. We published a notice outlining our reasons for this determination in the **Federal Register** on October 25, 1983 (48 FR 49244).

References Cited

A complete list of references cited in this rulemaking is available on the Internet at *http://www.regulations.gov* and upon request from the New Mexico Ecological Services Field Office (see **FOR FURTHER INFORMATION CONTACT**).

Authors

The primary authors of this proposed rule are the staff members of the New Mexico Ecological Services Field Office.

List of Subjects in 50 CFR Part 17

Endangered and threatened species, Exports, Imports, Reporting and recordkeeping requirements, Transportation.

Proposed Regulation Promulgation

Accordingly, we propose to amend part 17, subchapter B of chapter I, title 50 of the Code of Federal Regulations, as set forth below:

PART 17—[AMENDED]

■ 1. The authority citation for part 17 continues to read as follows:

Authority: 16 U.S.C. 1361–1407; 16 U.S.C. 1531–1544; 16 U.S.C. 4201–4245; Pub. L. 99–625, 100 Stat. 3500; unless otherwise noted.

■ 2. In § 17.11(h), add an entry for ''Sucker, Zuni bluehead'' to the List of Endangered and Threatened Wildlife in alphabetical order under Fishes to read as set forth below:

§ 17.11 Endangered and threatened wildlife.

* * * * *

(h) * * *

Species		Historic range	Vertebrate population where endangered or threatened	Status	When listed	Critical habitat	Special rules
Common name	Scientific name						
*	*	*	*	*	*		*
FISHES							
*	*	*	*	*	*		*
Sucker, Zuni bluehead.	*Catostomus discobolus yarrowi.*	U.S.A. (AZ, NM)	Entire	E	.....	NA	NA
*	*	*	*	*	*		*

* * * * *

Dated: January 14, 2013.

Daniel M Ashe,

Director, U.S. Fish and Wildlife Service.

[FR Doc. 2013–01303 Filed 1–24–13; 8:45 am]

BILLING CODE 4310–55–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

[Docket No. FWS–R2–ES–2013–0001; 4500030114]

RIN 1018–AZ24

Endangered and Threatened Wildlife and Plants; Endangered Status for Four Central Texas Salamanders and Designation of Critical Habitat

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Proposed rule; reopening of comment period.

SUMMARY: We, the U.S. Fish and Wildlife Service, announce the reopening of the public comment period on the August 22, 2012, proposed listing and proposed designation of critical habitat for the Austin blind salamander, Georgetown salamander, Jollyville Plateau salamander, and Salado salamander under the Endangered Species Act of 1973, as amended. Based on additional salamander locations we identified during the 60-day comment period, we are proposing to revise previously proposed critical habitat units for the Georgetown and Jollyville Plateau salamanders. We also announce the availability of a draft economic analysis of the proposed designation of critical habitat for the four central Texas salamanders, an amended required determinations section of the proposal, an amended exclusions section of the proposal, and the availability of a refined impervious cover analysis. We are reopening the comment period to allow all interested parties an opportunity to comment simultaneously on the original proposed rule, this revised proposed rule, the associated draft economic analysis, the amended required determinations and exclusions sections, and the refined impervious cover analysis. Comments previously submitted need not be resubmitted, as they will be fully considered in preparation of the final rule.

Document Availability: You may obtain copies of the original proposed rule, this revised proposed rule, the draft economic analysis, and the refined impervious cover analysis on the Internet at *http://www.regulations.gov* at Docket No. FWS–R2–ES–2012–0035 or Docket No. FWS–R2–ES–2013–0001 or by mail from the Austin Ecological Services Field Office (see **FOR FURTHER INFORMATION CONTACT**).

DATES: We will consider comments received or postmarked on or before March 11, 2013. Comments submitted electronically using the Federal eRulemaking Portal (see **ADDRESSES** section, below) must be received by 11:59 p.m. Eastern Time on the closing date.

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

(1) *Electronically:* Go to the Federal eRulemaking Portal: *http://www.regulations.gov.* Submit comments on the listing proposal to Docket No. FWS–R2–ES–2012–0035, and submit comments on the critical habitat proposal and associated draft economic analysis to Docket No. FWS–R2–ES–2013–0001. See **SUPPLEMENTARY INFORMATION** for an explanation of the two dockets.

(2) *By hard copy:* Submit comments on the listing proposal by U.S. mail or hand-delivery to: Public Comments Processing, Attn: FWS–R2–ES–2012–0035; Division of Policy and Directives Management; U.S. Fish and Wildlife Service; 4401 N. Fairfax Drive, MS 2042–PDM; Arlington, VA 22203. Submit comments on the critical habitat proposal and draft economic analysis by U.S. mail or hand-delivery to: Public Comments Processing, Attn: FWS–R2–ES–2013–0001; Division of Policy and Directives Management; U.S. Fish and Wildlife Service; 4401 N. Fairfax Drive, MS 2042–PDM; Arlington, VA 22203.

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

FOR FURTHER INFORMATION CONTACT: Adam Zerrenner, Field Supervisor, U.S. Fish and Wildlife Service, Austin Ecological Services Field Office, 10711 Burnet Rd, Suite 200, Austin, TX 78758; by telephone 512–490–0057; or by facsimile 512–490–0974. Persons who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 800–877–8339.

SUPPLEMENTARY INFORMATION:

Public Comments

We will accept written comments and information during this reopened comment period on our proposed designation of critical habitat for the four central Texas salamanders that was published in the **Federal Register** on August 22, 2012 (77 FR 50768), this revised proposed rule, our draft economic analysis (DEA) of the proposed designation, the amended required determinations and exclusions sections, and the refined impervious cover analysis. We are also notifying the public that we will publish two separate rules for the final listing determination and the final critical habitat

determination for the 4 central Texas salamanders. The final listing rule will publish under the existing Docket No. FWS–R2–ES–2012–0035 and the final critical habitat designation will publish under Docket No. FWS–R2–ES–2013–0001.

We request that you provide comments specifically on our listing determination under Docket No. FWS–R2–ES–2012–0035. We will consider information and recommendations from all interested parties. We are particularly interested in comments concerning:

(1) Biological, commercial trade, or other relevant data concerning any threats (or lack thereof) to these species and regulations that may be addressing those threats.

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

(3) Any information on the biological or ecological requirements of these species, and ongoing conservation measures for these species and their habitats.

(4) Land use designations including current or planned activities in the areas occupied by the species and possible impacts of these activities on the four central Texas salamanders and on proposed critical habitat.

We request that you provide comments specifically on the critical habitat determination and related economic analysis under Docket No. FWS–R2–ES–2013–0001. We will consider information and recommendations from all interested parties. We are particularly interested in comments concerning:

(5) The reasons why we should or should not designate habitat as ''critical habitat'' under section 4 of the Act (16 U.S.C. 1531 *et seq.*) including whether there are threats to the species from human activity, the degree of which can be expected to increase due to the designation, and whether that increase in threat outweighs the benefit of designation, such that the designation of critical habitat may not be prudent.

(6) Specific information on:

(a) The amount and distribution of the four central Texas salamanders and their habitats;

(b) What areas, that are currently occupied by these species and that contain features essential to their conservation, should be considered for critical habitat and why;

(c) Special management considerations or protection that may be needed in critical habitat areas we are proposing, including managing for the potential effects of climate change;

(d) What areas not occupied at the time of listing are essential for the conservation of these species and why;

(e) How subterranean populations of these four salamander species are distributed underground; and

(f) The interconnectedness of salamander habitats in terms of hydrology, and whether salamanders are able to move between sites through underground aquifer conduits.

(7) Information on the projected and reasonably likely impacts of climate change on the four central Texas salamanders and proposed critical habitat.

(8) Any probable economic, national security, or other relevant impacts of designating any area that may be included in the final critical habitat designation; in particular, we seek information on any impacts on small entities, and the benefits of including or excluding areas that are subject to these impacts.

(9) Whether any specific areas we are proposing for critical habitat designation should be considered for exclusion under section 4(b)(2) of the Act, and whether the benefits of potentially excluding any specific area outweigh the benefits of including that area under section 4(b)(2) of the Act, in particular for those areas that may benefit from the Buttercup Habitat Conservation Plan (HCP), Lakeline HCP, and Barton Springs Pool HCP.

(10) Whether we could improve or modify our approach to designating critical habitat in any way to provide for greater public participation and understanding, or to better accommodate public concerns and comments.

If you submitted comments or information on the proposed rule (77 FR 50768) during the initial comment period from August 22, 2012, to October 22, 2012, please do not resubmit them. We will incorporate them into the public record as part of this comment period, and we will fully consider them in the preparation of our final determination. Our final determination concerning critical habitat will take into consideration all written comments and any additional information we receive during both comment periods. On the basis of public comments, we may, during the development of our final determination, find that areas proposed are not essential, are appropriate for exclusion under section 4(b)(2) of the Act, or are not appropriate for exclusion.

You may submit your comments and materials concerning the proposed rule or DEA by one of the methods listed in the **ADDRESSES** section. We request that you send comments only by the methods described in the **ADDRESSES** section.

If you submit a comment via *http://www.regulations.gov,* your entire comment—including any personal identifying information—will be posted on the Web site. We will post all hardcopy comments on *http://www.regulations.gov* as well. If you submit a hardcopy comment that includes personal identifying information, you may request at the top of your document that we withhold this information from public review. However, we cannot guarantee that we will be able to do so.

Comments and materials we receive, as well as supporting documentation we used in preparing the proposed rule and DEA, will be available for public inspection on *http://www.regulations.gov* at Docket No. FWS–R2–ES–2012–0035 and Docket No. FWS–R2–ES–2013–0001, or by appointment, during normal business hours, at the U.S. Fish and Wildlife Service, Austin Ecological Services Field Office (see **FOR FURTHER INFORMATION CONTACT**). You may obtain copies of the proposed rule and the DEA on the Internet at *http://www.regulations.gov* at Docket Number FWS–R2–ES–2012–0035 or Docket No. FWS–R2–ES–2013–0001, or by mail from the Austin Ecological Services Field Office (see **FOR FURTHER INFORMATION CONTACT** section).

Background

It is our intent to discuss only those topics directly relevant to the listing and designation of critical habitat for the four central Texas salamanders in this document. For more information on the four central Texas salamanders, their habitat, or previous Federal actions, refer to the proposed listing rule published in the **Federal Register** on August 22, 2012 (77 FR 50768), which is available online at *http://www.regulations.gov* (at Docket Number FWS–R2–ES–2012–0035 or Docket No. FWS–R2–ES–2013–0001) or from the Austin Ecological Services Field Office (see **FOR FURTHER INFORMATION CONTACT**).

On August 22, 2012, we published a proposed rule to designate critical habitat for the four central Texas salamanders (77 FR 50768). We proposed to designate approximately 5,983 acres (ac) (2,440 hectares (ha)) in 52 units located in Travis, Williamson, and Bell Counties, Texas, as critical habitat. That proposal had a 60-day comment period, ending October 22, 2012. We held a public meeting and

hearing in Round Rock, Texas, on September 5, 2012, and a second public meeting and hearing in Austin, Texas, on September 6, 2012.

Refined Impervious Cover Analysis

In our August 22, 2012, proposed rule (77 FR 50768), under *Factor A. The Present or Threatened Destruction, Modification, or Curtailment of Its Habitat or Range,* we used the best available information at that time to calculate the extent and magnitude of impervious cover within the watersheds occupied by the four central Texas salamander species. Impervious cover degrades stream habitat in three ways: (1) Introducing and concentrating contaminants in surface runoff, (2) increasing the rate at which sediment is deposited into a stream, and (3) altering the natural flow regime of streams. We used an impervious cover analysis in the proposed rule (77 FR 50768) to help inform our analysis of the threat of urbanization to the four central Texas salamanders. This refined analysis will help inform the final listing determination of the four central Texas salamanders.

For the August 22, 2012, impervious cover analysis, we used the national Watershed Boundary Dataset to delineate 15 watersheds occupied by the four central Texas salamander species. Although the data for this impervious cover analysis were derived using the finest scale hydrologic units readily available at that time in the Watershed Boundary Dataset, they were too large to offer any reference to the location of salamander-occupied spring sites in relation to the location of impervious cover within the watersheds. Because this analysis did not take into account whether the salamander sites are found upstream or downstream of impervious surfaces associated with developed areas, our previous impervious cover analysis within each watershed may not necessarily be an indicator of how much impervious cover is actually impacting water quality at known salamander sites.

Since the publication of our August 22, 2012, proposed rule (77 FR 50768), we obtained new information that has allowed us to refine our impervious cover analysis and determine where impervious cover is in relation to known salamander sites. This refined analysis is based on the National Hydrography Dataset Plus watershed dataset, which is a nationally consistent watershed dataset developed by the U.S. Environmental Protection Agency and U.S. Geological Survey. The National Hydrography Dataset Plus integrates the National Hydrography Dataset with the National Elevation Dataset and the Watershed Boundary Dataset to locate and identify smaller watersheds than can be found in the Watershed Boundary Dataset itself. We then used ESRI software to create an aspect map and a set of 5-feet (ft) (2-meter (m)) contour lines to help guide the identification and mapping of even smaller watersheds that specifically drain into individual salamander spring sites (springsheds). In our refined analysis, we calculated impervious cover within 113 springsheds occupied by the 4 central Texas salamander species. We also compared the results of our refined impervious cover analysis with two additional impervious cover analyses conducted by SWCA Environmental Consultants (SWCA) and the City of Austin (COA).

Increases in impervious cover cause measurable stream degradation (Klein 1979, p. 959; Bannerman *et al.* 1993, pp. 251–254, 256–258; Center for Watershed Protection 2003, p. 91; Coles et al. 2012, p. 4). The best available scientific literature indicates that detrimental effects to salamander habitat are likely to begin having significant negative impact on salamander populations at 10 percent impervious cover in a springshed. This is in agreement with Bowles *et al.* (2006, pp. 113, 117–118), which found lower Jollyville Plateau salamander densities in watersheds with more than 10 percent impervious cover. Based upon our refined impervious cover analysis, we have found that the Jollyville Plateau salamander has the highest number of springsheds with habitat degrading levels of impervious cover (57 out of 91). Results from COA data are similar to our findings, and suggest that an additional three Jollyville Plateau salamander sites have habitat-degrading levels of impervious cover. Conversely, our data show that the watersheds encompassing Georgetown and Salado salamander habitat are relatively low in impervious cover. However, the high human population growth rate expected in Williamson and Bell Counties indicates that impervious cover has the potential of approaching levels that could negatively impact the Georgetown and Salado salamanders' continued existence. In addition, SWCA's analysis demonstrates that recent development and quarry creation in some Georgetown salamander springsheds may have already increased impervious cover past the threshold of habitat degradation.

For more detailed information or to obtain copies of our refined impervious cover analysis, go to *http://www.regulations.gov* and search for Docket Number FWS–R2–ES–2012–0035, or you may obtain copies by mail from the Austin Ecological Field Services Office (see **FOR FURTHER INFORMATION CONTACT**).

Critical Habitat

Section 3 of the Act defines critical habitat as the specific areas within the geographical area occupied by a species, at the time it is listed in accordance with the Act, on which are found those physical or biological features essential to the conservation of the species and that may require special management considerations or protection, and specific areas outside the geographical area occupied by a species at the time it is listed, upon a determination that such areas are essential for the conservation of the species. If the proposed rule is made final, section 7 of the Act will prohibit destruction or adverse modification of critical habitat by any activity funded, authorized, or carried out by any Federal agency. Federal agencies proposing actions affecting critical habitat must consult with us on the effects of their proposed actions, under section 7(a)(2) of the Act.

Consideration of Impacts Under Section 4(b)(2) of the Act

Section 4(b)(2) of the Act requires that we designate or revise critical habitat based upon the best scientific data available, after taking into consideration the economic impact, impact on national security, or any other relevant impact of specifying any particular area as critical habitat. We may exclude an area from critical habitat if we determine that the benefits of excluding the area outweigh the benefits of including the area as critical habitat, provided such exclusion will not result in the extinction of the species.

When considering the benefits of inclusion for an area, we consider the additional regulatory benefits that area would receive from the protection from adverse modification or destruction as a result of actions with a Federal nexus (activities conducted, funded, permitted, or authorized by Federal agencies), the educational benefits of mapping areas containing essential features that aid in the recovery of the listed species, and any benefits that may result from designation due to State or Federal laws that may apply to critical habitat.

When considering the benefits of exclusion, we consider, among other things, whether exclusion of a specific area is likely to result in conservation; the continuation, strengthening, or encouragement of partnerships; or implementation of a management plan. In the case of the four central Texas

salamanders, the benefits of critical habitat include public awareness of the presence of the species and the importance of habitat protection, and, where a Federal nexus exists, increased habitat protection for the four central Texas salamanders due to protection from adverse modification or destruction of critical habitat. In practice, situations with a Federal nexus exist primarily on Federal lands or for projects undertaken by Federal agencies.

The final decision on whether to exclude any areas will be based on the best scientific data available at the time of the final designation, including information obtained during the comment period and information about the economic impact of designation. Accordingly, we have prepared a DEA concerning the proposed critical habitat designation, which is available for review (see *http://www.regulations.gov* at Docket Number FWS–R2–ES–2013–0001, or contact the Austin Ecological Services Field Office (see **FOR FURTHER INFORMATION CONTACT**)) and comment (see **ADDRESSES**).

Changes From Previously Proposed Critical Habitat

In this document, we are notifying the public of changes to the proposed critical habitat designation. Based on additional information we received during the August 22, 2012, to October 22, 2012, comment period on the proposed rule, in this document we propose to revise Units 2, 3, 5, 8, and 12 for the Georgetown salamander, and Units 3, 4, 5, 9, 10, 17, 22, 23, and 28 for the Jollyville Plateau salamander. All other areas proposed on August 22, 2012, remain as proposed at 77 FR 50768 for designation as critical habitat.

The proposed revisions for the Georgetown salamander critical habitat Units 2, 3, 5, 8, and 12 are adjustments in the locations of these units based on clarifying information we received since the proposed rule was published. Proposed Unit 2 is located 130 ft (40 m) southeast from the location we gave in the August 22, 2012, proposed rule. Proposed Unit 3 is located 2,350 ft (715 m) to the northeast of the location we gave in the August 22, 2012, proposed rule. Unit 5 is located 165 ft (50 m) to the southwest from the location we gave in the August 22, 2012, proposed rule. In Unit 8, the Knight Spring location is located 165 ft (50 m) west of the location we gave in the August 22, 2012, proposed rule. Lastly, Unit 12 is located 200 ft (60 m) to the northwest of the location we gave in the August 22, 2012, proposed rule. The total number of proposed critical habitat units, landownership by type, and size of the proposed critical habitat units remain the same for the Georgetown salamander as provided in the August 22, 2012, proposed rule.

For the Jollyville Plateau Salamander, we received additional locations where salamanders are known to occur that we are using to revise proposed Units 3, 4, 5, 9, 10, 17, 22, 23, and 28. Based on eight new locations, we are combining proposed Units 3, 4, and 5 into one proposed critical habitat unit, Unit 3 (Buttercup Creek Unit). Unit 3 now contains a total of 699 ac (283 ha) of proposed critical habitat. In proposed Unit 9, we are proposing to add one additional spring location (Wheless 2), which results in an increase in the proposed unit's area increasing from 135 ac (55 ha) to 145 ac (59 ha). In proposed Unit 10, we are proposing to add two new locations, Blizzard 2 and 3, which increases the size of this proposed unit from 68 ac (28 ha) to 88 ac (36 ha). In proposed Unit 17, we are proposing to add eight new locations, which changes the size of this proposed unit from 1,157 ac (468 ha) to 1,198 ac (485 ha). Based on five new additional locations, we are proposing to combine previously proposed Units 22 and 23 into one unit, Unit 22 (Sylvia Spring Area Unit). Unit 22 now contains a total of 238 ac (96 ha) of proposed critical habitat. In proposed Unit 28, we are proposing to add one new location called Stillhouse Hollow, but the proposed addition of this location does not result in a change to the size of the unit. In total for the Jollyville Plateau salamander, we previously proposed 4,460 ac (1,816 ha) of critical habitat in 33 units, which we have revised based on new locations, and we are now proposing 4,934 ac (1,997 ha) in 30 units.

Proposed Critical Habitat Designation

In Tables 1 and 2 below, we present the revised proposed critical habitat units for the Georgetown and Jollyville Plateau salamanders. Also, we provide revised unit descriptions for Jollyville Plateau salamander Units 3 and 22. Further detail for both surface and subsurface critical habitat components may be found in the August 22, 2012, proposed rule (77 FR 50768).

TABLE 1—PROPOSED CRITICAL HABITAT UNITS FOR THE GEORGETOWN SALAMANDER

Critical habitat unit	Land ownership by type	Size of unit in acres (hectares)
1. Cobb Unit	Private	83 (34)
2. Cowen Creek Spring Unit	Private	68 (28)
3. Bat Well Unit	Private	68 (28)
4. Walnut Spring Unit	Private, County	68 (28)
5. Twin Springs Unit	Private, County	68 (28)
6. Hogg Hollow Spring Unit	Private, Federal	68 (28)
7. Cedar Hollow Spring Unit	Private	68 (28)
8. Lake Georgetown Unit	Federal, Private	132 (53)
9. Water Tank Cave Unit	Private	68 (28)
10. Avant Spring Unit	Private	68 (28)
11. Buford Hollow Spring Unit	Federal, Private	68 (28)
12. Swinbank Spring Unit	City, Private	68 (28)
13. Shadow Canyon Unit	City, Private	68 (28)
14. San Gabriel Springs Unit	City	68 (28)
Total		1,031 ac (423 ha)

NOTE: Area sizes may not sum due to rounding. Area estimates reflect all land within critical habitat unit boundaries.

TABLE 2—REVISED PROPOSED CRITICAL HABITAT UNITS FOR THE JOLLYVILLE PLATEAU SALAMANDER

Critical habitat unit	Land ownership by type	Size of unit in acres (hectares)
1. Krienke Spring Unit	Private	68 (28)
2. Brushy Creek Spring Unit	Private	68 (28)
3. Buttercup Creek Unit	Private, State, City	699 (283)
6. Avery Spring Unit	Private	237 (96)
7. PC Spring Unit	Private	68 (28)
8. Baker and Audubon Spring Unit	Private	110 (45)
9. Wheless Spring Unit	Private, County	145 (59)
10. Blizzard R-Bar-B Spring Unit	Private	88 (36)
11. House Spring Unit	Private	68 (28)
12. Kelly Hollow Spring Unit	Private	68 (28)
13. MacDonald Well Unit	Private, County	68 (28)
14. Kretschmarr Unit	Private, County	112 (45)
15. Pope and Hiers (Canyon Creek) Spring Unit	Private	68 (28)
16. Fern Gully Spring Unit	Private, City	68 (28)
17. Bull Creek 1 Unit	Private, City, County	1,198 (485)
18. Bull Creek 2 Unit	Private, City, County	237 (96)
19. Bull Creek 3 Unit	Private, City	254 (103)
20. Moss Gulley Spring Unit	City, County	68 (28)
21. Ivanhoe Spring Unit	City	68 (28)
22. Sylvia Spring Area Unit	Private, City, County	238 (96)
24. Long Hog Hollow Unit	Private	68 (28)
25. Tributary 3 Unit	Private	68 (28)
26. Sierra Spring Unit	Private	68 (28)
27. Troll Spring Unit	Private	98 (40)
28. Stillhouse Unit	Private	203 (82)
29. Salamander Cave Unit	Private	68 (28)
30. Indian Spring Unit	Private	68 (28)
31. Spicewood Spring Unit	Private	68 (28)
32. Balcones District Park Spring Unit	Private, City	68 (28)
33. Tributary 4 Unit	Private, City	159 (64)
Total		4,934 ac (1,997 ha)

NOTE: Area sizes may not sum due to rounding. Area estimates reflect all land within critical habitat unit boundaries.

Jollyville Plateau Salamander

Unit 3: Buttercup Creek Unit

Unit 3 consists of 699 ac (283 ha) of City of Austin, State of Texas, and private land in southern Williamson County and northern Travis County, Texas. The unit is located just east of Anderson Mill Road. Lakeline Boulevard, a major thoroughfare, crosses the northeast area of the unit. The unit is mostly covered with residential property. A quarry is in the northwestern edge of the unit. An undeveloped area of parks and setbacks is in the south central and southeastern part of the unit. This unit contains 13 caves: Hunter's Lane Cave, Testudo Tube, Bluewater Cave #1, Bluewater Cave #2, TWASA Cave, Illex Cave, Buttercup Creek Cave, Godzilla Cave, Hideaway Cave, Salamander Squeeze Cave, Treehouse Cave, Whitewater Cave, and Flea Cave, which are all occupied by the Jollyville Plateau salamander. All caves except Hunter's Lane Cave, Testudo Tube, Bluewater Cave #1, and Bluewater Cave #2 are located in preserves set up as mitigation property under the Buttercup habitat conservation plan (HCP), which is held by the City of Austin. This HCP covers adverse impacts to the endangered Tooth Cave ground beetle (*Rhadine persephone*). Although the salamander is not covered under the Buttercup HCP, the protection afforded these caves by the HCP provides some benefit for the species.

The Lakeline Mall HCP covers the Testudu Tube Cave location. As part of the mitigation for the Lakeline Mall HCP, Testudo Tube Cave must be protected and managed in perpetuity. Hunter's Lane Cave is located in Discovery Well Preserve, which is State land leased to the City of Cedar Park. This preserve was purchased by the Texas Department of Transportation (formally Texas Turnpike Authority Division) as mitigation for impacts to the Tooth Cave ground beetle from the construction of the U.S. Highway 183 alternate highway project. The mitigation actions from these HCPs and highway project provide some benefit to the Jollyville Plateau salamander by establishing preserve areas that limit development near the caves. Bluewater Cave #1 and Bluewater Cave #2 are located on public land within older development. All caves in this unit except Bluewater Cave #1 and Hunter's Lane Cave contain the Tooth Cave ground beetle. The unit contains all the primary constituent elements essential for the conservation of the Jollyville Plateau salamander.

The unit requires special management because of the potential for groundwater pollution from current and future development in the watershed, potential for vandalism, and depletion of groundwater (see *Special Management Considerations or Protection* section of the proposed listing and critical habitat rule (77 FR 50768; August 22, 2012)).

The proposed critical habitat designation includes the caves. The unit was further delineated by drawing a circle with a radius of 980 ft (300 m) around the cave, representing the extent of the subterranean critical habitat.

Unit 22: Sylvia Spring Area Unit

Unit 22 consists of 238 ac (96 ha) of private, City of Austin, and Williamson County land in northern Travis County and southwestern Williamson County, Texas. The unit is located east of the intersection of Callanish Park Drive and Westerkirk Drive and north of the intersection of Spicewood Springs Road and Yaupon Drive. Spicewood Springs Road crosses the unit from southwest to east. Residential and commercial

development is found in most of the unit. An undeveloped stream corridor crosses the unit from east to west. This unit contains Small Sylvia Spring, Sylvia Spring Area 2, Sylvia Spring Area 3, Sylvia Spring Area 4, Spicewood Valley Park Spring, Tanglewood Spring, Tanglewood 2, and Tanglewood 3, which are occupied by the Jollyville Plateau salamander. Small Sylvia Spring, Sylvia Spring Area 2, Sylvia Spring Area 3, Sylvia Spring Area 4, and Spicewood Valley Park Spring are located on an unnamed tributary to Tanglewood Creek. Tanglewood Spring, Tanglewood 2, and Tanglewood 3 are located on Tanglewood Creek, a tributary to Bull Creek. The unit contains the primary constituent elements essential for the conservation of the species.

The unit requires special management because of the potential for groundwater pollution from current and future development in the watershed, potential for vandalism, and depletion of groundwater (see *Special Management Considerations or Protection* section of the proposed listing and critical habitat rule (77 FR 50768; August 22, 2012)).

The proposed designation includes the spring outlets and outflow up to the high water line and 160 ft (50 m) of downstream habitat. The unit was further delineated by drawing a circle with a radius of 980 ft (300 m) around the springs, representing the extent of the subterranean critical habitat. We joined the edges of the resulting circles.

Amended Exclusions

In our August 22, 2012, proposed rule (77 FR 50768), we stated that we would evaluate whether certain lands in the proposed critical habitat designation for Jollyville Plateau salamander in the Bull Creek 3 Unit (Unit 19 for the Jollyville Plateau salamander) are appropriate for exclusion from the final designation under section 4(b)(2) of the Act. We are now adding the following land in the proposed critical habitat for the Austin blind salamander to the list of areas we are considering for exclusion from the final critical habitat designation.

TABLE 3—AREAS CONSIDERED FOR EXCLUSION BY CRITICAL HABITAT UNIT FOR THE AUSTIN BLIND SALAMANDER

Unit	Specific area	Areas meeting the definition of critical habitat, in acres (hectares)	Areas considered for possible exclusion, in acres (hectares)
Unit 1: Barton Springs Unit	Barton Springs Pool HCP	120 ac (49 ha)	22 ac (9 ha)

Under section 4(b)(2) of the Act, we consider any other relevant impacts, in addition to economic impacts and impacts on national security. We consider a number of factors including whether the landowners have developed any HCPs or other management plans for the area, or whether there are conservation partnerships that would be encouraged by designation of, or exclusion from, critical habitat. In addition, we look at any tribal issues, and consider the government-to-government relationship of the United States with tribal entities.

Land and Resource Management Plans, Conservation Plans, or Agreements Based on Conservation Partnerships

We consider a current land management or conservation plan (HCP as well as other types) to provide adequate management or protection if it meets the following criteria:

(1) The plan is complete and provides the same or better level of protection from adverse modification or destruction than that provided through a consultation under section 7 of the Act;

(2) There is a reasonable expectation that the conservation management strategies and actions will be implemented for the foreseeable future, based on past practices, written guidance, or regulations; and

(3) The plan provides conservation strategies and measures consistent with currently accepted principles of conservation biology.

Barton Springs Pool Habitat Conservation Plan

We are considering the exclusion of non-Federal lands covered by the Barton Springs Pool HCP. We are requesting comments on the benefit to the Austin blind salamander from this HCP.

The Permittee (City of Austin) is authorized to take (kill, harm, or harass) the endangered Barton Springs salamander (*Eurycea sosorum*) at the four spring sites collectively known as Barton Springs, incidental to activities for the operation and maintanence of the pool and adjacent spring sites as described in the original Permittee's (City of Austin) application and habitat conservation plan. The Barton Springs Pool HCP currently requires the following measures for the mitigation of incidental take of the Barton Springs salamander during routine pool maintanence and cleaning. These measures are also being applied to the Austin blind salamander as if it were a listed species:

- Cleaning of the shallow end without lowering the entire pool.
- Visual searching for stranded salamanders after lowering the pool.
- Lowering of the beach.
- Cleaning of the fissures, the new ''beach'' habitat, and adjacent springs using low-pressure hoses.
- Installation of an underwater walkway and a stainless steel railing in the deep end.
- Maintenance of 11,000 square feet (1,022 square meters) of ''beach'' habitat.
- Restricting public access to Eliza and Sunken Garden (Old Mill) Springs.
- Daily inspections of all spring sites for vandalism, habitat disturbance, and exotic species.
- Implementation of a program to increase public awareness and community support for the salamanders.
- Establishment of a conservation and research fund for the salamanders.
- Reduce loadings of contaminants into Barton Springs from current development and activities in the Barton Springs Zone of the Edwards Aquifer.
- Creation of a captive breeding facility for the Barton Springs and Austin blind salamanders.

The measures described above will provide conservation benefits to the Austin blind salamander by minimizing the death of individuals during routine pool maintenance, preventing habitat disturbance from vandalism, and maintaining water quality in the springs.

Draft Economic Analysis

The purpose of the DEA is to identify and analyze the potential economic impacts associated with the proposed critical habitat designation for the four central Texas salamanders. The DEA separates conservation measures into two distinct categories according to ''without critical habitat'' and ''with critical habitat'' scenarios. The ''without

critical habitat'' scenario represents the baseline for the analysis, considering protections otherwise afforded to the four central Texas salamanders (e.g., under the Federal listing and other Federal, State, and local regulations). The ''with critical habitat'' scenario describes the incremental impacts specifically due to designation of critical habitat for the species. In other words, these incremental conservation measures and associated economic impacts would not occur but for the designation. Conservation measures implemented under the baseline (without critical habitat) scenario are described qualitatively within the DEA, but economic impacts associated with these measures are not quantified. Economic impacts are only quantified for conservation measures implemented specifically due to the designation of critical habitat (i.e., incremental impacts). For a further description of the methodology of the analysis, see Chapter 2, ''FRAMEWORK FOR THE ANALYSIS'' of the DEA.

The DEA provides estimated costs of the foreseeable potential economic impacts of the proposed critical habitat designation for the four central Texas salamanders over the next 23 years, which was determined to be the appropriate period for analysis, because limited planning information is available for most activities to forecast activity levels for projects beyond a 23-year timeframe. It identifies potential incremental costs as a result of the proposed critical habitat designation; these are those costs attributed to critical habitat over and above those baseline costs attributed to listing.

The DEA quantifies economic impacts of the four central Texas salamanders conservation efforts associated with the following categories of activity: (1) Development, (2) water management activities, (3) transportation projects, (4) utility projects, (5) mining, and (6) livestock grazing. Economic impacts are estimated for development, transportation, mining, and species and habitat management activities. No impacts are forecast for water management activities, utility projects, and livestock grazing activities. For these activities, no projects with a Federal nexus were identified within the study area.

Total present value impacts anticipated to result from the designation of all areas proposed as salamander critical habitat are approximately $29 million over 23 years. All incremental costs are administrative in nature and result from the consideration of adverse modification in section 7 consultations and re-initiation of consultations for existing management plans. Proposed Unit 1 for the Austin blind salamander and proposed Unit 32 for the Jollyville Plateau salamander are likely to experience the greatest incremental impacts. Impacts in proposed Unit 1 for the Austin blind salamander are estimated at $3.7 million in present value terms (13.0 percent of total present value impacts), and result from a portion of the consultation associated with the Mopac Expressway and approximately 21 consultations annually on development projects withinproposed Unit 1 itself and the Lake Austin watershed. Impacts in proposed Unit 32 for the Jollyville Plateau salamander are estimated at $2.9 million in present value terms (10.1 percent of total present value impacts), and result from a portion of the consultations associated with three transportation projects and approximately 17 consultations annually on development projects within proposed Unit 32 itself and the Walnut Creek watershed. Overall, consultations associated with development activities account for approximately 98.8 percent of the incremental impacts in this analysis.

As we stated earlier, we are soliciting data and comments from the public on the DEA, as well as all aspects of the proposed rule and our amended required determinations. We may revise the proposed rule or supporting documents to incorporate or address information we receive during the public comment period. In particular, we may exclude an area from critical habitat if we determine that the benefits of excluding the area outweigh the benefits of including the area, provided the exclusion will not result in the extinction of this species.

Required Determinations—Amended

In our August 22, 2012, proposed rule (77 FR 50768), we indicated that we would defer our determination of compliance with several statutes and executive orders until the information concerning potential economic impacts of the designation and potential effects on landowners and stakeholders became available in the DEA. We have now made use of the DEA data to make these determinations. In this document, we affirm the information in our proposed rule concerning Executive Order (E.O.) 12866 (Regulatory Planning and Review), E.O. 12630 (Takings), E.O. 13132 (Federalism), E.O. 12988 (Civil Justice Reform), E.O. 13211 (Energy, Supply, Distribution, and Use), the Unfunded Mandates Reform Act (2 U.S.C. 1501 *et seq.*), the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the National Environmental Policy Act (42 U.S.C. 4321 *et seq.*), and the President's memorandum of April 29, 1994, ''Government-to-Government Relations with Native American Tribal Governments'' (59 FR 22951). However, based on the DEA data, we are amending our required determinations concerning the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) and E.O. 12630 (Takings).

Regulatory Flexibility Act (5 U.S.C. 601 et seq.)

Under the Regulatory Flexibility Act (RFA; 5 U.S.C. 601 *et seq.*), as amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA; 5 U.S.C. 801 *et seq.*), whenever an agency must publish a notice of rulemaking for any proposed or final rule, it must prepare and make available for public comment a regulatory flexibility analysis that describes the effects of the rule on small entities (i.e., small businesses, small organizations, and small government jurisdictions). However, no regulatory flexibility analysis is required if the head of the agency certifies the rule will not have a significant economic impact on a substantial number of small entities. The SBREFA amended the RFA to require Federal agencies to provide a certification statement of the factual basis for certifying that the rule will not have a significant economic impact on a substantial number of small entities. Based on our DEA of the proposed designation, we provide our analysis for determining whether the proposed rule would result in a significant economic impact on a substantial number of small entities. Based on comments we receive, we may revise this determination as part of our final rulemaking.

According to the Small Business Administration, small entities include small organizations such as independent nonprofit organizations; small governmental jurisdictions, including school boards and city and town governments that serve fewer than 50,000 residents; and small businesses (13 CFR 121.201). Small businesses include manufacturing and mining concerns with fewer than 500 employees, wholesale trade entities with fewer than 100 employees, retail and service businesses with less than $5 million in annual sales, general and heavy construction businesses with less than $27.5 million in annual business, special trade contractors doing less than $11.5 million in annual business, and agricultural businesses with annual sales less than $750,000. To determine if potential economic impacts to these

small entities are significant, we considered the types of activities that might trigger regulatory impacts under this designation as well as types of project modifications that may result. In general, the term ''significant economic impact'' is meant to apply to a typical small business firm's business operations.

To determine if the proposed designation of critical habitat for the four central Texas salamanders would affect a substantial number of small entities, we considered the number of small entities affected within particular types of economic activities, such as development, transportation, and mining activities as well as re-initiated programmatic consultations for five existing conservation plans. In order to determine whether it is appropriate for our agency to certify that this proposed rule would not have a significant economic impact on a substantial number of small entities, we considered each industry or category individually. In estimating the numbers of small entities potentially affected, we also considered whether their activities have any Federal involvement. Critical habitat designation will not affect activities that do not have any Federal involvement; designation of critical habitat only affects activities conducted, funded, permitted, or authorized by Federal agencies. In areas where the four central Texas salamanders are present, Federal agencies already are required to consult with us under section 7 of the Act on activities they fund, permit, or implement that may affect the species. If we finalize this proposed critical habitat designation, consultations to avoid the destruction or adverse modification of critical habitat would be incorporated into the existing consultation process.

In the DEA, we evaluated the potential economic effects on small entities resulting from implementation of conservation actions related to the proposed designation of critical habitat for the four central Texas salamanders. Impacts to transportation activities are expected to be incurred largely by Federal and State agencies. These entities are not considered small. Also, re-initiations of consultations regarding the Balcones Canyonlands Preserve, Buttercup Creek HCP, Four Points HCP, Lakeline Mall HCP, and Williamson County Regional HCP are not anticipated to involve small entities. However, incremental impacts associated with residential and commercial development and surface mining may be borne by small entities. In regards to development and assuming the average small entity has annual revenues of approximately $4.6 million, the per-entity cost to participate in a consultation represents approximately 0.02 percent of annual revenues if each consultation is undertaken by a different small entity. If all consultations occurring in a given year (approximately 163) are undertaken by the same developer, then the cost to participate in these consultations represents approximately 3.1 percent of annual revenues. In regards to mining, there are four small businesses engaged in limestone mining, and we anticipate that two of these small entities could incur incremental administrative costs as a result of a critical habitat designation. Assuming the average small entity has annual revenues of approximately $10 million, the per-entity cost to participate in a consultation represents approximately less than 0.01 percent of annual revenues. Even in the event that a single small entity bears third-party costs for both consultations in a single year, the total impact represents less than 0.02 percent of annual revenues. Overall, we do not believe that, if made final, the designation of critical habitat for the four central Texas salamanders will have a significant impact to the small business sector. Please refer to the DEA of the proposed critical habitat designation for a more detailed discussion of potential economic impacts.

The Service's current understanding of recent case law is that Federal agencies are only required to evaluate the potential impacts of rulemaking on those entities directly regulated by the rulemaking; therefore, they are not required to evaluate the potential impacts to those entities not directly regulated. The designation of critical habitat for an endangered or threatened species only has a regulatory effect where a Federal action agency is involved in a particular action that may affect the designated critical habitat. Under these circumstances, only the Federal action agency is directly regulated by the designation, and, therefore, consistent with the Service's current interpretation of RFA and recent case law, the Service may limit its evaluation of the potential impacts to those identified for Federal action agencies. Under this interpretation, there is no requirement under the RFA to evaluate the potential impacts to entities not directly regulated, such as small businesses. However, Executive Orders 12866 and 13563 direct Federal agencies to assess costs and benefits of available regulatory alternatives in quantitative (to the extent feasible) and qualitative terms. Consequently, it is the current practice of the Service to assess to the extent practicable these potential impacts, if sufficient data are available, whether or not this analysis is believed by the Service to be strictly required by the RFA. In other words, while the effects analysis required under the RFA is limited to entities directly regulated by the rulemaking, the effects analysis under the Act, consistent with the E.O. regulatory analysis requirements, can take into consideration impacts to both directly and indirectly impacted entities, where practicable and reasonable.

In summary, we have considered whether the proposed designation would result in a significant economic impact on a substantial number of small entities. Information for this analysis was gathered from the Small Business Administration, stakeholders, and the Service. For the above reasons and based on currently available information, we certify that, if promulgated, the proposed critical habitat designation will not have a significant economic impact on a substantial number of small business entities. Therefore, an initial regulatory flexibility analysis is not required.

Takings—Executive Order 12630

In accordance with Executive Order 12630 (Government Actions and Interference with Constitutionally Protected Private Property Rights), we have analyzed the potential takings implications of designating critical habitat for the four central Texas salamanders in a takings implications assessment. As discussed above, the designation of critical habitat affects only Federal actions. Although private parties that receive Federal funding, assistance, or require approval or authorization from a Federal agency for an action may be indirectly impacted by the designation of critical habitat, the legally binding duty to avoid destruction or adverse modification of critical habitat rests squarely on the Federal agency. The economic analysis found that no significant ecomonic impacts are likely to result from the designation of critical habitat for the four central Texas salamanders. Because the Act's critical habitat protection requirements apply only to Federal agency actions, few conflicts between critical habitat and private property rights should result from this designation. Based on information contained in the economic analysis assessment and described within this document, it is not likely that economic impacts to a property owner would be of a sufficient magnitude to support a

takings action. Therefore, the takings implications assessment concludes that this designation of critical habitat for the four central Texas salamanders does not pose significant takings implications for lands within or affected by the designation.

Authors

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

List of Subjects in 50 CFR Part 17

Endangered and threatened species, Exports, Imports, Reporting and recordkeeping requirements, Transportation.

Proposed Regulation Promulgation

Accordingly, we propose to further amend the proposed amendments to part 17, subchapter B of chapter I, title 50 of the Code of Federal Regulations, as published on August 22, 2012, at 77 FR 50768, as set forth below:

PART 17—[AMENDED]

■ 1. The authority citation for part 17 continues to read as follows:

Authority: 16 U.S.C. 1361–1407; 1531–1544; and 4201–4245, unless otherwise noted.

■ 2. Amend § 17.95(d), as proposed to be amended at 77 FR 50768, by:

■ a. Revising proposed paragraphs (d)(5), (d)(7), (d)(9), (d)(11), and (d)(15) of the proposed entry for the ''Georgetown Salamander (*Eurycea naufragia*)'' and

■ b. Revising proposed paragraphs (d)(5) and (d)(8), removing and reserving proposed paragraphs (d)(9) and (d)(10), revising proposed paragraphs (d)(14), (d)(19), and (d)(27), removing and reserving proposed paragraph (d)(28), and revising proposed paragraph (d)(33) of the proposed entry for the ''Jollyville Plateau Salamander (*Eurycea tonkawae*)'', to read as follows:

§ 17.95 Critical habitat—fish and wildlife.

* * * * *

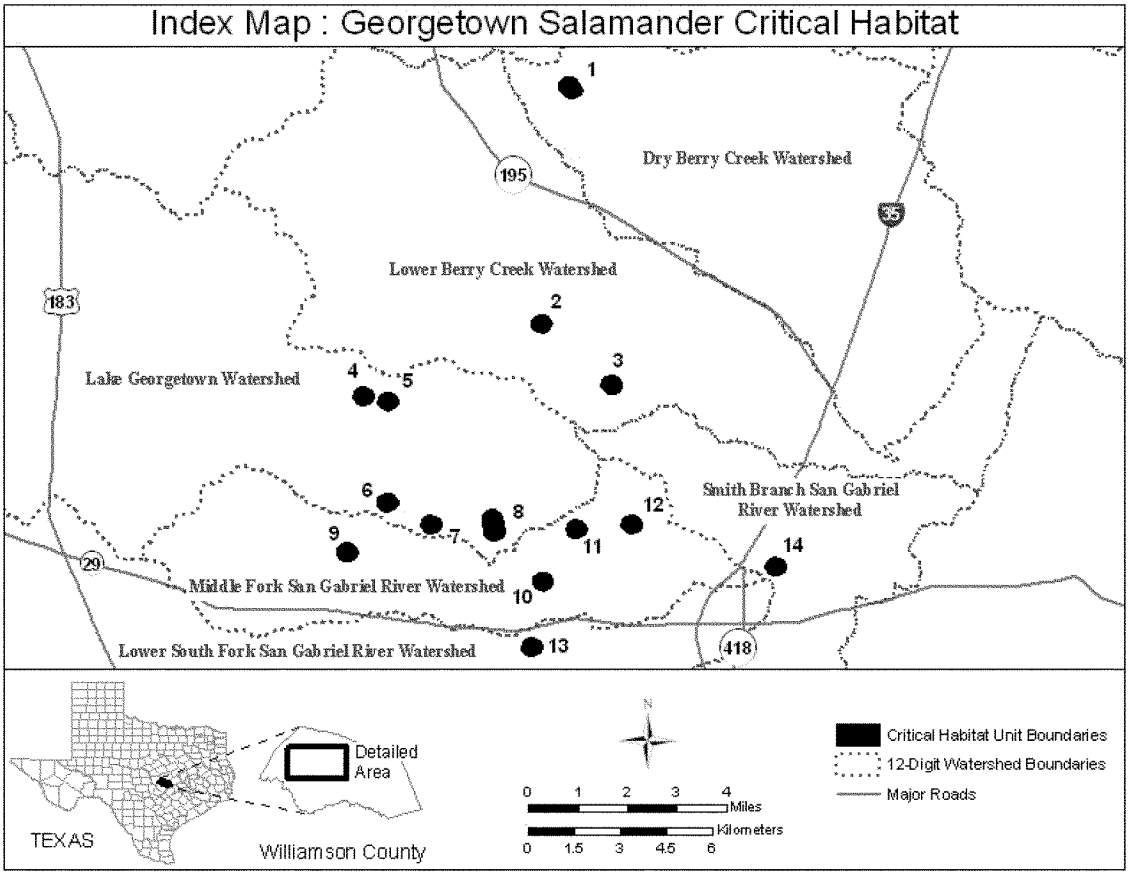
(d) *Amphibians.*

* * * * *

Georgetown Salamander (*Eurycea naufragia*)

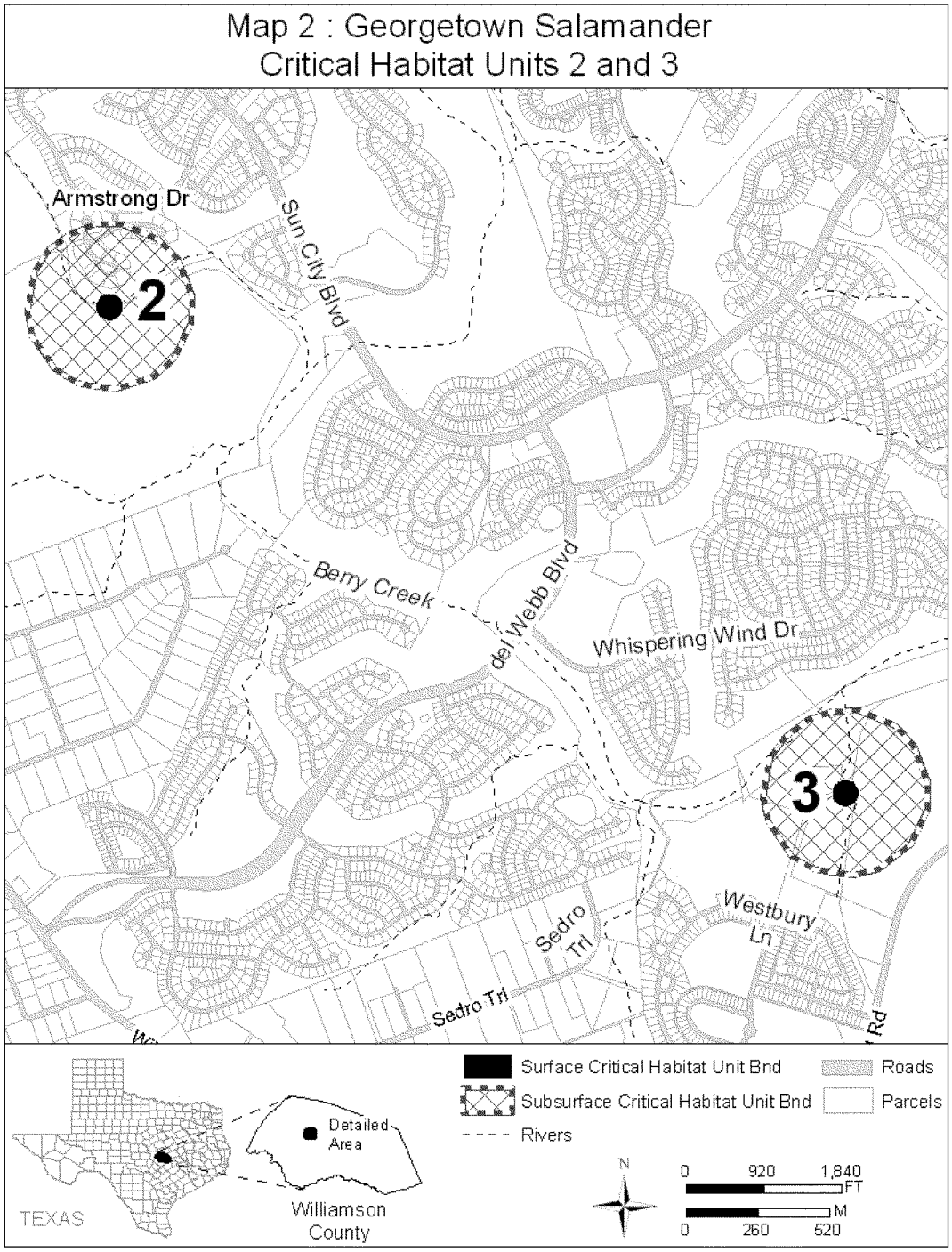
* * * * *

(5) Index map follows:



* * * * *

(7) Unit 2: Cowen Creek Spring Unit, Williamson County, Texas. Map of Units 2 and 3 follows:

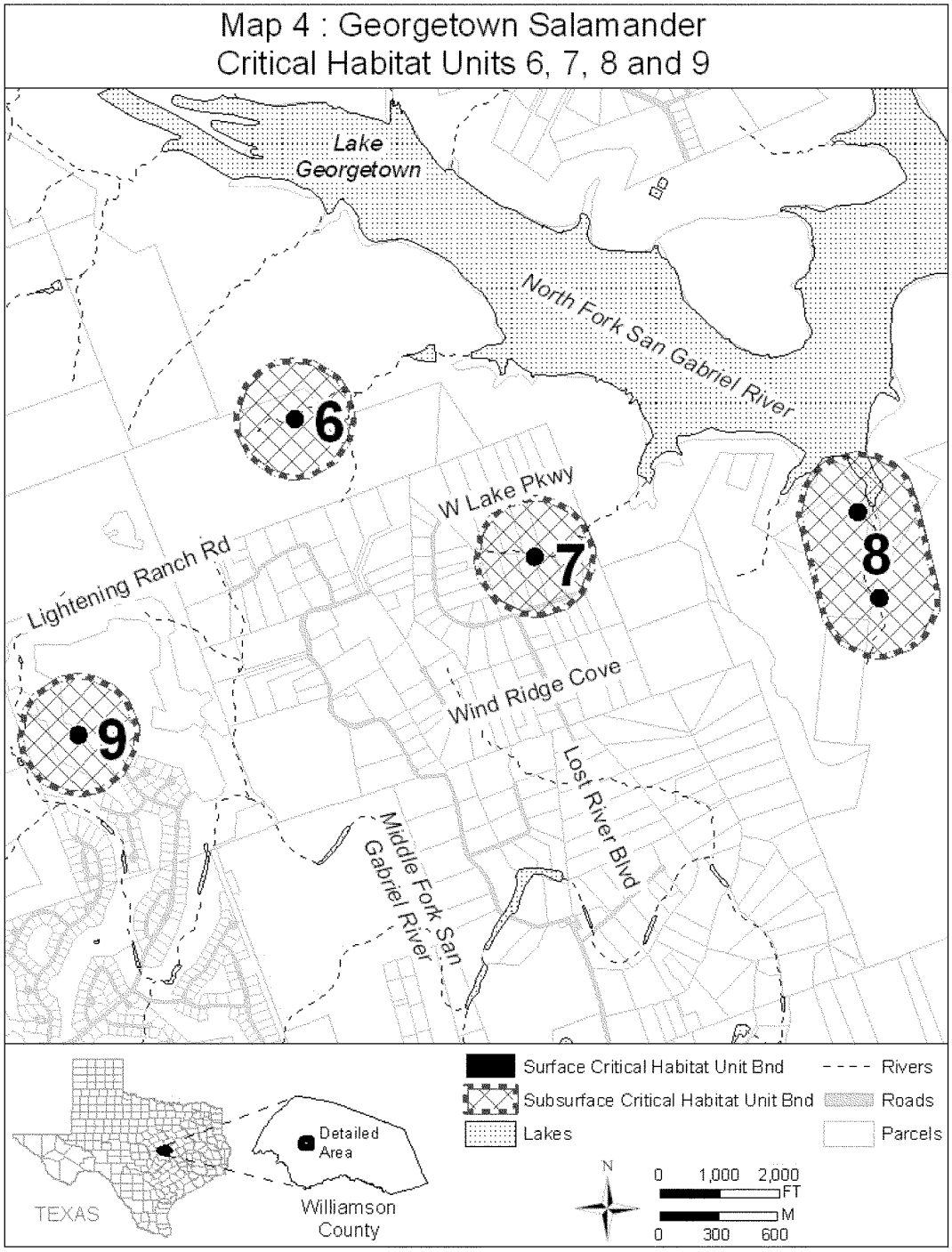


* * * * *

(9) Unit 4: Walnut Spring Unit,Williamson County, Texas. Map of Units 4 and 5 follows:

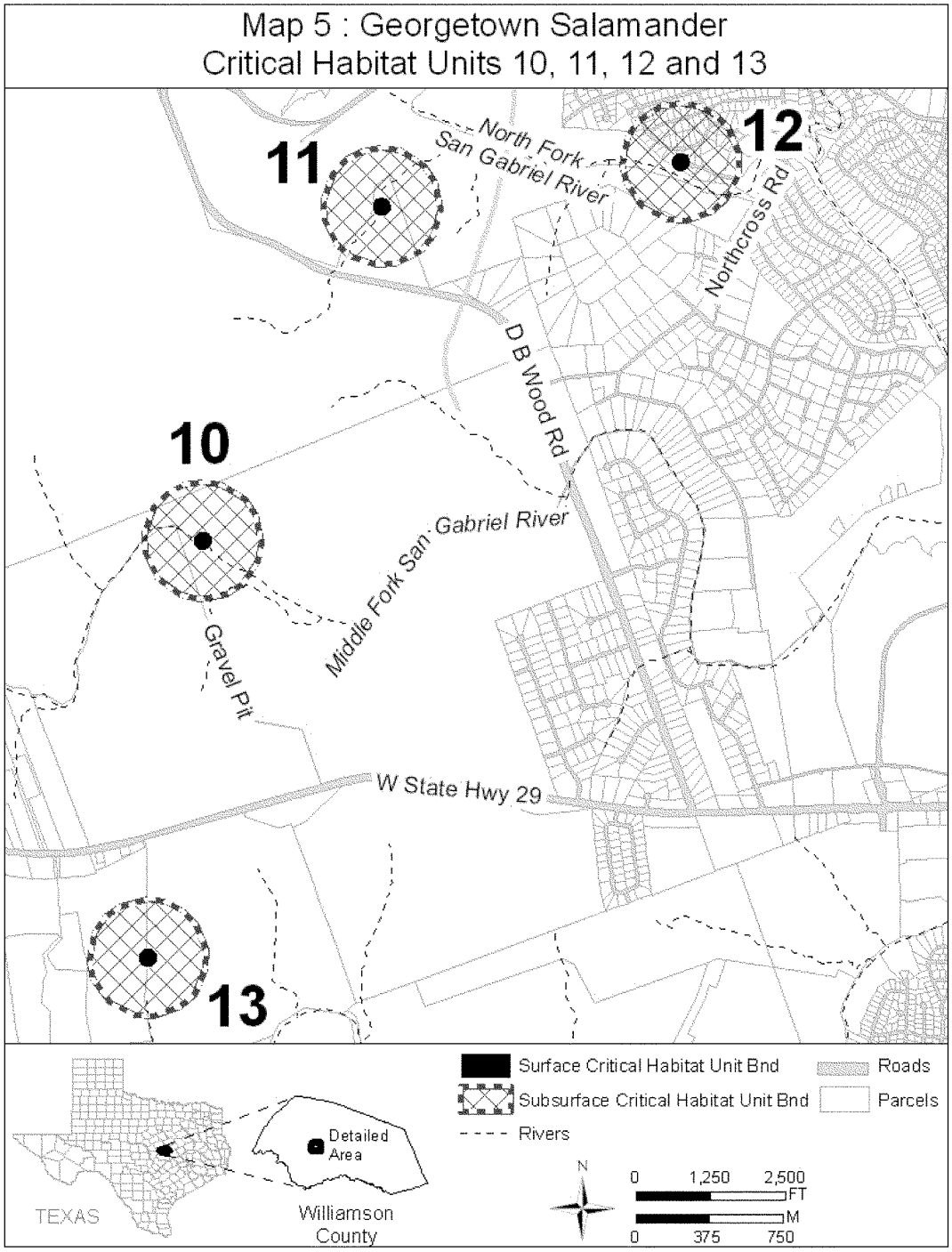
* * * * *

(11) Unit 6: Hogg Hollow Spring Unit, Williamson County, Texas. Map of Units 6, 7, 8, and 9 follows:



* * * * *

(15) Unit 10: Avant Spring Unit, Williamson County, Texas. Map of Units 10, 11, 12, and 13 follows:

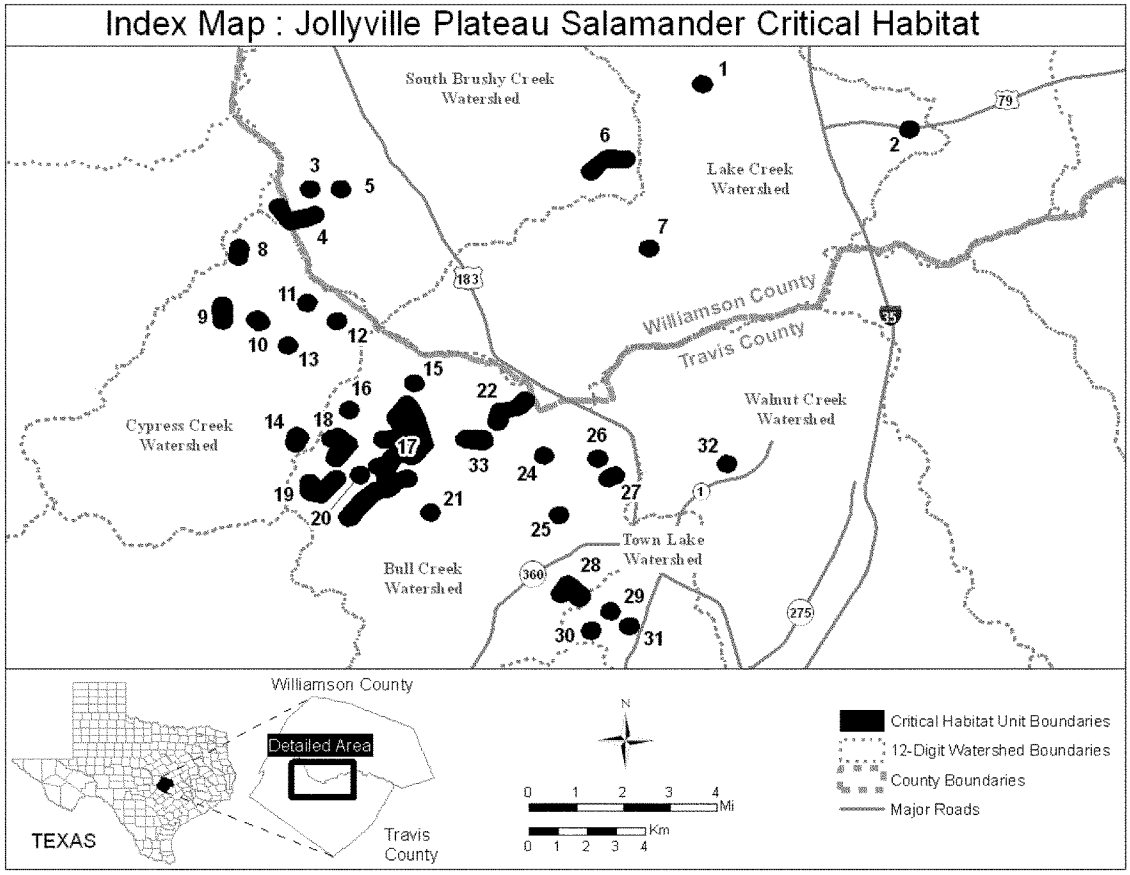


* * * * *

Jollyville Plateau Salamander (*Eurycea tonkawae*)

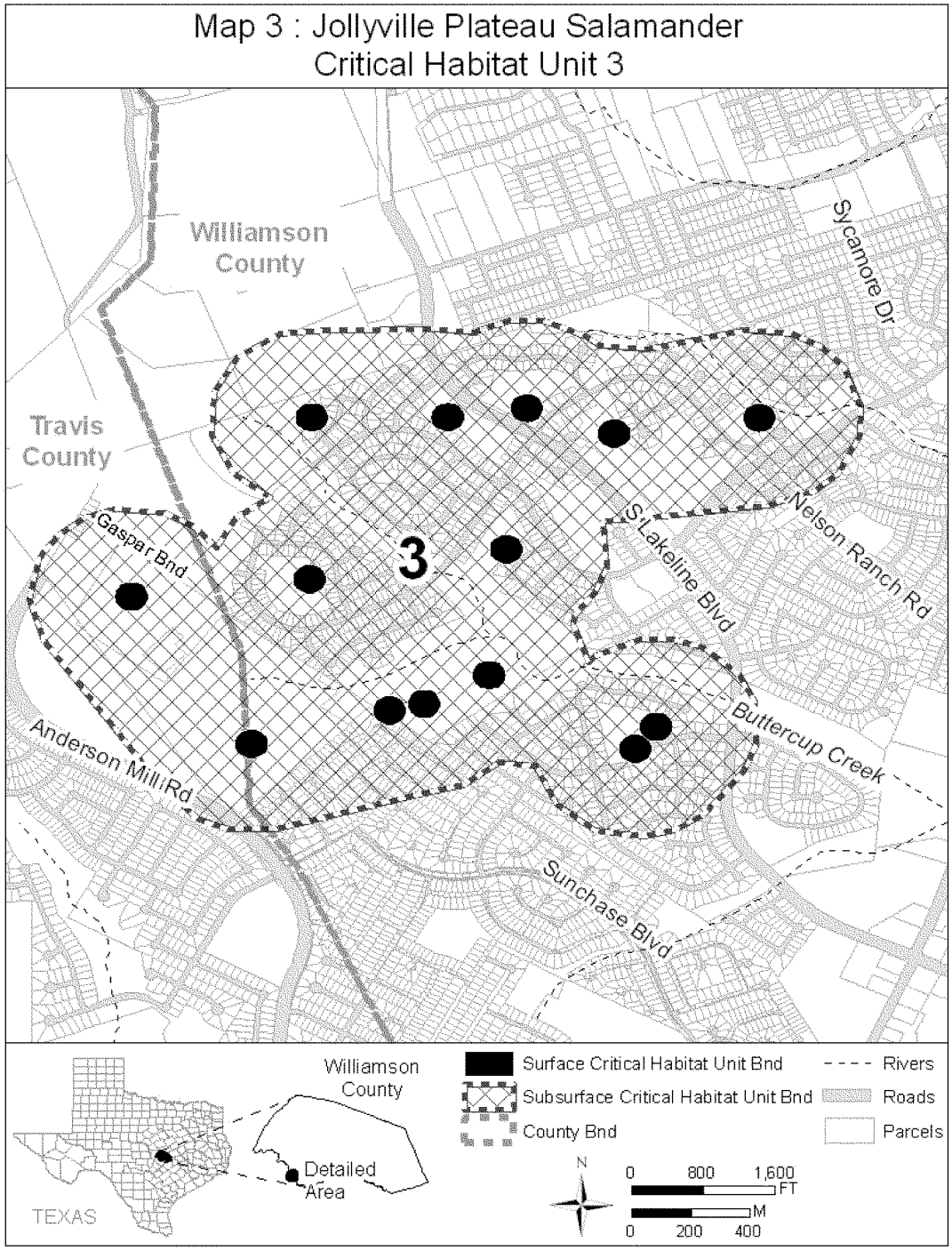
(5) Index map follows:

* * * * *



* * * * *

(8) Unit 3: Buttercup Creek Unit, Williamson and Travis Counties, Texas. Map of Unit 3 follows:

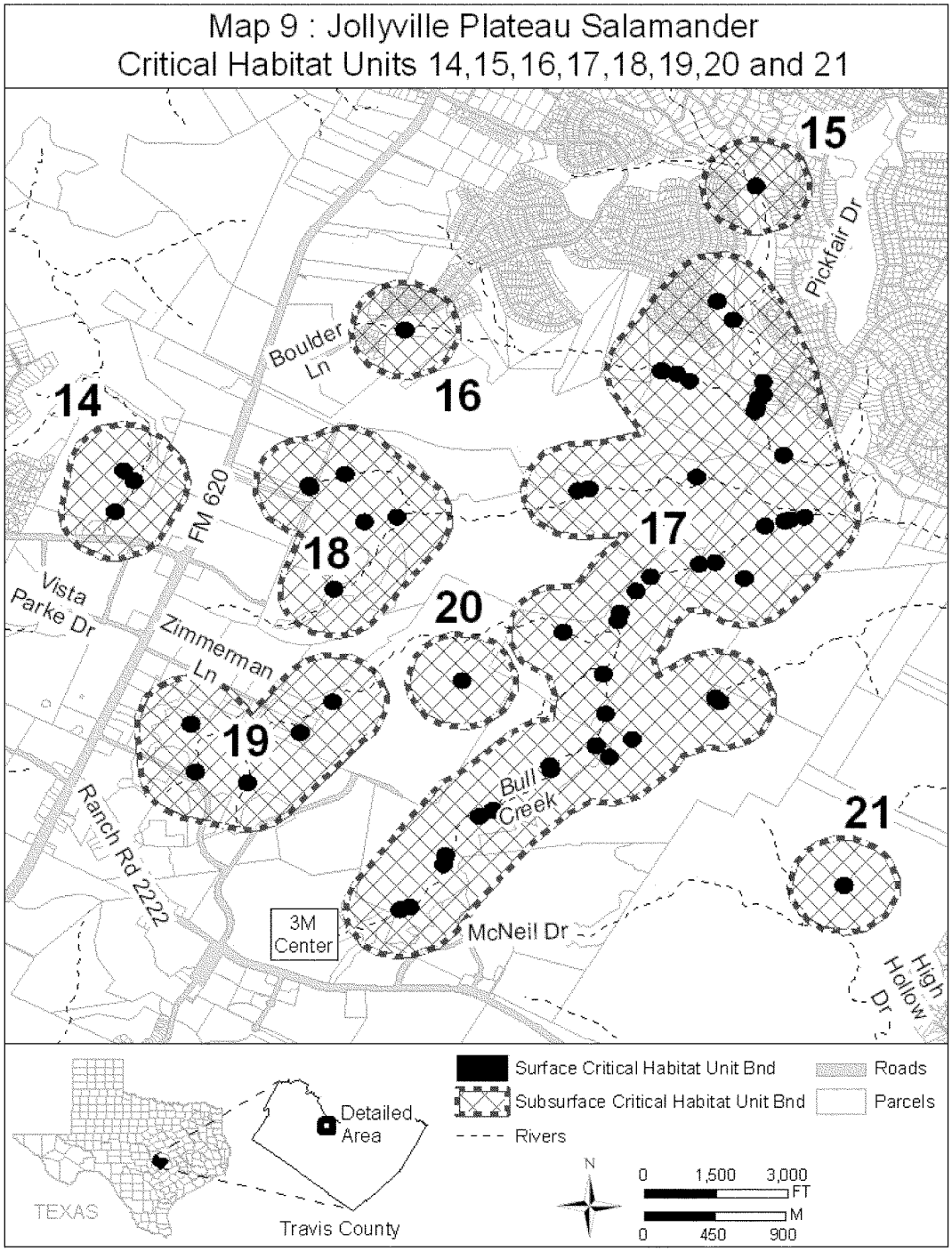


* * * * *

(14) Unit 9: Wheless Spring Unit, Travis County, Texas. Map of Units 9 and 10 follows:

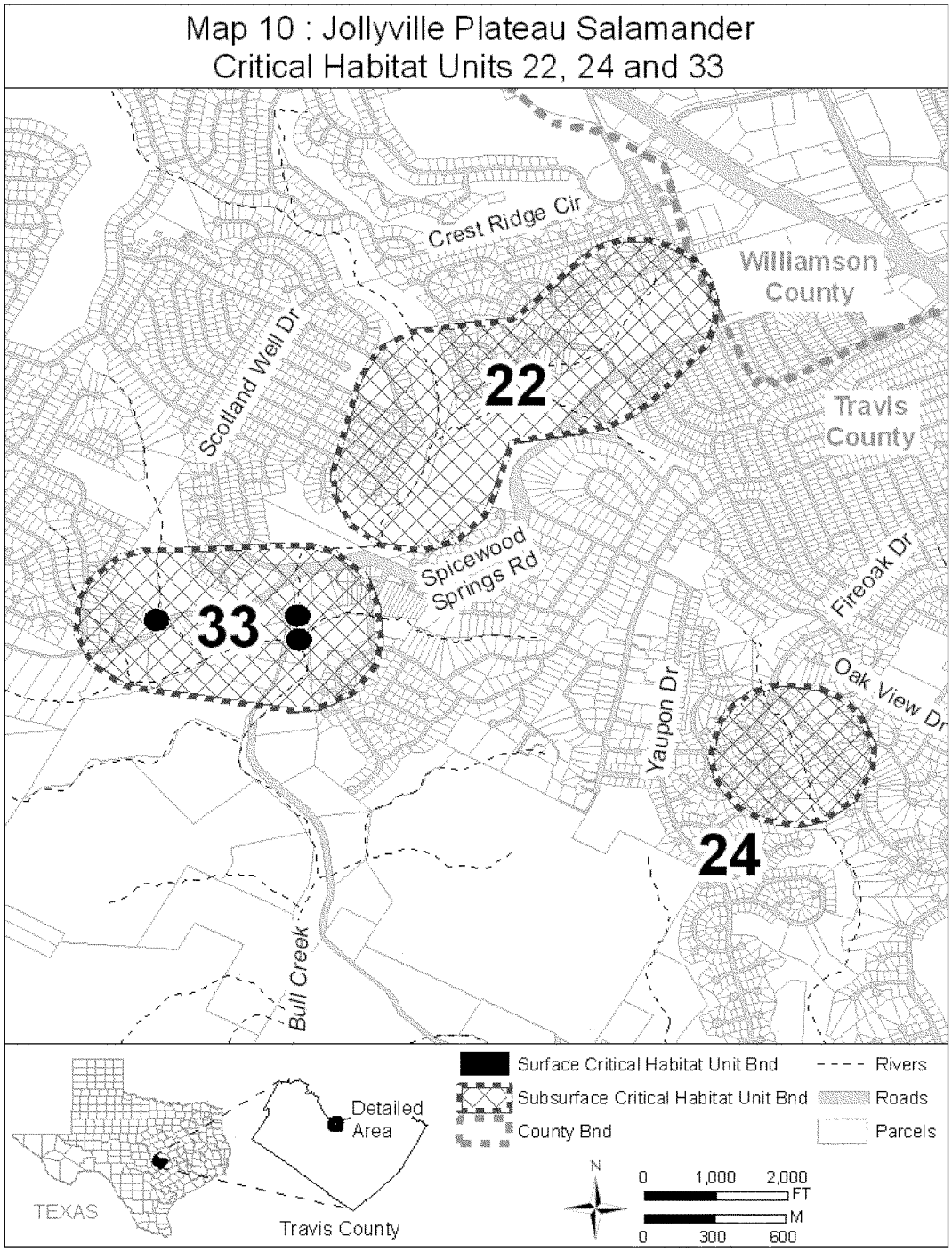
* * * * *

(19) Unit 14: Kretschmarr Unit, Travis County, Texas. Map of Units 14, 15, 16, 17, 18, 19, 20, and 21 follows:



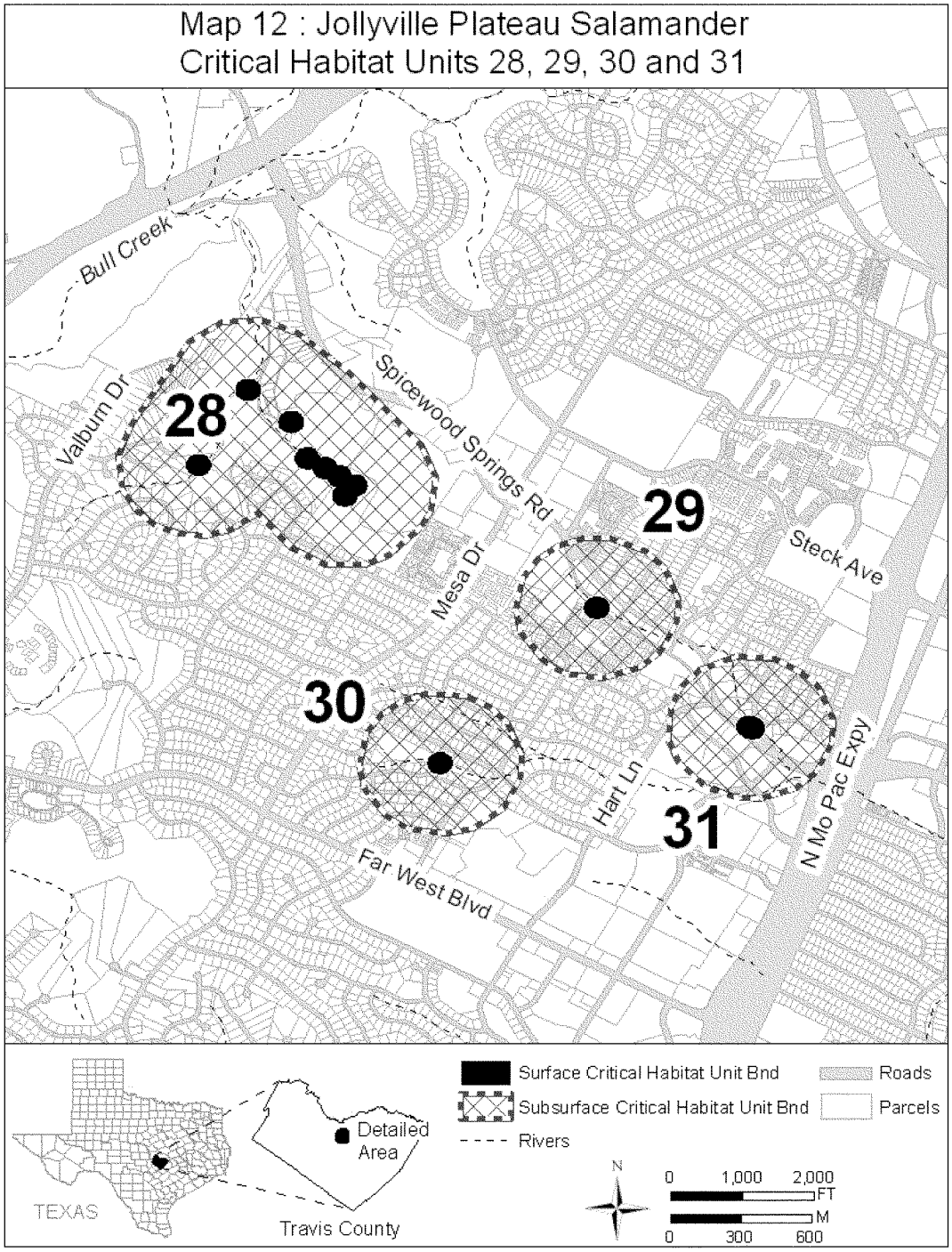
* * * * *

(27) Unit 22: Sylvia Spring Area Unit, Travis County, Texas. Map of Units 22, 24, and 33 follows:



* * * * *

(33) Unit 28: Stillhouse Unit, Travis County, Texas. Map of Units 28, 29, 30, and 31 follows:



* * * * *

Dated: January 15, 2013.

Michael J. Bean,

Acting Principal Deputy Assistant Secretary for Fish and Wildlife and Parks.

[FR Doc. 2013–01307 Filed 1–24–13; 8:45 am]

BILLING CODE 4310–55–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 622

RIN 0648–AS65

Fisheries of the Caribbean, Gulf, and South Atlantic; Aquaculture

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

ACTION: Supplemental Notice of Intent (NOI) to prepare a supplement to the final programmatic environmental impact statement (SFPEIS); request for comments.

SUMMARY: The Gulf of Mexico Fishery Management Council (Council) previously published a NOI for the Fishery Management Plan for Regulating Offshore Marine Aquaculture in the

Gulf of Mexico (FMP; formerly the Draft Generic Amendment to Gulf of Mexico Fishery Management Plans for Offshore Aquaculture) on September 2, 2004. A notice of availability for the draft programmatic environmental impact statement (PEIS) was published on September 12, 2008. On June 26, 2009, a notice of availability was published for the final PEIS.

This supplemental NOI is intended to inform the public of NMFS and the Council's decision to consider new information from the Deepwater Horizon (DWH) MC252 blowout. This information is needed in order to consider potential changes to the environment linked to the DWH blowout and determine if and how such changes may affect the actions and alternatives analyzed in the FMP. Comments are being solicited on the range of issues related to the DWH blowout to be addressed in the SFPEIS.

DATES: Written comments on the range of issues to be addressed in the SFPEIS will be accepted until February 25, 2013.

ADDRESSES: You may submit comments on the supplemental NOI identified by NOAA–NMFS–2008–0233 by any of the following methods:

- *Electronic Submissions:* Submit all electronic public comments via the Federal e-Rulemaking Portal: *http://www.regulations.gov.* Go to *www.regulations.gov/#!docketDetail;D=NOAA-NMFS-2008-0233,* click the ''Comment Now!'' icon, complete the required fields, and enter or attach your comments.
- *Mail:* Submit written comments to Jess Beck, Southeast Regional Office, NMFS, 263 13th Avenue South, St. Petersburg, FL 33701.

Instructions: Comments sent by any other method, to any other address or individual, or received after the end of the comment period, may not be considered by NMFS. All comments received are a part of the public record and will generally be posted for public viewing on *www.regulations.gov* without change. All personal identifying information (*e.g.,* name, address, etc.), confidential business information, or otherwise sensitive information submitted voluntarily by the sender will be publicly accessible. NMFS will accept anonymous comments (enter ''N/A'' in the required fields if you wish to remain anonymous). Attachments to electronic comments will be accepted in Microsoft Word, Excel, or Adobe PDF file formats only.

Electronic copies of the FMP, which includes a final programmatic environmental impact statement (FPEIS), an initial regulatory flexibility analysis (IRFA), and a regulatory impact review (RIR) may be obtained from the Southeast Regional Office Web site at *http://sero.nmfs.noaa.gov/sf/AquacultureHomepage.htm* or may be downloaded from the Council's Web site at *http://gulfcouncil.org/fishery_management_plans/aquaculture_management.php.*

FOR FURTHER INFORMATION CONTACT: Jess Beck, 727–824–5301, email: *Jess.Beck@noaa.gov.*

SUPPLEMENTARY INFORMATION: Aquaculture in the Gulf is managed under the FMP. The FMP was prepared by the Council and is implemented through regulations at 50 CFR part 622 under the authority of the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act).

Background

Worldwide demand for protein is increasing and fisheries production will not likely be adequate to supply the world demand for fisheries products without supplementation through aquaculture. In the United States, approximately 84 percent of all seafood consumed is currently imported from other countries, creating an annual trade deficit of over 9 billion dollars. It is estimated by 2025, two million more metric tons of seafood will be needed over and above what is consumed today. Commercial wild-capture fishery production has remained stable or declined in recent decades, due to overfishing and increasingly stringent management restrictions.

Aquaculture is one method to meet current and future demands for seafood. Prior to the FMP, there was no process for accommodating commercial-scale offshore aquaculture in Federal waters of the Gulf of Mexico (Gulf), other than live rock aquaculture which is authorized under Amendments 2 and 3 to the Fishery Management Plan for Coral and Coral Reefs of the Gulf. NMFS may issue an exempted fishing permit (EFP) to conduct offshore aquaculture in Federal waters; however, an EFP is of limited duration and is not intended for commercial production of fish and shellfish. The Council developed the FMP under the authority of the Magnuson-Stevens Act to authorize the development of commercial aquaculture operations in Federal waters of the Gulf. The FMP was initiated to provide a comprehensive framework for authorizing and regulating offshore aquaculture activities. The FMP also establishes a programmatic approach for evaluating the potential impacts of proposed aquaculture operations in the Gulf.

A NOI for the FMP was published on September 2, 2004 (69 FR 53682). A notice of availability for the draft PEIS was published on September 12, 2008 (73 FR 53001). On June 26, 2009, a notice of availability was published for the final PEIS (74 FR 30569). The FMP entered into effect by operation of law on September 3, 2009.

On April 20, 2010, an explosion occurred on the DWH MC252 oil rig, resulting in the release of an estimated 4.9 million bbl (779 million L) of oil into the Gulf. In addition, 1.84 million gal (6.96 million L) of Corexit 9500A dispersant were applied as part of the effort to constrain the spill. The well was successfully capped in a coordinated effort on July 15, 2010.

This supplemental NOI is intended to inform the public of NMFS and the Council's decision to consider new information from the DWH MC252 blowout. This information is needed in order to consider potential changes to the environment linked to the DWH blowout and determine if and how such changes may affect the actions and alternatives analyzed in the FMP. Comments are being solicited on the range of issues related to the DWH blowout to be addressed in the SFPEIS. Availability of the draft SFPEIS will be published at a later date in the **Federal Register**.

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

Dated: January 18, 2013.

James P. Burgess,

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

[FR Doc. 2013–01562 Filed 1–24–13; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 622

RIN 0648–BC66

Fisheries of the Caribbean, Gulf of Mexico, and South Atlantic; Reef Fish Fishery of the Gulf of Mexico; Amendment 37

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

ACTION: Notice of availability; request for comments.

SUMMARY: The Gulf of Mexico Fishery Management Council (Council) has

submitted Amendment 37 to the Fishery Management Plan for the Reef Fish Resources of the Gulf of Mexico (FMP) for review, approval, and implementation by NMFS. Amendment 37 proposes to modify the gray triggerfish rebuilding plan; revise the commercial and recreational sector's annual catch limits (ACLs) and annual catch targets (ACTs) for gray triggerfish; revise the recreational sector accountability measures (AMs) for gray triggerfish; revise the gray triggerfish recreational bag limit; establish a commercial trip limit for gray triggerfish; and establish a fixed closed season for the gray triggerfish commercial and recreational sectors. The intent of Amendment 37 is to end overfishing of gray triggerfish and help achieve optimum yield (OY) for the gray triggerfish resource in accordance with the requirements of the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act).

DATES: Written comments must be received on or before March 26, 2013.

ADDRESSES: You may submit comments on this document, identified by ''NOAA–NMFS–2012–0199'', by any of the following methods:

• *Electronic Submission:* Submit all electronic public comments via the Federal e-Rulemaking Portal. Go to *www.regulations.gov/#!docketDetail;D=NOAA-NMFS-2012-0199,* click the ''Comment Now!'' icon, complete the required fields, and enter or attach your comments.

• *Mail:* Submit written comments to Rich Malinowski, Southeast Regional Office, NMFS, 263 13th Avenue South, St. Petersburg, FL 33701.

Instructions: Comments sent by any other method, to any other address or individual, or received after the end of the comment period, may not be considered by NMFS. All comments received are a part of the public record and will generally be posted for public viewing on *www.regulations.gov* without change. All personal identifying information (*e.g.,* name, address, etc.), confidential business information, or otherwise sensitive information submitted voluntarily by the sender will be publicly accessible. NMFS will accept anonymous comments (enter ''N/A'' in the required fields if you wish to remain anonymous). Attachments to electronic comments will be accepted in Microsoft Word, Excel, or Adobe PDF file formats only.

Electronic copies of the amendment may be obtained from the Southeast Regional Office Web site at *http://sero.nmfs.noaa.gov.*

FOR FURTHER INFORMATION CONTACT: Rich Malinowski, Southeast Regional Office, NMFS, telephone 727–824–5305; email: *rich.malinowski@noaa.gov.*

SUPPLEMENTARY INFORMATION: The reef fish fishery of the Gulf of Mexico (Gulf) is managed under the FMP. The FMP was prepared by the Council and is implemented through regulations at 50 CFR part 622 under the authority of the Magnuson-Stevens Act. The Magnuson-Stevens Act also requires that NMFS, upon receiving a plan or amendment, publish an announcement in the **Federal Register** notifying the public that the plan or amendment is available for review and comment. All gray triggerfish weights discussed in this proposed rule are in round weight.

Background

The Magnuson-Stevens Act requires NMFS and regional fishery management councils to prevent overfishing and achieve, on a continuing basis, the OY from federally managed fish stocks. These mandates are intended to ensure fishery resources are managed for the greatest overall benefit to the nation, particularly with respect to providing food production and recreational opportunities, and protecting marine ecosystems. To further this goal, the Magnuson-Stevens Act requires fishery managers to specify their strategy to rebuild overfished stocks to a sustainable level within a certain time frame, to minimize bycatch and bycatch mortality to the extent practicable, and to establish AMs for a stock to ensure ACLs are not exceeded. Amendment 37 addresses these issues for gray triggerfish.

Status of the Gray Triggerfish Stock

The last Southeast Data, Assessment, and Review (SEDAR) benchmark stock assessment for gray triggerfish was completed in 2006 (SEDAR 9). SEDAR 9 indicated that the gray triggerfish stock was both overfished and possibly undergoing overfishing. Subsequently, Amendment 30A to the FMP established a gray triggerfish rebuilding plan beginning in the 2008 fishing year (73 FR 38139, July 3, 2008). In 2011, a SEDAR update stock assessment for gray triggerfish determined that the gray triggerfish stock was still overfished and was additionally undergoing overfishing. The 2011 update assessment indicated the 2008 gray triggerfish rebuilding plan had not made adequate progress toward ending overfishing and rebuilding the stock. NMFS informed the Council of this determination in a letter dated March 13, 2012. NMFS also requested that the Council work to end overfishing of gray triggerfish immediately and to revise the gray triggerfish stock rebuilding plan.

As a way to more quickly implement measures to end overfishing and rebuild the stock, the Council requested and NMFS implemented a temporary rule to reduce the gray triggerfish commercial and recreational ACLs and ACTs (77 FR 28308, May 14, 2012). The temporary rule also established an in-season AM for the gray triggerfish recreational sector to be more consistent with the commercial sector AMs and provide for an additional level of protection to ensure that the recreational ACL is not exceeded and that the risk of overfishing is reduced. These interim measures were then extended through May 15, 2013, to ensure that the more permanent measures being developed through Amendment 37 could be implemented without a lapse in these more protective management measures (77 FR 67303, November 9, 2012).

Actions Contained in Amendment 37

Amendment 37 proposes to modify the gray triggerfish rebuilding plan, revise the commercial and recreational sector's ACLs and ACTs for gray triggerfish (the commercial ACT is expressed as the commercial quota in the regulatory text), revise the recreational sector AMs for gray triggerfish, revise the gray triggerfish recreational bag limit, establish a commercial trip limit for gray triggerfish, and establish a fixed closed season for the gray triggerfish commercial and recreational sectors.

Modifications to the Gray Triggerfish Rebuilding Plan

Amendment 37 would revise the rebuilding plan for gray triggerfish. The gray triggerfish stock is currently in the 5th year of a rebuilding plan that began in 2008. Amendment 37 would modify the rebuilding plan in response to the results from the 2011 SEDAR 9 Update and the Council's subsequent Scientific and Statistical Committee (SSC) review and recommendations for the gray triggerfish allowable biological catch (ABC). The modified rebuilding plan would be based on a constant fishing mortality rate that does not exceed the fishing mortality rate at OY.

ACLs and ACTs

Amendment 37 would revise the ACLs for the gray triggerfish commercial and recreational sectors. Amendment 37 would also revise the ACTs (commercial ACT expressed as a quota in the regulatory text) for both sectors.

The Council's SSC reviewed the gray triggerfish 2011 SEDAR 9 Update. The SSC recommended that the ABC for gray

triggerfish for the 2012 and 2013 fishing years be set at 305,300 lb (138,346 kg). Based on this recommendation, the commercial and recreational ACLs and ACTs for the gray triggerfish need to be updated.

In Amendment 30A to the FMP, the Council established a 21 percent commercial and 79 percent recreational allocation of the gray triggerfish ABC (73 FR 38139, July 3, 2008). These allocations are used to set the commercial and recreational sector-specific ACLs. The ABC recommended by the SSC is 305,300 lb (138,482 kg) and the combined sector ACLs are equal to the ABC. Based on the allocations established in Amendment 30A to the FMP, Amendment 37 would set a reduced commercial ACL of 64,100 lb (29,075 kg), and a reduced recreational ACL of 241,200 lb (109,406 kg).

The Generic Annual Catch Limit Amendment developed by the Council and implemented by NMFS (76 FR 82044, December 29, 2011) established a standardized procedure to set sector-specific ACTs based on the ACLs. ACTs are intended to account for management uncertainty and provide a buffer that better ensures a sector does not exceed its designated ACL. The Council chose to use this procedure, which resulted in a 5 percent buffer between the commercial ACL and ACT, and a 10 percent buffer between the recreational ACL and ACT. Therefore, Amendment 37 would set the commercial ACT (commercial quota) at 60,900 lb (27,624 kg), and the recreational ACT at 217,100 lb (98,475 kg). The proposed ACLs and ACTs in Amendment 37 are the same as those currently in place as implemented through the temporary rule for gray triggerfish (77 FR 28308, May 14, 2012). The current commercial gray triggerfish quota functions as the commercial ACT.

AMs

Amendment 37 proposes to modify the gray triggerfish recreational sector AMs. Currently, the AM for the recreational sector is triggered if the recreational ACL is exceeded and requires NMFS to reduce the length of the following year's fishing season by the amount necessary to ensure that recreational landings do not exceed the recreational ACT during the following year. Amendment 37 would replace this AM with an in-season AM, in the form of a recreational season closure that would prohibit the recreational harvest of gray triggerfish after the recreational ACT is reached or projected to be reached. This in-season AM would provide an additional level of protection to help ensure that the recreational ACL is not exceeded and reduce the risk of overfishing. Amendment 37 would also add an overage adjustment that would apply if the recreational sector ACL is exceeded and gray triggerfish are overfished. This post-season AM would reduce the recreational ACL and ACT for the following year by the amount of the ACL overage in the prior fishing year, unless the best scientific information available determines that a greater, lesser, or no overage adjustment is necessary.

Commercial Trip Limit

Currently, there is no trip limit for the commercial sector. Amendment 37 would establish a commercial trip limit for gray triggerfish of 12 fish. This trip limit would allow commercial reef fish fisherman to harvest their incidental catch of gray triggerfish. This trip limit would be applicable until the commercial ACT (commercial quota) is reached or projected to be reached during a fishing year and the commercial sector is closed.

Seasonal Closure of the Commercial and Recreational Sectors

Amendment 37 would establish a seasonal closure of the gray triggerfish commercial and recreational sectors in the Gulf from June through July, each year. This fixed seasonal closure would occur during gray triggerfish peak spawning season and during the period with the highest percentage of recreational landings.

Recreational Bag Limit

Gray triggerfish currently are part of the 20-fish aggregate reef fish recreational bag limit. As such, there is currently no specific limit for recreational gray triggerfish landings as long as the total is 20 fish or less. Amendment 37 would establish a 2-fish gray triggerfish recreational bag limit within the 20-fish aggregate reef fish bag limit. This recreational bag limit would be applicable until the recreational ACT is reached or projected to be reached during a fishing year and the recreational sector is closed.

Proposed Rule for Amendment 37

A proposed rule that would implement Amendment 37 has been drafted. In accordance with the Magnuson-Stevens Act, NMFS is evaluating Amendment 37 to determine whether it is consistent with the FMP, the Magnuson-Stevens Act, and other applicable law. If the determination is affirmative, NMFS will publish the proposed rule in the **Federal Register** for public review and comment.

Consideration of Public Comments

The Council submitted Amendment 37 for Secretarial review, approval, and implementation. NMFS' decision to approve, partially approve, or disapprove Amendment 37 will be based, in part, on consideration of comments, recommendations, and information received during the comment period on this notice of availability.

Public comments received by 5 p.m. eastern time, on March 26, 2013, will be considered by NMFS in the approval/disapproval decision regarding Amendment 37.

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

Dated: January 17, 2013.

Kara Meckley,

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

[FR Doc. 2013–01431 Filed 1–24–13; 8:45 am]

BILLING CODE 3510–22–P

Notices

Federal Register
Vol. 78, No. 17
Friday, January 25, 2013

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

Food and Nutrition Service

Agency Information Collection Activities: Proposed Collection; Comment Request—Supplemental Nutrition Assistance Program Forms: Applications, Periodic Reporting and Notices

AGENCY: Food and Nutrition Service, USDA.

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, this Notice invites the general public and other public agencies to comment on proposed information collections. This collection is an extension, without change, of a currently approved burden for the applications, periodic reporting and notices burden calculations for the Supplemental Nutrition Assistance Program (SNAP).

DATES: Written comments must be submitted on or before March 26, 2013 to be assured consideration.

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

Comments may be sent to Angela Kline, Chief, Certification Policy Branch, Program Development Division, Food and Nutrition Service, U.S. Department of Agriculture, 3101 Park Center Drive, Room 812, Alexandria, VA 22302. Comments may also be submitted via fax to the attention of Angela Kline at 703–305–2486. Comments will also be accepted through the Federal eRulemaking Portal. Go to *http://www.regulations.gov* and follow the online instructions for submitting comments electronically.

All comments will be open for public inspection during regular business hours (8:30 a.m. to 5:00 p.m., Monday through Friday) at the office of the Food and Nutrition Service, U.S. Department of Agriculture, 3101 Park Center Drive, Room 800, Alexandria, Virginia 22302.

All comments will be summarized and included in the request for Office of Management and Budget approval of the information collection. All comments will become a matter of public record.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of this information collection should be directed to Angela Kline at 703–305–2495.

SUPPLEMENTARY INFORMATION:

Title: Supplemental Nutrition Assistance Program Forms: Applications, Periodic Reporting and Notices.

OMB Number: 0584–0064.

Form Number: None.

Expiration Date: March 31, 2013.

Type of Request: Extension of a currently approved collection.

Abstract: This notice extends the Applications, Periodic Reporting and Notices burden for the Supplemental Nutrition Assistance Program (SNAP). The Federal procedures for implementing the application and certification procedures in the Act are in Parts 271, 272 and 273 of the Title 7 of the Code of Federal Regulation. Part 271 contains general information and definitions, Part 272 contains requirements for participating State agencies and Part 273 contains procedures for the certification of eligible households.

FNS is currently undertaking an extensive review of the burden associated with the application and certification procedures for SNAP. The Agency anticipates releasing a revised Notice within 2013, to reflect the results of this research. This Notice serves to extend the existing burden estimates.

Reporting Burden

Application To Participate in SNAP

Section 273.2 of the SNAP regulations requires that each applicant household complete and file an application, either in paper or electronic form. The application contains detailed information about each household member and their income, employment, shelter expenses, medical expenses (if applicable) and resources that is necessary to determine if the applicant household is entitled to assistance. The application process also includes verification of certain information provided on the application and an interview where the State agency worker asks a series of questions and clarifies information from the application.

Application for SNAP Recertification

Section 273.10(f) of the regulations requires that all households participating in SNAP be assigned certification periods of a definite length. Under section 273.14, in order to continue participating in SNAP, ongoing households must apply for recertification prior to the end of their current certification periods. The recertification process also includes the verification of information, if it has changed, and an interview.

Periodic Reports

Monthly Reports—Under section 273.21, households subject to monthly reporting are required to submit reports of their circumstances on a monthly basis. The report requests the information necessary to determine eligibility and benefits of affected households. Households subject to monthly reporting are assigned certification periods of 12 months and submit 11 monthly reports a year plus the application for recertification.

Quarterly Reports—Per section 273.12 (a)(4), State agencies may require households to report changes on a quarterly basis. Since households are not required to submit a separate quarterly report when they submit an application for recertification, the quarterly report is submitted 3 times a year.

Simplified or Periodic Reports—Section 273.12(a)(5), allows State agencies to establish a simplified reporting (SR) system, under which most households are only required to

report when the household's gross monthly income exceeds 130 percent of the Federal poverty level or when an able-bodied adult without dependents (ABAWD) does not meet the minimum weekly work hour requirement. State agencies have the option of including most households assigned a certification period of at least 4 months in their SR systems; households assigned certification periods greater than 6 months must submit a periodic report by the sixth month. State agencies may opt to require households to submit periodic reports at intervals from every 4 months to every 6 months. SR households that are certified for longer than 6 months must submit a periodic report.

Change Reports—Under section 273.12(a), households not subject to one of the periodic reporting systems (monthly, quarterly reporting or simplified reporting) are assigned to a reporting system commonly referred to as change or incident reporting. Households assigned to change reporting must report most changes in household circumstances within 10 days from the date that the change becomes known to the household.

Notices

Notice of Eligibility or Denial—This notice is used by State agencies to advise households of the disposition of their application for initial certification or recertification. If the household is denied, the notice contains the reason(s) for the denial and advises the household of its right to appeal.

Notice of Late/Incomplete Report—This notice is used by State agencies to advise ongoing households when they have failed to submit the required monthly, quarterly or semiannual report altogether or, if the household submitted an incomplete report.

Notice of Missed Interviews (NOMI)—As the name implies, the NOMI is issued by State agencies to households that fail to appear for their scheduled initial or recertification interview, or in the case of households subject to telephone interviews, fail to contact the State agency or receive telephone calls initiated by the local office. The household may respond to the notice by requesting that the interview be rescheduled.

Notice of Expiration (NOE)—State agencies are required to mail a NOE to currently participating households at least 30 days prior to the expiration of their current certification period. The NOE is usually accompanied by the Application for Recertification. The NOE advises the household that its certification period is expiring and that to continue receiving assistance; the household must file its application for recertification in a timely manner.

Notice of Adverse Action (NOAA)—The NOAA is issued by State agencies to participating households whose benefits will be reduced or terminated as the result of a change in household circumstances.

Adequate Notice—An adequate notice is sent to households by the State agency when the household's benefits are reduced or terminated based on information reported by the household itself. Adequate notices can also be used when mass changes occur. Mass changes are certain changes initiated by the State or Federal government that may affect the entire caseload or significant portions of the caseload.

Request for Contact (RFC)—The RFC notice is used to contact the household when the State agency receives information regarding a potential change in a household's eligibility or benefits and such information is not sufficient for the State agency to determine exactly how the household's status would be affected.

Transitional Benefits Notice (TN)—State agencies that opt to provide transitional benefits must provide eligible families a TN that includes detailed and specific information about the household's transitional benefits and rights. Because the TN and the NOE are very similar, the reporting burden associated with the TN is included in the reporting burden for the NOE.

Recordkeeping

Case Records—State agencies must keep records as may be necessary to ascertain whether the program is being conducted in compliance with the Act and the regulations. The Act and Section 272.1(f) of the regulations require States to maintain such records for a period of 3 years from date of origin. States are allowed to store records using automated retrieval systems and other features that do not rely exclusively on the collection and retention of paper records.

Duplicate Participation System—Section 272.4(e) of the regulations require State agencies to search their files for duplicates in order to prevent individuals from receiving benefits in more than one household and to prevent households from receiving benefits in more than one jurisdiction within the State. The Act further requires State agencies to establish a system that will prevent an individual from receiving both food coupons and cash benefits in lieu of coupons in an SSI cash-out State or under a cash-out demonstration project.

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(a) Affected Public	(b) Description of Collection Activity	(c) No. Respondents	(d) No. Responses Per Respondent	(e) Total Annual Responses (cxd)	(f) Hours Per Response	(g) Total Burden (exf)
Reporting						
Individuals	Application to participate in the FSP	10,967,909	1	10,967,909	0.320	3,509,731
Households	Application for Recertification	10,121,739	1	10,121,739	0.320	3,238,956
	Additional Application for Recertification affected by Final Rule 7 CFR 273.12(a)(5), formerly 7 CFR 273.12(a)(1)(vii)	3,940,307	1	3,940,307	0.134	526,425
	Monthly Report	142,506	11	1,567,566	0.120	188,108
	Quarterly Report	799,469	3	2,398,407	0.130	311,793
	Semiannual or Simplified Reporting	10,788,683	1	10,788,683	0.130	1,402,529
	Change Report	1,664,843	1	1,664,843	0.080	133,187
	Notice of Missed Interviews	1,693,242	1	1,693,242	0.020	33,865
	Notice of Adverse Action (NOAA)	47,696	1	47,696	0.020	954
	Adequate Notice	8,430	1	8,430	0.020	169
	Request for Contact	763,132	1	763,132	0.030	22,894
	Deepwater HorizonReporting	10,967,909	0	1,104,000	0.004	4,600
	Total Individual/Household Burden	**14,908,216**	**3.02**	**45,065,954**	**0.208**	**9,373,211**
State Agencies	Application to participate in the FSP	53	206,942	10,967,909	0.320	3,509,731
	Application for Recertification	53	190,976	10,121,739	0.320	3,238,956
	Additional Application for Recertification affected by Final Rule 7 CFR 273.12(a)(5), formerly 7 CFR 273.12(a)(1)(vii)	50	78,809	3,940,323	0.184	724,154
	Monthly Reports	53	29,577	1,567,566	0.180	282,162
	Quarterly Report	1	2,398,407	2,398,407	0.200	479,681
	Semiannual or Simplified Report	47	229,546	10,788,683	0.180	1,941,963
	Change Report	53	31,412	1,664,843	0.180	299,672
	Notice of Eligibility or Denial	53	397,918	21,089,658	0.030	632,690
	Notice of Late Incomplete Report	53	663	35,125	0.030	1,054
	Notice of Missed Interviews	53	35,498	1,881,380	0.020	37,628
	Notice of Expiration of Certification	53	190,976	10,121,739	0.030	303,652
	Notice of Adverse Action (NOAA)	53	17,998	953,915	0.030	28,617
	Adequate Notice	53	3,976	210,752	0.030	6,323
	Request for Contact	53	17,998	953,915	0.030	28,617
	OMB Control Number: 0584-0083, 0584-0496	53	5	274	1.007	276
	Total State Agency Reporting	**53**	**1,447,099**	**76,696,228**	**0.150**	**11,515,176**

(a) Affected Public	(b) Description of Recordkeeping Activity	(c) No. Record-keepers	(d) No. Records Per Record-keeper	(e) Total Annual Records (cxd)	(f) Hours Per Record	(g) Total Recordkeeping Burden (exf)
Recordkeeping						
Local agencies	Case Files	2724	46693	127192304	0.030	3815769.121
	Monitoring Duplicate Participation	2724	17098	46576077.01	0.004	194066.677
	Total Recordkeeping	**2724**	**63,792**	**173,768,381**	**0.023**	**4009835.798**

Summary of Estimated Burden

Affected Public: State and local government agencies administering SNAP and Individuals/Households.

Estimated Number of Respondents: 14,910,993.

Estimated Number of Responses per Respondent: 19.820.

Estimated Total Number of Annual Responses: 295,530,563.

Estimated Hours per Response: .0842.

Estimated Total Annual Burden: 24,898,223.

Dated: January 18, 2013.

Audrey Rowe,

Administrator, Food and Nutrition Service.

[FR Doc. 2013–01550 Filed 1–24–13; 8:45 am]

BILLING CODE 3410–30–C

DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

[Docket No. FSIS–2012–0049]

Ongoing Equivalence Verifications of Foreign Food Regulatory Systems

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Notice.

SUMMARY: The Food Safety and Inspection Service (FSIS) is describing the new methodology it is employing to conduct ongoing equivalence verifications of the regulatory systems of countries that export meat, poultry, or processed egg products to the United States. FSIS uses a three-part approach that includes: (1) Document reviews, (2) on-site system audits, and (3) port-of-entry (POE) reinspections. FSIS conducts document reviews at least yearly. FSIS conducts on-site system audits at least once every three years. FSIS determines the scope and

frequency of on-site systems audits and POE reinspections through analysis of the results of its document reviews and an assessment of a country's performance. This performance-based approach allows FSIS to direct its resources to foreign food regulatory systems that pose greater risk to public health compared to others; make its international program more consistent with its domestic inspection system; and improve the linkage between POE reinspections and on-site audits. As a result, FSIS is able to effectively prevent unsafe imports from entering this country.

DATES: Comments on this notice should be received by March 26, 2013.

ADDRESSES: FSIS invites interested persons to submit comments on this notice. Comments may be submitted by one of the following methods:

- *Federal eRulemaking Portal:* This Web site provides the ability to type short comments directly into the comment field on this Web page or attach a file for lengthier comments. Go to *http://www.regulations.gov.* Follow the on-line instructions at that site for submitting comments.
- *Mail, including CD–ROMs:* Send to Docket Clerk, U.S. Department of Agriculture, Food Safety and Inspection Service, Patriots Plaza 3, 1400 Independence Avenue SW., Mailstop 3782, Room 8–163A, Washington, DC 20250–3700.
- *Hand- or Courier-Delivered Submittals:* Deliver to Patriots Plaza 3, 355 E. Street SW., Room 8–163A, Washington, DC 20250–3700.

Instructions: All items submitted by mail or electronic mail must include the Agency name and docket number FSIS–2012–0049. Comments received in response to this docket will be made available for public inspection and posted without change, including any personal information, to *http://www.regulations.gov.*

Docket: For access to background documents or comments received, go to the FSIS Docket Room at Patriots Plaza 3, 355 E. Street SW., Room 8–164, Washington, DC 20250–3700 between 8:00 a.m. and 4:30 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Mary Stanley, Director, International Policy Division, Office of Policy and Program Development, FSIS, USDA, South Agriculture Building, Room 2925, 1400 Independence Avenue SW., Washington, DC 20250; Telephone: (202) 720–0287, Fax: (202) 720–4929 or Email: *mary.stanley@fsis.usda.gov.*

SUPPLEMENTARY INFORMATION:

Background

The Federal Meat Inspection Act (FMIA) (21 U.S.C. 620) and the Poultry Products Inspection Act (PPIA) (21 U.S.C. 466) prohibit the importation of meat and poultry products into the United States if such products are adulterated or misbranded, and unless they comply with all the inspection and other provisions of the Acts and regulations that are applied to U.S. domestic products. The Egg Products Inspection Act (EPIA) (21 U.S.C. 1046) prohibits the importation of egg products unless they have been processed under an approved continuous inspection system of the government of the foreign country of origin and comply with all other provisions of the Act and regulations that apply to U.S. domestic products.

The USDA has had a comprehensive program to assess foreign meat and poultry establishments since 1967. Initially, the Department inspected certified foreign establishments to determine whether they were ''at least equal to'' comparable U.S. establishments. Department officials were stationed in Washington, DC, Argentina, Costa Rica, Australia, New Zealand, Denmark, Germany, Belgium, and Canada. This program continued until 1988, when it was substantially revised, and all overseas auditors were recalled to Washington, DC. On-site establishment inspections continued under the revised program based upon past on-site audit findings and POE reinspection results.

In 1994, the concept of equivalence was introduced in the *Agreement on the Application of Sanitary and Phytosanitary Measures* (the SPS Agreement), which appears in the Final Act of the Uruguay Round of Multilateral Trade Negotiations signed in Marrakech. The SPS Agreement became effective in January 1995, concurrently with establishment of the World Trade Organization (WTO), which superseded the General Agreement on Tariffs and Trade (GATT) as the umbrella organization for international trade. Because the U.S. is a signatory to the SPS Agreement and a member of the WTO, FSIS amended its regulations to require foreign meat and poultry food regulatory systems to be ''equivalent to'' comparable U.S. requirements (60 FR 38667; July 28, 1995).

In the late-1990's, FSIS shifted the emphasis of its on-site audits from inspecting establishments to assessing a country's food regulatory system. This change was announced in the **Federal Register** on December 17, 1999 (64 FR 70690; December 17, 1999). Under this approach, the scope of on-site audits was broadened to include country laws and documents related to program implementation; records of establishment operations, inspection results, and enforcement activities; chemical residue controls from farm to slaughter; microbiological and chemical testing programs; laboratory support, sampling programs, and sampling and testing methodologies; and other U.S. import requirements such as pathogen reduction and HACCP programs.

Statutory requirements for equivalence are set forth in 9 CFR 327.2 for meat products, 9 CFR 381.196 for poultry products, and 9 CFR 590.910 for egg products. FSIS has categorized these requirements into six ''equivalence components.'' Specifically, FSIS evaluates a country's national government to ensure that it is imposing equivalent requirements with respect to: (1) Government oversight, (2) statutory authority and food safety regulations, (3) sanitation, (4) hazard analysis and critical control points (HACCP), (5) chemical residues, and (6) microbiological testing programs. This comprehensive process is described fully on the FSIS Web site at *http://www.fsis.usda.gov/pdf/eqprocess.pdf.*

Any country can apply for eligibility to export meat, poultry, or egg products to the U.S. Based on its review of the information and documentation that the country submits, FSIS decides whether the foreign country's food regulatory system meets all U.S. import requirements in the same or an equivalent manner and cumulatively provides the same level of public health protection as that attained domestically. If so, FSIS plans an on-site audit of the entire foreign meat, poultry, or egg products regulatory system. When both the document analysis and on-site audit review show that the country meets U.S. requirements, FSIS publishes a proposed rule in the **Federal Register** that announces the results of the first two steps and proposes to add the country to its list of eligible exporting countries in the regulations. After analysis of public comments, FSIS makes a final decision about whether the country's system is equivalent based upon all available information and publishes a final rule in the **Federal Register** announcing its determination on country eligibility.

Once a foreign country's inspection system is deemed equivalent,[1] FSIS

[1] FSIS regulations list 46 countries as eligible to export meat, nine countries as eligible to export poultry, and two countries as eligible to export egg products to the United States (see 9 CFR 327.2(b),

continues to evaluate the country's inspection system to ensure equivalence is maintained. FSIS performs this activity through a three-part process, involving: (1) Document reviews, (2) on-site system audits, and (3) POE reinspections.

In 2008, FSIS held a public meeting with the National Advisory Committee on Meat and Poultry Inspection (NACMPI) to review and discuss international equivalence and the approach to verifying the equivalence of foreign food regulatory systems as the means of ensuring the safety of imported food products (73 FR 48190; August 18, 2008). FSIS requested NACMPI's guidance on: (1) Whether elements of the ''triad of protection'' (*i.e.,* document reviews, on-site audits, and POE reinspections) should be changed; (2) Whether regulatory information and compliance history from foreign countries should affect audits and re-inspections; and (3) Whether the scope and frequency of on-site audits and POE re-inspections should be adjusted based on the capability of a country to share useful regulatory information and compliance history.

After reviewing all comments and materials presented at the meeting, NACMPI recommended that FSIS maintain its three-part approach to equivalence but direct Agency resources according to the relative risks and historical compliance presented by each foreign food regulatory system. NACMPI stated that considering the foreign food regulatory system's past performance provides a more objective and efficient method of allocating FSIS resources to address food safety risks and public health concerns than conducting annual on-site audits. NACMPI also recommended that FSIS standardize its methods for the collection of information from foreign governments, collaborate with the Codex Alimentarius Commission (CODEX) concerning the Codex Committee on Food Import and Export Inspection and Certification Systems' new work on guidance for on-site audits,[2] and incorporate specific elements into its ongoing verification activities. These specific elements included the use of the three-tiered approach based on risk. With respect to audits, NACMPI recommended the standardized application of on-site audit criteria and an historical evaluation of the trading country's on-site audit outcomes. As for document reviews, it recommended an assessment of the exporting country's on-going ability and willingness to share data, as well as the quality of data shared. Finally, with respect to POE re-inspections, NACMPI recommended the targeting of high-risk product and high-risk imports for sampling and other verification activities during reinspection. NACMPI also recommended that FSIS maintain open communication with all involved in the import process.

New Approach

In 2009, in response to NACMPI's recommendations, FSIS modified its three-part method for verifying the equivalence of foreign food regulatory systems by developing a performance-based approach for determining the scope and frequency of its on-site systems audits and POE reinspections. Thus, FSIS transitioned from an annual on-site audit to less frequent on-site audits based on performance. FSIS makes information about all on-site audits available to the public on its Web site.

It took FSIS some time to work through the mechanics of this transition. Fully training its auditors and other aspects of the transition occurred over a period of years rather than on a fixed date. Preparation of this notice to announce this transition also took longer than contemplated. Now that the transition is fully in place, FSIS is announcing it to the public.

Document Reviews

As part of the transition, FSIS developed the Self-Reporting Tool (SRT), which structures the criteria used to assess each component of initial and on-going equivalence through a series of questions. FSIS uses the SRT to collect information for the Agency's document review of a foreign country's food safety system. FSIS conducts these document reviews at least annually. Along with responses to the questions in the SRT, FSIS asks exporting countries to submit their inspection system laws, regulations, and policy issuances to support their answers. FSIS asks countries to update this information as changes in U.S. domestic policy warrant the need for additional information from foreign governments to demonstrate that an equivalent inspection system is being maintained, or as changes are made in the foreign country's system. Also through the SRT, FSIS requests that foreign governments report what actions they take when non-compliant products are shipped. The SRT affords countries the opportunity to advise FSIS of any new controls they have implemented since their last submission (*e.g.,* microbial baseline studies, ongoing risk assessments, internal audit programs) to demonstrate the effectiveness of their food safety regulatory systems.

The SRT represents a significant improvement over the collection mechanisms used by FSIS in the past. FSIS previously used the Self-Assessment Tool (SAT), which was limited to initial equivalence requests and not updated on a regular basis. Unlike the SAT, the SRT collects information for both the initial and ongoing equivalence verification processes. Doing so makes it easier for countries to update their information. In addition, it allows FSIS to standardize its collection of information. This standardization improves the quality of information that FSIS receives and, thus, improves FSIS's ability to evaluate a country's performance.

The SRT permits FSIS to identify key documents on which to evaluate system effectiveness and to assess any impacts that an administrative or legislative change has had on a foreign regulatory system. It also enables FSIS to monitor corrective actions that countries take in response to shipping non-compliant product to the U.S. The current and detailed information that the SRT provides allows FSIS to conduct more comprehensive assessments of foreign countries' food safety regulatory systems while remaining at USDA Headquarters in Washington, DC. These comprehensive assessments allow FSIS to use its resources more effectively and efficiently, both on and off site, while still ensuring the safety of imported products.

On-Site Systems Audits

Under this new approach, FSIS conducts on-site audits of countries eligible to export product to the U.S. at least once every three years. The new approach provides for at least the same level of public health protection as FSIS's previous approach with annual on-site audits. During an on-site systems audit, an FSIS auditor (or an audit team, when necessary) verifies that the national government is adequately implementing the country's food safety laws and regulations, and that through its oversight of its inspection personnel, the government is verifying that establishments' process controls (*e.g.,*

381.196(b), and 590.910(b)). However, some of these countries have outstanding issues that will require additional document submission and review, as well as on-site equivalence verification prior to resuming exports. In 2012, only 29 countries actively exported meat, poultry, and egg products to the United States. FSIS maintains a list of eligible countries, along with their status and whether they are approved to export meat, poultry, and egg products to the United States: *http://www.fsis.usda.gov/pdf/Countries_Products_Eligible_for_Export.pdf.*

[2] *Guidelines for the Design, Operation, Assessment and Accreditation of Food Import and Export Inspection and Certification* (CAC/GL 26–1997).

laboratory testing programs, sanitation standard operating procedures, and HACCP) are effective. When the FSIS auditor determines that controls are not being implemented as designed, and there is significant question as to whether the products produced are safe, unadulterated, and properly labeled and packaged, he or she takes appropriate action.

The frequency and scope of on-site audits are based on the results of FSIS's country performance assessment. The performance assessment focuses on each eligible country's overall food safety performance relative to the performance of other eligible countries. The first step in the assessment is a statistical analysis of compliance data from POE reinspections and previous on-site audits of the country's government offices, establishments, and laboratories. Because a single, composite measure cannot completely characterize a country's performance, FSIS incorporates a number of supplemental, qualitative factors into its assessment.

The supplemental factors are derived from the Codex Alimentarius Commissions' *Guidelines on the Judgment of Equivalence of Sanitary Measures associated with Food Inspection and Certification systems* (*CAC/GL 53–2003*), and the principles outlined in the joint Food and Agricultural Office of the United Nations (FAO) and World Health Organization (WHO) publication *Assuring Food Safety and Quality: Guidelines for Strengthening National Food Control Systems.*[3] These factors include: The results of audits, inspections, and field examinations conducted by FSIS and third countries; the use of risk analysis principles; the impact of organizational, structural, or administrative change in an exporting country's competent authority; the availability of contingency plans in the country for containing and mitigating the effects of food safety emergencies; the competent authority's willingness and ability to take appropriate actions to manage food safety incidents; and the effectiveness of foodborne disease surveillance systems. For each supplemental factor, FSIS assigns a level of advancement (LOA) to measure the foreign food regulatory system's ability to demonstrate compliance with that supplemental factor. FSIS assigns countries LOA levels 1, 2, or 3, with 3 being the highest level.

For example, one supplemental factor that FSIS evaluates is whether the Agency has knowledge that an exporting country applies risk analysis principles in its food safety system. A country that could not demonstrate that its risk management decisions are generally supported by a scientific risk assessment would receive a level one LOA. A country that could demonstrate that its risk management decisions are generally supported by scientific principles and evidence, including risk assessments, would receive a level two LOA. A country that could demonstrate that it consistently bases its risk management decisions on risk assessments would receive a level three LOA.

FSIS uses the statistical analysis results and the LOA assignments to characterize a country's recent food safety performance as well-performing, average-performing, or adequately-performing (*i.e.,* the country is eligible to export meat, poultry, and egg products to the U.S., but its performance has not reached the same level of confidence as that of its peers).

In general, countries that are performing well receive less frequent, more narrowly defined on-site audits, while ''adequately-performing'' countries receive more frequent and more comprehensive audits. FSIS selects the specific facilities to be audited (*i.e.,* government offices, establishments, and laboratories) by evaluating the volume of products that are produced, the relative hazards associated with those products, the government's compliance history, and previous POE reinspection results. When selecting establishments to visit during an on-site systems audit, FSIS directs its resources to establishments with larger production volumes, that produce product associated with a higher level of risk,[4] that produce product identified during previous on-site audits as being non-compliant, or that produce product for which there were positive microbiological or residue POE reinspection results.

As noted above, FSIS schedules on-site systems audits at a minimum frequency of once every three years. Under this approach, adequately performing countries receive audits every year, average-performing countries receive audits every two years, and countries that are performing well receive audits every three years. This frequency is based on NACMPI's recommendation that FSIS adopt a risk-informed approach. It is also based on FSIS's determination, in light of the audits that it has conducted over the years, that annual visits are not necessary to countries whose systems are performing in an average way or well. Visits every two or three years to these countries, given the other information that is available to FSIS, provide the necessary assurance that products of these foreign systems generally will be safe, unadulterated, and properly labeled and packaged. FSIS welcomes comment on this judgment.

In addition to the periodic audits, FSIS conducts more targeted ''for cause'' audits. The Agency conducts these audits in response to repetitive POE findings of public health significance or other conditions representing a lack of process control within a country's food safety system.

POE Reinspections

FSIS's POE activities monitor the effectiveness of exporting countries' inspection systems and overall food safety programs. All shipments of meat, poultry, and egg products that enter the U.S. must be presented to an FSIS inspector either at one of the approximately 130 official FSIS import facilities located at major ocean ports and land border crossings, or at an alternative location designated by the Agency (see 9 CFR 327.6, 381.199, and 590.925). FSIS reinspects every shipment for eligibility through certification by the national government, acceptable condition of the product, and labeling compliance. In addition, FSIS performs more detailed, random reinspections that include physical examination of product and of hermetically sealed containers, as well as microbiological and chemical testing. If products meet FSIS's standards, they are marked as ''Inspected and Passed'' and released into U.S. commerce. However, if FSIS identifies non-compliant products, it notifies both the government of the country that exported the products and the importer, marks the products as ''Refused Entry,'' and prohibits the products from entering U.S. commerce.

In order to focus its resources on the products that may pose the greatest threat to public health, FSIS uses the country performance assessment described above, and other factors such as product type and species, to determine the scope and frequency of the randomly assigned POE activities such as pathogen testing, food chemistry

[3] FAO/WHO. 2003. *Assuring Food Safety and Quality: Guidelines for Strengthening National Food Control Systems.* Food and Nutrition Paper No. 76. Food and Agriculture Organization of the United Nations. Rome, Italy (available at: *http://www.who.int/foodsafety/publications/fs_management/guidelines_foodcontrol/en/*).

[4] For example, raw ground beef is considered to be a ''riskier'' product than raw intact beef because the contaminated meat surface is broken into small fragments and spread throughout the ground product.

sampling, and species verification. In addition, on May 29, 2012, FSIS launched a comprehensive, Web-based data analytics system called the Public Health Information System (PHIS) as part of its efforts to collect, consolidate, and analyze data. PHIS builds upon the previous Automated Import Inspection System (AIIS) used by FSIS since 1979 through the increased integration of FSIS's existing data streams. PHIS also enables FSIS to collect information from external sources through an electronic interface with Customs and Border Protection's Automated Commercial Environment (ACE), including foreign government electronic certification systems. These enhancements further support a performance-based approach to POE reinspection.

As with AIIS, PHIS automatically schedules a more intensive reinspection (*i.e.,* increased follow-up sampling) of shipments from foreign establishments that produce products failing reinspection at POE, or products identified as the sole raw material source for ground beef that has tested positive for pathogenic STEC in the U.S. PHIS provides the ability to automatically adjust frequencies for pathogen testing, food chemistry sampling, and species verification based on a particular countries performance classification.

If non-compliant imported shipments are detected, FSIS works with the government of the country that exported the product to ensure that appropriate corrective actions are effected. As indicated previously, the foreign government reports through the SRT what actions it will take when non-compliant products are shipped. That information serves as the basis for FSIS's follow-up verification activities.

If a country makes any modifications to its inspection system, FSIS requires that the country update its responses to FSIS's SRT accordingly (see 9 CFR 327.2(a)(2)(iii), 381.196(a)(2)(iii), and 590.910(a)). Changes to the SRT may affect the results of a country's performance assessment, which then may affect the scope and frequency of subsequent equivalence verification activities. Thus, FSIS's performance-based approach improves the linkage between POE reinspections and on-site audits.

Furthermore, if repeated failures from a particular establishment indicate a loss of process control, and FSIS finds that the foreign country's corrective actions are not effective, FSIS will take action to suspend the eligibility of the establishment and may conclude that a ''for cause'' on-site audit is necessary. When multiple establishments in a country repeatedly fail POE reinspections, FSIS will consider elevating its action to a system level that could affect the eligibility of the foreign inspection system.

Additional Public Notification

FSIS will announce this notice on-line through the FSIS Web page located at *http://www.fsis.usda.gov/regulations_&_policies/Federal_Register_Notices/index.asp.*

FSIS also will make copies of this **Federal Register** publication available through the FSIS Constituent Update, which is used to provide information regarding FSIS policies, procedures, regulations, **Federal Register** notices, FSIS public meetings, and other types of information that could affect or would be of interest to constituents and stakeholders. The Update is communicated via Listserv, a free electronic mail subscription service for industry, trade groups, consumer interest groups, health professionals and other individuals who have asked to be included. The Update is available on the FSIS Web page. Through the Listserv and the Web page, FSIS is able to provide information to a much broader and more diverse audience.

In addition, FSIS offers an email subscription service which provides automatic and customized access to selected food safety news and information. This service is available at *http://www.fsis.usda.gov/News_&_Events/Email_Subscription/.* Options range from recalls to export information to regulations, directives and notices. Customers can add or delete subscriptions themselves, and have the option to password protect their accounts.

USDA Nondiscrimination Statement

The U.S. Department of Agriculture (USDA) prohibits discrimination in all its programs and activities on the basis of race, color, national origin, gender, religion, age, disability, political beliefs, sexual orientation, and marital or family status. (Not all prohibited bases apply to all programs.)

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To file a written complaint of discrimination, write USDA, Office of the Assistant Secretary for Civil Rights, 1400 Independence Avenue SW., Washington, DC 20250–9410 or call 202–720–5964 (voice and TTY). USDA is an equal opportunity provider and employer.

Done in Washington, DC, on January 18, 2013.

Alfred V. Almanza,

Administrator.

[FR Doc. 2013–01511 Filed 1–24–13; 8:45 am]

BILLING CODE 3410–DM–P

COMMISSION ON CIVIL RIGHTS

Agenda and Notice of Public Meetings of the Massachusetts Advisory Committee

Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights (Commission), and the Federal Advisory Committee Act (FACA), that a planning meeting of the Massachusetts Advisory Committee to the Commission will convene at 12:00 p.m. (ET) on Tuesday, February 12, 2013, at the McCarter and English Law Office, 265 Franklin Street, Boston, MA 02110. The purpose of the meetings are orientation and project planning.

Members of the public are entitled to submit written comments. The comments must be received in the regional office by Tuesday, March 12, 2013. Comments may be mailed to the Eastern Regional Office, U.S. Commission on Civil Rights, 1331 Pennsylvania Avenue, Suite 1150, Washington, DC 20425, faxed to (202) 376–7548, or emailed to *ero@usccr.gov.* Persons who desire additional information may contact the Eastern Regional Office at 202–376–7533.

Persons needing accessibility services should contact the Eastern Regional Office at least 10 working days before the scheduled date of the meeting.

Records generated from this meeting may be inspected and reproduced at the Eastern Regional Office, as they become available, both before and after the meeting. Persons interested in the work of this advisory committee are advised to go to the Commission's Web site, *www.usccr.gov,* or to contact the Eastern Regional Office at the above phone number, email or street address.

The meetings will be conducted pursuant to the provisions of the rules and regulations of the Commission and FACA.

Dated in Washington, DC, on January 22, 2013.

David Mussatt,

Acting Chief, Regional Programs Coordination Unit.

[FR Doc. 2013–01539 Filed 1–24–13; 8:45 am]

BILLING CODE 6335–01–P

DEPARTMENT OF COMMERCE

Submission for OMB Review; Comment Request

The Department of Commerce will submit to the Office of Management and Budget (OMB) for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. chapter 35).

Agency: U.S. Census Bureau.

Title: Report of Building or Zoning Permits Issued for New Privately-Owned Housing Units.

Form Number(s): C–404.

OMB Control Number: 0607–0094.

Type of Request: Extension of a currently approved collection.

Burden Hours: 17,594.

Number of Respondents: 19,425.

Average Hours per Response: 9 minutes.

Needs and Uses: The Census Bureau is requesting a three-year extension of a currently approved collection of the Form C–404, otherwise known as the Building Permits Survey (BPS). The key estimates from the survey are the numbers of new housing units authorized by building permits; data are also collected on the valuation of the housing units.

The Census Bureau produces statistics used to monitor activity in the large and dynamic construction industry. Given the importance of this industry, several of the statistical series have been designated as Principal Economic Indicators. Two such indicators are directly dependent on the key estimates from the BPS: (1) New Residential Construction (which includes Housing Units Authorized by Building Permits, Housing Starts, and Housing Completions), and (2) New Residential Sales. These statistics help state, local, and federal governments, as well as private industry, analyze this important sector of the economy. The building permit series are available monthly based on a sample of building permit offices, and annually based on the entire universe of permit offices. Published data from the survey can be found on the Census Bureau's Web site at *www.census.gov/permits.*

The Census Bureau collects these data primarily by mail using the Form C–404 or online using an online version of the same questionnaire. Some data are also collected via receipt of electronic files. Form C–404 requests information on the number and valuation of new residential housing units authorized by building permits.

The Census Bureau uses the Form C–404 to collect data that provide estimates of the number and valuation of new residential housing units authorized by building permits. About one-half of the permit offices are requested to report monthly. The remaining offices are surveyed once per year. We use the data, a component of the index of leading economic indicators, to estimate the number of housing units authorized, started, completed, and sold (single-family only). The Census Bureau also uses these data to select samples for its demographic surveys. In addition, the Census Bureau uses the detailed geographic data in the development of annual population estimates that are used by government agencies to allocate funding and other resources to local areas. Policymakers, planners, businesses, and others use the detailed geographic data to monitor growth and plan for local services, and to develop production and marketing plans. The BPS is the only source of statistics on residential construction for states and smaller geographic areas.

Affected Public: State, local, or Tribal governments.

Frequency: Monthly and annually.

Respondent's Obligation: Voluntary.

Legal Authority: Title 13 U.S.C. 182.

OMB Desk Officer: Brian Harris-Kojetin, (202) 395–7314.

Copies of the above information collection proposal can be obtained by calling or writing Jennifer Jessup, Departmental Paperwork Clearance Officer, (202) 482–0336, Department of Commerce, Room 6616, 14th and Constitution Avenue NW., Washington, DC 20230 (or via the Internet at *jjessup@doc.gov*).

Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to Brian Harris-Kojetin, OMB Desk Officer either by fax (202–395–7245) or email (*bharrisk@omb.eop.gov*).

Dated: January 18, 2013.

Glenna Mickelson,

Management Analyst, Office of the Chief Information Officer.

[FR Doc. 2013–01481 Filed 1–24–13; 8:45 am]

BILLING CODE 3510–07–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–941]

Certain Kitchen Appliance Shelving and Racks From the People's Republic of China; 2010–2011; Final Results of Antidumping Duty Administrative Review

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

SUMMARY: On October 9, 2012, the Department of Commerce (''Department'') published its *Preliminary Results* of the antidumping duty order on certain kitchen appliance shelving and racks from the People's Republic of China (''PRC'').[1] We gave interested parties an opportunity to comment on the *Preliminary Results.* After reviewing interested parties' comments and information received, we have made no changes for the final results of review. The final antidumping duty margins for this review are listed below in the ''Final Results of the Review'' section of this notice. The period of review (''POR'') is September 1, 2010, through August 31, 2011.

DATES: *Effective Date:* January 25, 2013.

FOR FURTHER INFORMATION CONTACT: Emeka Chukwudebe, AD/CVD Operations, Office 9, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230; telephone: (202) 482–0219.

SUPPLEMENTARY INFORMATION:

Background

The Department published the *Preliminary Results* on October 9, 2012. In accordance with 19 CFR 351.309(c)(1)(ii), we invited parties to comment on our *Preliminary Results.*[2] On November 28, 2012, New King Shan (Zhu Hai) Co., Ltd. (''NKS'') filed a case brief. On December 3, 2012, Nashville Wire Products Inc. and SSW Holding Company, Inc. (collectively, ''Petitioners'') filed a rebuttal brief.

Analysis of Comments Received

All issues raised in the case and rebuttal briefs by parties are addressed in the ''Certain Kitchen Appliance Shelving and Racks from the People's Republic of China: Issues and Decision

[1] *See Certain Kitchen Appliance Shelving and Racks From the People's Republic of China: Antidumping Duty Administrative Review, 2010–2011,* 77 FR 61385 (October 9, 2012) (''*Preliminary Results*'').

[2] *See id.,* 77 FR 61386.

Memorandum for the Final Results and Final Partial Rescission of the Second Antidumping Duty Administrative Review,'' dated concurrently with this notice (''Issues & Decision Memo''). A list of the issues raised by interested parties is attached to this notice as Appendix I. The Issues & Decision Memo is a public document and is on file electronically via Import Administration's Antidumping and Countervailing Duty Centralized Electronic Service System (''IA ACCESS''). IA ACCESS is available to registered users at *http://iaaccess.trade.gov* and in the Central Records Unit, room 7046 of the main Department of Commerce building. In addition, a complete version of the Issues & Decision Memo can be accessed directly on the Internet at *http://www.trade.gov/ia.* The signed Issues & Decision Memo and the electronic versions of the Issues & Decision Memo are identical in content.

Scope of the Order

The products covered by the order are certain kitchen appliance shelving and racks.[3] The merchandise subject to the order is currently classifiable under the Harmonized Tariff Schedule of the United States (''HTSUS'') subheadings 8418.99.8050, 8418.99.8060, 7321.90.5000, 7321.90.6090, 8516.90.8000, 7321.90.6040, 8516.90.8010 and 8419.90.9520. Although the HTSUS subheadings are provided for convenience and customs purposes, the Department's written description of the scope of the order remains dispositive.[4]

Changes Since the Preliminary Results

Based on the comments received from the interested parties, we have made no changes to the *Preliminary Results.* For a discussion of the issues, *see* the Issues & Decision Memo.

Final Partial Rescission

Pursuant to 19 CFR 351.213(d)(1), the Department will rescind an administrative review, in whole or in part, if a party that requested the review withdraws the request within 90 days of the date of publication of the initiation notice of the requested review. As noted in the *Preliminary Results,* Petitioners timely requested an administrative review for Asia Pacific CIS (Wuxi) Co., Ltd., Hengtong Hardware Manufacturing (Huizhou) Co., Ltd., Jiangsu Weixi Group, Co., and Leader Metal Industry Co., Ltd. (aka Marmon Retail Services Asia); companies that had previously not received a separate rate in earlier segments of this proceeding. Then Petitioners timely withdrew their requests for review of the aforementioned companies.[5] Petitioners were the only parties to request an administrative review of those companies.

For the final results, the Department is rescinding the review with respect to those companies for which this review was initiated but had not received a separate rate in earlier segments of this proceeding. As described above, Petitioners withdrew their review request covering those companies. The Department did not rescind this review in the *Preliminary Results* for those companies that had not established their eligibility for a separate rate in earlier segments of this proceeding and were considered part of the PRC-wide entity, which could potentially be under review for the final results of this administrative review.[6] The PRC-wide entity did not come under review for these final results. Therefore, the Department is rescinding this review with respect to the above-identified companies.

Final Results of the Review

The dumping margins for the POR are as follows:

Exporter	Weighted-average dumping margin
New King Shan (Zhu Hai) Co., Ltd	0.00%

Assessment Rates

Consistent with these final results, and pursuant to section 751(a)(2)(B) of the Tariff Act of 1930, as amended (''the Act''), and 19 CFR 351.212(b), the Department will direct U.S. Customs and Border Protection (''CBP'') to assess antidumping duties on all appropriate entries. The Department intends to issue assessment instructions to CBP 15 days after the date of publication of the final results of review. Pursuant to 19 CFR 351.212(b)(1), the Department will calculate importer (or customer) -specific assessment rates based on the ratio of the total amount of the dumping margins calculated for the examined sales to the total entered value of those same sales. The Department will instruct CBP to assess antidumping duties on all appropriate entries covered by this review if any importer-specific assessment rate is above *de minimis.*

The Department recently announced a refinement to its assessment practice in non-market economy (''NME'') cases. Pursuant to this refinement in practice, for entries that were not reported in the U.S. sales databases submitted by companies individually examined during this review, the Department will instruct CBP to liquidate such entries at the NME-wide rate. In addition, if the Department determines that an exporter under review had no shipments of the subject merchandise, any suspended entries that entered under that exporter's case number (*i.e.,* at that exporter's rate) will be liquidated at the NME-wide rate.[7]

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 by section 751(a)(2)(C) of the Act: (1) For the exporter listed above, the cash deposit rate will be established in the final results of this review (except, if the rate is zero or *de minimis, i.e.,* less than 0.5 percent, no cash deposit will be required for that company); (2) 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; (3) 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 that for the PRC-wide entity; and (4) 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 exporter that supplied that non-PRC exporter. These deposit requirements, when imposed, shall remain in effect until further notice.

Disclosure

We will disclose the calculations performed within five days of the date of publication of this notice to parties in this proceeding in accordance with 19 CFR 351.224(b).

[3] *See id.,* 77 FR 61385–86.

[4] *See Certain Kitchen Appliance Shelving and Racks from the People's Republic of China: Amended Final Determination of Sales at Less Than Fair Value and Notice of Antidumping Duty Order,* 74 FR 46971 (September 14, 2009).

[5] *See Preliminary Results,* 77 FR 61386.

[6] *See id.; see also Certain Oil Country Tubular Goods From the People's Republic of China: Final Results of Antidumping Duty Administrative Review; 2010–2011,* 77 FR 74644, 74645 (December 17, 2012).

[7] *See Non-Market Economy Antidumping Proceedings: Assessment of Antidumping Duties,* 76 FR 65694 (October 24, 2011).

Notification to Importers Regarding the Reimbursement of Duties

This notice serves as a final reminder to importers of their responsibility under 19 CFR 351.402(f) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this POR. Failure to comply with this requirement could result in the Department's presumption that reimbursement of antidumping duties has occurred and the subsequent assessment of doubled antidumping duties.

Administrative Protective Orders

This notice also serves as a reminder to parties subject to administrative protective orders (''APO'') of their responsibility concerning the return or destruction of proprietary information disclosed under APO in accordance with 19 CFR 351.305, which continues to govern business proprietary information in this segment of the proceeding. Timely written notification of the return or destruction of APO materials, or conversion to judicial protective order, is hereby requested. Failure to comply with the regulations and terms of an APO is a violation which is subject to sanction.

We are issuing and publishing this administrative review and notice in accordance with sections 751(a)(1) and 777(i) of the Act.

Dated: January 17, 2013.

Paul Piquado,

Assistant Secretary for Import Administration.

Appendix I—Issues & Decision Memorandum

General Issues

Comment I: Selection of Financial Ratios
Comment II: Liquidation Instructions

[FR Doc. 2013–01584 Filed 1–24–13; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[C–570–988, C–331–803, C–533–854, C–560–825, C–557–814, C–549–828, and C–552–815]

Certain Frozen Warmwater Shrimp From the People's Republic of China, Ecuador, India, Indonesia, Malaysia, Thailand, and the Socialist Republic of Vietnam: Initiation of Countervailing Duty Investigations

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

DATES: *Effective Date:* January 25, 2013.

FOR FURTHER INFORMATION CONTACT: Dustin Ross, AD/CVD Operations, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230; telephone: (202) 482–0747.

SUPPLEMENTARY INFORMATION:

The Petitions

On December 28, 2012, the Department of Commerce (''Department'') received petitions filed in proper form by the Coalition of Gulf Shrimp Industries (''the petitioner''),[1] a trade or business association whose members manufacture, produce, or wholesale a domestic like product in the United States.[2] In response to the Department's requests, the petitioner provided timely information supplementing the Petitions on January 9, 2013, January 10, 2013, January 11, 2013, and January 14, 2013.

In accordance with section 702(b)(1) of the Tariff Act of 1930, as amended (''the Act''), the petitioner alleges that manufacturers, producers, or importers of certain frozen warmwater shrimp from the People's Republic of China (''China''), Ecuador, India, Indonesia, Malaysia, Thailand, and the Socialist Republic of Vietnam (''Vietnam''), receive countervailable subsidies within the meaning of sections 701 and 771(5) of the Act, and that such imports are materially injuring, or threatening material injury to, the domestic industry producing frozen shrimp in the United States.

The Department finds that the petitioner filed the Petitions on behalf of the domestic industry because they are an interested party as defined in section 771(9)(E) of the Act, and the petitioner has demonstrated sufficient industry support, pursuant to section 771(4)(E) of the Act, with respect to the investigations that it requests the Department initiate.[3]

Period of Investigation

The period of investigation is January 1, 2011, through December 31, 2011.

Scope of the Investigations

The products covered by these investigations are certain frozen warmwater shrimp (''frozen shrimp'') from China, Ecuador, India, Indonesia, Malaysia, Thailand, and Vietnam. For a full description of the scope of each of these investigations, please see the ''Scope of the Investigations'' in Appendix I to this notice.

Comments on Scope of Investigations

During our review of the Petitions, the Department had discussions pertaining to the proposed scope with the petitioner to ensure that the scope language in the Petitions was an accurate reflection of the products for which the domestic industry is seeking relief. The petitioner determined the proposed scope should be clarified, and it filed a modification to the language of the scope described in the Petitions to reflect those clarifications.[4] Moreover, as discussed in the preamble to the regulations,[5] we are setting aside a period of time for interested parties to raise issues regarding product coverage. This period for scope comments is intended to provide the Department with ample opportunity to consider all issues and to consult with parties prior to the issuance of the preliminary determinations. The Department encourages interested parties to submit such comments by 5:00 p.m. EST on Wednesday, February 6, 2013, which is 20 calendar days from the signature date of this notice.

Filing Requirements

All submissions to the Department must be filed electronically using Import Administration's Antidumping and Countervailing Duty Centralized Electronic Service System (''IA ACCESS''). An electronically filed document must be received successfully in its entirety by the Department's

[1] The members of the Coalition of Gulf Shrimp Industries are: Bayou Shrimp Processors, Inc.; Bluewater Shrimp Company, Inc.; Carson & Co., Inc.; C.F. Gollott & Sons Seafood, Inc.; Dean Blanchard Seafood, Inc.; Dominick Seafood; Fisherman's Reef Packing Plant; Golden Gulf Coast Pkg. Co., Inc. (and Gollott's Oil Dock & Ice House); Graham Fisheries, Inc.; Graham Shrimp, Inc.; Gulf Crown Seafood Co., Inc.; Gulf Fish Inc.; Gulf Island Shrimp & Seafood, LLC; Gulf Pride Enterprises, Inc.; Hi-Seas of Dulac, Inc.; Indian Ridge Shrimp Co.; JBS Packing Co., Inc.; Lafitte Frozen Foods Corp.; M&M Shrimp (Biloxi Freezing and Processing); Ocean Springs Seafood Market, Inc.; Paul Piazza & Sons, Inc.; R.A. Lesso Brokerage Co., Inc.; Sea Pearl Seafood Co., Inc.; Smith and Sons Seafood; Tidelands Seafood Co., Inc.; Tommy's Seafood; Vincent Piazza & Sons Seafood, Inc.; Wood's Fisheries; Mariah Jade Shrimp Company LLC; David Chauvin's Seafood Company, LLC; and Rountree Enterprises, Inc. (dba Leonard & Sons Shrimp Co. and R&R Fisheries).

[2] *See* Petitions for the Imposition of Countervailing Duties on Certain Frozen Warmwater Shrimp from the People's Republic of China, Ecuador, India, Indonesia, Malaysia, Thailand, and the Socialist Republic of Vietnam, dated December 28, 2012, (''the Petitions'').

[3] *See* ''Determination of Industry Support for the Petition'' below.

[4] *See Certain Frozen Warmwater Shrimp from China, Ecuador, India, Indonesia, Malaysia, Thailand, and Vietnam*—Petitioner's Response To The Department's January 4, 2013 Supplemental Questions to the Petition, dated January 9, 2013 at Exhibit I–SQ–3.

[5] *See Antidumping Duties; Countervailing Duties,* 62 FR 27296, 27323 (May 19, 1997).

electronic records system, IA ACCESS, by the time and date set by the Department. Documents excepted from the electronic submission requirements must be filed manually (*i.e.,* in paper form) with the Import Administration's APO/Dockets Unit, Room 1870, U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230, and stamped with the date and time of receipt by the deadline established by the Department.[6]

Consultations

Pursuant to section 702(b)(4)(A)(ii) of the Act, the Department invited representatives of the Governments of China, Ecuador, India, Indonesia, Malaysia, Thailand, and Vietnam for consultations with respect to the Petitions.

Consultations were held with the government of China via teleconference on January 10, 2013.[7] Consultations were held in Washington, DC, with the Royal Thai Government on January 11, 2013;[8] with the governments of India, Indonesia, and Malaysia on January 14, 2013;[9] with the government of Vietnam on January 15, 2013;[10] and with the government of Ecuador on January 16, 2013.[11] All memoranda are on file electronically via IA ACCESS. Access to IA ACCESS is available in the Central Records Unit (''CRU''), Room 7046, of the main Department of Commerce Building.

Determination of Industry Support for the Petitions

Section 702(b)(1) of the Act requires that a petition be filed on behalf of the domestic industry. Section 702(c)(4)(A) of the Act provides that a petition meets this requirement if the domestic producers or workers who support the petition account for: (i) at least 25 percent of the total production of the domestic like product; and (ii) more than 50 percent of the production of the domestic like product produced by that portion of the industry expressing support for, or opposition to, the petition. Moreover, section 702(c)(4)(D) of the Act provides that, if the petition does not establish support of domestic producers or workers accounting for more than 50 percent of the total production of the domestic like product, the Department shall: (i) Poll the industry or rely on other information in order to determine if there is support for the petition, as required by subparagraph (A); or (ii) determine industry support using a statistically valid sampling method to poll the industry.

Section 771(4)(A) of the Act defines the ''industry'' as the producers as a whole of a domestic like product. Thus, to determine whether a petition has the requisite industry support, the statute directs the Department to look to producers and workers who produce the domestic like product. The U.S. International Trade Commission (''ITC''), which is responsible for determining whether ''the domestic industry'' has been injured, must also determine what constitutes a domestic like product in order to define the industry. While both the Department and the ITC must apply the same statutory definition regarding the domestic like product (*see* section 771(10) of the Act), they do so for different purposes and pursuant to a separate and distinct authority. In addition, the Department's determination is subject to limitations of time and information. Although this may result in different definitions of the like product, such differences do not render the decision of either agency contrary to law.[12]

Section 771(10) of the Act defines the domestic like product as ''a product which is like, or in the absence of like, most similar in characteristics and uses with, the article subject to an investigation under this title.'' Thus, the reference point from which the domestic like product analysis begins is ''the article subject to an investigation'' (*i.e.,* the class or kind of merchandise to be investigated, which normally will be the scope as defined in the petition).

With regard to the domestic like product, the petitioner does not offer a definition of domestic like product distinct from the scope of the investigations. Based on our analysis of the information submitted on the record, we have determined that certain frozen warmwater shrimp, as defined in the scope of the investigations, constitutes a single domestic like product and we have analyzed industry support in terms of that domestic like product.[13]

In determining whether the petitioner has standing under section 702(c)(4)(A) of the Act, we considered the industry support data contained in the Petitions with reference to the domestic like product as defined in the ''Scope of the Investigations'' section above. To establish industry support, the petitioner provided its production of the domestic like product in 2011 and compared this to the total production of the domestic like product by the entire domestic industry.[14] The petitioner calculated total 2011 production of the domestic like product based on data on the volume of frozen shrimp produced in the United States in 2011 from the

[6] *See http://www.gpo.gov/fdsys/pkg/FR-2011-07-06/pdf/2011-16352.pdf* for details of the Department's Electronic Filing Requirements, which went into effect on August 5, 2011. Information on help using IA ACCESS can be found at *https://iaaccess.trade.gov/help.aspx* and a handbook can be found at *https://iaaccess.trade.gov/help/Handbook%20on%20Electronic%20Filing%20Procedures.pdf.*

[7] *See* Ex-Parte Memorandum, ''Consultations with Officials from the Government of the PRC'' (January 14, 2013).

[8] *See* Ex-Parte Memorandum, ''Consultations with Officials from the Royal Thai Government on the Countervailing Duty Petition regarding Frozen Warmwater Shrimp'' (January 11, 2013) (''Thailand Consultation Memorandum'').

[9] *See* Ex-Parte Memorandum, ''Consultations with Officials from the Government of India (''GOI'') on the Countervailing Duty Petition on Certain Frozen Warmwater Shrimp from India'' (January 17, 2013) (''India Consultation Memorandum''), Ex-Parte Memorandum, ''Consultations with the Officials from the Government of the Republic of Indonesia on the Countervailing Duty Petition regarding Frozen Warmwater Shrimp'' (January 15, 2013), and Ex-Parte Memorandum, ''Consultations with Officials from the Government of the Malaysia,'' (January 15, 2013), respectively.

[10] *See* Ex-Parte Memorandum, ''Consultations with Officials from the Government of Vietnam on the Countervailing Duty Petition on Certain Frozen Warmwater Shrimp from Vietnam'' (January 17, 2013) (''Vietnam Consultation Memorandum'').

[11] *See* Ex-Parte Memorandum, ''Consultations with Officials from the Government of Ecuador (''GOE'') on the Countervailing Duty Petition on Certain Frozen Warmwater Shrimp from Ecuador,'' (January 16, 2013).

[12] *See USEC, Inc.* v. *United States,* 132 F. Supp. 2d 1, 8 (CIT 2001) (citing *Algoma Steel Corp., Ltd.* v. *United States,* 688 F. Supp. 639, 644 (CIT 1988), *aff'd* 865 F.2d 240 (Fed. Cir. 1989)).

[13] For a discussion of the domestic like product analysis in these cases, *see* ''Countervailing Duty Investigation Initiation Checklist: Certain Frozen Warmwater Shrimp from the People's Republic of China'' (''*China Initiation Checklist''*), at Attachment II, Analysis of Industry Support for the Petitions Covering Certain Frozen Warmwater Shrimp from the People's Republic of China, Ecuador, India, Indonesia, Malaysia, Thailand, and Vietnam (''Attachment II''); ''Countervailing Duty Investigation Initiation Checklist: Certain Frozen Warmwater Shrimp from Ecuador'' (''*Ecuador Initiation Checklist''*), at Attachment II; ''Countervailing Duty Investigation Initiation Checklist: Certain Frozen Warmwater Shrimp from India'' (''*India Initiation Checklist''*), at Attachment II; ''Countervailing Duty Investigation Initiation Checklist: Certain Frozen Warmwater Shrimp from Indonesia'' (''*Indonesia Initiation Checklist''*), at Attachment II; ''Countervailing Duty Investigation Initiation Checklist: Certain Frozen Warmwater Shrimp from Malaysia'' (''*Malaysia Initiation Checklist''*), at Attachment II; ''Countervailing Duty Investigation Initiation Checklist: Certain Frozen Warmwater Shrimp from Thailand'' (''*Thailand Initiation Checklist''*), at Attachment II; ''Countervailing Duty Investigation Initiation Checklist: Certain Frozen Warmwater Shrimp from Vietnam'' (''*Vietnam Initiation Checklist''*), at Attachment II. These checklists are on file via IA ACCESS.

[14] *See* Volume I of the Petitions, at I–6, I–7, and Exhibits I–5 through I–7 and I–21; *see also* the petitioner's January 9, 2013, ''Response To The Department's January 4, 2013 Supplemental Questions to the Petition,'' at 2–6 and Exhibits I–SQ–4 through I–SQ–11.

National Oceanic and Atmospheric Administration (''NOAA''). The Department contacted NOAA officials with respect to these data on January 11, 2013, to learn the means by which NOAA derived these production amounts.[15] The petitioner noted in the Petitions that the data from NOAA included both warmwater and coldwater frozen shrimp processed in 2011. To adjust the NOAA data to reflect only the processing of warmwater shrimp, the petitioner used data on landings of coldwater shrimp from the National Marine Fisheries Service, a division of NOAA. The petitioner explained that this is the same methodology and data used by the Department in prior antidumping investigations on frozen warmwater shrimp.[16] We contacted NOAA with respect to the data relied upon by the petitioner, and are satisfied with the quality and accuracy of that data. However, during our communications with NOAA, NOAA provided us with updated 2011 figures. Accordingly, we have relied upon the updated NOAA data for purposes of measuring industry support.[17]

On January 11, 2013, the Government of Thailand raised concerns about industry support during its consultations with the Department.[18] On January 14, 2013, the Government of India (''GOI'') also raised concerns about industry support during its consultations with the Department.[19] The GOI reiterated those same concerns in a letter filed on January 16, 2013.[20] On January 14, 2013, Marine Gold Products Limited, Thai Union Frozen Products Public Co., Ltd., Thai Union Seafood Co., Ltd., Pakfood Public Company Limited, and Thai Royal Frozen Food Co., Ltd. (collectively, ''Thai Exporters''), self-identified foreign producers and exporters of subject merchandise, also filed a submission challenging industry support. On January 15, 2013, the Government of Vietnam commented on industry support during its consultations with the Department.[21] On January 15, 2013, the petitioner filed a response to the Thai Exporters' industry support challenge. On January 16, 2013, the Seafood Exports Association of India, an association of foreign producers and exporters of subject merchandise, also filed a submission challenging industry support. On January 17, 2013, the petitioner filed a response to the GOI's letter.[22]

Based on information provided in the Petitions, supplemental submissions, and other information readily available to the Department, we determine that the petitioner has met the statutory criteria for industry support under section 702(c)(4)(A)(i) of the Act because the domestic producers (or workers) who support the Petitions account for at least 25 percent of the total production of the domestic like product.[23] Based on information provided in the Petitions and supplemental submissions, the domestic producers and workers have met the statutory criteria for industry support under section 702(c)(4)(A)(ii) of the Act because the domestic producers (or workers) who support the Petitions account for more than 50 percent of the production of the domestic like product produced by that portion of the industry expressing support for, or opposition to, the Petitions. Accordingly, the Department determines that the Petitions were filed on behalf of the domestic industry within the meaning of section 702(b)(1) of the Act.[24]

The Department finds that the petitioner filed the Petitions on behalf of the domestic industry because it is an interested party as defined in section 771(9)(E) of the Act and it has demonstrated sufficient industry support, pursuant to section 771(4)(E) of the Act, with respect to the CVD investigations that it is requesting the Department initiate.[25]

Injury Test

Because China, Ecuador, India, Indonesia, Malaysia, Thailand, and Vietnam are ''Subsidies Agreement Countries'' within the meaning of section 701(b) of the Act, section 701(a)(2) of the Act applies to these investigations. Accordingly, the ITC must determine whether imports of the subject merchandise from China, Ecuador, India, Indonesia, Malaysia, Thailand, and Vietnam materially injure, or threaten material injury to, a U.S. industry.

Allegations and Evidence of Material Injury and Causation

The petitioner alleges that imports of the subject merchandise are benefitting from countervailable subsidies and that such imports are causing, or threaten to cause, material injury to the U.S. industry producing the domestic like product. The petitioner alleges that subject imports from China and Vietnam exceed the negligibility threshold provided for under section 771(24)(A) of the Act. In addition, the petitioner alleges that subject imports from Ecuador, India, Indonesia, Malaysia, and Thailand exceed the negligibility threshold provided for under section 771(24)(B) of the Act, which states that in countervailing duty petitions, imports of subject merchandise from developing countries must exceed the negligibility threshold of 4 percent.

The petitioner contends that the industry's injured condition is illustrated by reduced market share; underselling and price depression or suppression; lost sales and revenue; reduced shipments and production; increased inventories; decline in financial performance; and reduction in employment data and wages paid.[26] We have assessed the allegations and supporting evidence regarding material injury, threat of material injury, and causation, and we have determined that these allegations are properly supported by adequate evidence and meet the statutory requirements for initiation.[27]

[15] *See* Memorandum to the File from Vicki Flynn, Office of Policy, Regarding National Oceanic and Atmospheric Administration Statistics (January 11, 2013).

[16] *See* Volume I of the Petitions, at I–6, I–7, and Exhibit I–4 (which contains the ''AD Investigation Initiation Checklist: Certain Frozen and Canned Warmwater Shrimp from Thailand'' (Public Version) (January 20, 2004)).

[17] For further discussion, *see* Memorandum to the File, ''National Oceanic and Atmospheric Administration (''NOAA'') Statistics,'' (January 15, 2013).

[18] *See* Thailand Consultation Memorandum.

[19] *See* India Consultation Memorandum.

[20] *See* Letter from the GOI dated January 16, 2013, ''Petition filed by the Coalition of Gulf Shrimp Industries on 28 December 2012 seeking initiation of a countervailing duty investigation against imports of Certain Frozen Warmwater Shrimp from, *inter alia,* India.''

[21] *See* Vietnam Consultation Memorandum.

[22] For further discussion of these submissions, *see China Initiation Checklist, Ecuador Initiation Checklist, India Initiation Checklist, Indonesia Initiation Checklist, Malaysia Initiation Checklist, Thailand Initiation Checklist,* and *Vietnam Initiation Checklist,* at Attachment II.

[23] *See China Initiation Checklist, Ecuador Initiation Checklist, India Initiation Checklist, Indonesia Initiation Checklist, Malaysia Initiation Checklist, Thailand Initiation Checklist,* and *Vietnam Initiation Checklist,* at Attachment II.

[24] *See id.*

[25] *See id.*

[26] *See* Volume I of the Petitions, at I–11 through I–57 and Exhibits I–11, I–13 through I–32, and General Issues Supplement, at 1, 6–7 and Exhibits I–SQ–1, I–SQ–2, I–SQ–12, and I–SQ–13.

[27] *See China Initiation Checklist, Ecuador Initiation Checklist, India Initiation Checklist, Indonesia Initiation Checklist, Malaysia Initiation Checklist, Thailand Initiation Checklist,* and *Vietnam Initiation Checklist,* at Attachment III, Analysis of Allegations and Evidence of Material Injury and Causation for the Petitions Covering Certain Frozen Warmwater Shrimp from the People's Republic of China, Ecuador, India, Indonesia, Malaysia, Thailand, and the Socialist Republic of Vietnam.

Initiation of Countervailing Duty Investigations

Section 702(b)(1) of the Act requires the Department to initiate a CVD investigation whenever an interested party files a CVD petition on behalf of an industry that: (1) alleges the elements necessary for an imposition of a duty under section 701(a) of the Act; and (2) is accompanied by information reasonably available to the petitioner supporting the allegations.

In the Petitions, the petitioner alleges that producers of frozen shrimp in China, Ecuador, India, Indonesia, Malaysia, Thailand and Vietnam benefited from countervailable subsidies bestowed by their respective governments. In addition to subsidies allegedly provided to processors of frozen shrimp, the Petitions include subsidies allegedly provided to producers of fresh shrimp. According to the petitioner, the producers of frozen shrimp often have their own integrated aquaculture operations or are cross-owned with farming operations that supply fresh shrimp.[28] In these situations, the petitioner states that subsidies tied to the production of fresh shrimp will be attributed to the processed product, citing 19 CFR 351.525(b)(5)(ii) and 351.525(b)(6)(iv). (With respect to cross-owned suppliers of fresh shrimp and the requirements of 19 CFR 351.525(b)(6)(iv), the petitioner points to the ITC's finding that fresh shrimp is overwhelmingly used to produce frozen shrimp [29] in support of its claim that fresh shrimp is ''primarily dedicated'' to the frozen product.)

Alternatively, the petitioner claims that the Department should investigate subsidies to producers of fresh shrimp and deem such subsidies to be provided with respect to the frozen product under section 771B of the Act, which addresses processed agricultural products (including fishery products). In support, the petitioner claims that: (i) The demand for fresh shrimp is substantially dependent on the demand for frozen shrimp and (ii) the processing of the fresh shrimp into frozen shrimp adds limited value and the essential character of the raw product is not changed. In support, the petitioner refers to the above-cited finding by the ITC and to its finding that processing adds 19–24 percent of the final value.[30] According to the petitioner, the Department has previously found this level of value added to be limited.[31] Moreover, the petitioner states that the essential character of the fresh shrimp is not changed with processing. Based on the petitioner's allegation in each of the Petitions regarding the relationship between fresh and frozen shrimp, the Department is including in its investigations programs that allegedly provide subsidies to producers of fresh shrimp as well as programs that allegedly provide subsidies to producers of frozen shrimp.

The Department has examined the Petitions on frozen shrimp from China, Ecuador, India, Indonesia, Malaysia, Thailand and Vietnam and finds that they comply with the requirements of section 702(b)(1) of the Act. Therefore, in accordance with section 702(b)(1) of the Act, we are initiating CVD investigations to determine whether manufacturers, producers, or exporters of frozen shrimp from the China, Ecuador, India, Indonesia, Malaysia, Thailand and Vietnam receive countervailable subsidies.

The People's Republic of China

Based on our review of the Petition, we find that there is sufficient information to initiate a CVD investigation of 25 alleged programs. For the other five programs, we have determined that the requirements for initiation have not been met. For a full discussion of the basis for our decision to initiate or not initiate on each program, see *China Initiation Checklist.*

Ecuador

Based on our review of the Petition, we find that there is sufficient information to initiate a CVD investigation of seven alleged programs. For the other two programs, we have determined that the requirements for initiation have not been met. For a full discussion of the basis for our decision to initiate or not initiate on each program, see *Ecuador Initiation Checklist.*

India

Based on our review of the Petition, we find that there is sufficient information to initiate a CVD investigation of 21 alleged programs. For one other program, we find that there is sufficient evidence to initiate on part of the allegation but that there is not sufficient evidence to initiate on another part of the allegation. For one program, we have determined that the requirements for initiation have not been met. For a full discussion of the basis for our decision to initiate or not initiate on each program, see *India Initiation Checklist.*

Indonesia

Based on our review of the Petition, we find that there is sufficient information to initiate a CVD investigation of 14 alleged programs. The petitioner also made a sufficient allegation of debt forgiveness and uncreditworthiness regarding a certain Indonesian producer/exporter of subject merchandise. We intend to investigate these allegations if this company is selected as a mandatory company respondent in the investigation. For one program, we have determined that the requirements for initiation have not been met. For a full discussion of the basis for our decision to initiate or not initiate on each program, see *Indonesia Initiation Checklist.*

Malaysia

Based on our review of the Petition, we find that there is sufficient information to initiate a CVD investigation of 16 alleged programs. For the other two programs, we have determined that the requirements for initiation have not been met. For a full discussion of the basis for our decision to initiate or not initiate on each program, see *Malaysia Initiation Checklist.*

Thailand

Based on our review of the Petition, we find that there is sufficient information to initiate a CVD investigation of 12 alleged programs. For the other three programs, we have determined that the requirements for initiation have not been met. For a full discussion of the basis for our decision to initiate or not initiate on each program, see *Thailand Initiation Checklist.*

Vietnam

Based on our review of the Petition, we find that there is sufficient information to initiate a CVD investigation of 20 alleged programs. For two programs, we have determined that the requirements for initiation have not been met. For a full discussion of the basis for our decision to initiate or not initiate on each program, see *Vietnam Initiation Checklist.*

[28] The petitioner has provided supporting information for these claims in each of the petitions. For a full discussion, *see* the *Initiation Checklist* for each country.

[29] U.S. International Trade Commission, *Frozen Warmwater Shrimp from Brazil, China, India, Thailand, and Vietnam,* Inv. Nos. 731–TA–1063, 1064, 1066–1068 (Review), USITC Pub. 4221 (March 2011) (*Shrimp AD Sunset*) at 6.

[30] *Shrimp AD Sunset* at Table III–11.

[31] The petitioner cites, *Rice From Thailand; Final Results of Countervailing Duty Administrative Review,* 56 FR 68, 69 (January 2, 1991) and *Final Affirmative Countervailing Duty Determination: Fresh, Chilled, and Frozen Pork from Canada,* 54 FR 30774, 30775 (July 24, 1989).

A public version of the initiation checklists for each investigation is available at *http://ia.ita.doc.gov/ia-highlights-and-news.html*).

Respondent Selection

For these investigations, the Department expects to select respondents based on U.S. Customs and Border Protection (CBP) data for U.S. imports of subject merchandise during the period of investigation under the following Harmonized Tariff Schedule of the United States (HTSUS) numbers: 0306.13.00.03, 0306.13.00.06, 0306.13.00.09, 0306.13.00.12, 0306.13.00.15, 0306.13.00.18, 0306.13.00.21, 0306.13.00.24, 0306.13.00.27, 0306.13.00.40, 1605.20.10.10, and 1605.20.10.30.

We intend to release the CBP data under Administrative Protective Order (APO) to all parties with access to information protected by APO shortly after the announcement of these case initiations. Interested parties may submit comments regarding the CBP data and respondent selection within seven calendar days of publication of this notice. Comments must be filed electronically using IA ACCESS. An electronically filed document must be received successfully in its entirety by the Department's electronic records system, IA ACCESS, by 5 p.m. Eastern time by the date noted above. Documents excepted from the electronic submission requirements must be filed manually (*i.e.,* in paper form) with the Import Administration's APO/Dockets Unit, Room 1870, U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230, and stamped with the date and time of receipt by the deadline noted above. We intend to make our decision regarding respondent selection within 20 days of publication of this **Federal Register** notice. Interested parties must submit applications for disclosure under APO in accordance with 19 CFR 351.305(b). Instructions for filing such applications may be found on the Department's Web site at *http://ia.ita.doc.gov/apo.*

Distribution of Copies of the Petitions

In accordance with section 702(b)(4)(A)(i) of the Act and 19 CFR 351.202(f), copies of the public version of the Petitions have been provided to the representatives of the Governments of China, Ecuador, India, Indonesia, Malaysia, Thailand, and Vietnam. Because of the particularly large number of producers/exporters identified in the Petitions, the Department considers the service of the public version of the Petitions to the foreign producers/exporters satisfied by the delivery of the public versions of the Petitions to the Governments of China, Ecuador, India, Indonesia, Malaysia, Thailand, and Vietnam, consistent with 19 CFR 351.203(c)(2).

ITC Notification

We have notified the ITC of our initiation, as required by section 702(d) of the Act.

Preliminary Determinations by the ITC

The ITC will preliminarily determine, within 45 days after the date on which the Petitions were filed, whether there is a reasonable indication that imports of subsidized frozen shrimp from China, Ecuador, India, Indonesia, Malaysia, Thailand, and Vietnam are materially injuring, or threatening material injury to, a U.S. industry.[32] Negative ITC determinations with respect to any country will result in the investigation being terminated for that country; otherwise, these investigations will proceed according to statutory and regulatory time limits.

Notification to Interested Parties

Interested parties must submit applications for disclosure under protective orders in accordance with 19 CFR 351.305. On January 22, 2008, the Department published *Antidumping and Countervailing Duty Proceedings: Documents Submission Procedures; APO Procedures,* 73 FR 3634. Parties wishing to participate in this investigation should ensure that they meet the requirements of these procedures (*e.g.,* the filing of letters of appearance as discussed at 19 CFR 351.103(d)).

Any party submitting factual information in an AD or CVD proceeding must certify to the accuracy and completeness of that information.[33] Parties are hereby reminded that revised certification requirements are in effect for company/government officials, as well as their representatives, in all segments of any AD or CVD proceedings initiated on or after March 14, 2011.[34] The formats for the revised certifications are provided at the end of the *Interim Final Rule.* Foreign governments and their officials may continue to submit certifications in either the format that was in use prior to the effective date of the *Interim Final Rule,* or in the format provided in the *Interim Final Rule.*[35] The Department intends to reject factual information submissions if the submitting party does not comply with the revised certification requirements.

This notice is issued and published pursuant to section 777(i) of the Act.

Dated: January 17, 2013.

Paul Piquado,

Assistant Secretary for Import Administration.

Appendix I

Scope of the Investigations

The scope of these investigations is certain frozen warmwater shrimp and prawns, whether wild-caught (ocean harvested) or farm-raised (produced by aquaculture), head-on or head-off, shell-on or peeled, tail-on or tail-off,[36] deveined or not deveined, cooked or raw, or otherwise processed in frozen form, regardless of size.

The frozen warmwater shrimp and prawn products included in the scope, regardless of definitions in the Harmonized Tariff Schedule of the United States (''HTSUS''), are products which are processed from warmwater shrimp and prawns through freezing and which are sold in any count size.

The products described above may be processed from any species of warmwater shrimp and prawns. Warmwater shrimp and prawns are generally classified in, but are not limited to, the *Penaeidae* family. Some examples of the farmed and wild-caught warmwater species include, but are not limited to, whiteleg shrimp (*Penaeus vannemei*), banana prawn (*Penaeus merguiensis*), fleshy prawn (*Penaeus chinensis*), giant river prawn (*Macrobrachium rosenbergii*), giant tiger prawn (*Penaeus monodon*), redspotted shrimp (*Penaeus brasiliensis*), southern brown shrimp (*Penaeus subtilis*), southern pink shrimp (*Penaeus notialis*), southern rough shrimp (*Trachypenaeus curvirostris*), southern white shrimp (*Penaeus schmitti*), blue shrimp (*Penaeus stylirostris*), western white shrimp (*Penaeus occidentalis*), and Indian white prawn (*Penaeus indicus*).

Frozen shrimp and prawns that are packed with marinade, spices or sauce are included in the scope. In addition, food preparations (including dusted shrimp), which are not ''prepared meals,'' that contain more than 20 percent by weight of shrimp or prawn are also included in the scope.

Excluded from the scope are: (1) Breaded shrimp and prawns; (2) shrimp and prawns generally classified in the *Pandalidae* family and commonly referred to as coldwater shrimp, in any state of processing; (3) fresh shrimp and prawns whether shell-on or peeled; (4) shrimp and prawns in prepared meals; (5) dried shrimp and prawns; (6)

[32] *See* section 703(a)(2) of the Act.

[33] *See* section 782(b) of the Act.

[34] *See Certification of Factual Information for Import Administration during Antidumping and Countervailing Duty Proceedings: Interim Final Rule,* 76 FR 7491 (February 10, 2011) (*Interim Final Rule*), amending 19 CFR 351.303(g)(1) and (2).

[35] *See Certification of Factual Information to Import Administration During Antidumping and Countervailing Duty Proceedings: Supplemental Interim Final Rule,* 76 FR 54697 (September 2, 2011).

[36] ''Tails'' in this context means the tail fan, which includes the telson and the uropods.

canned warmwater shrimp and prawns; and (7) certain ''battered shrimp'' (see below).

''Battered shrimp'' is a shrimp-based product: (1) That is produced from fresh (or thawed-from-frozen) and peeled shrimp; (2) to which a ''dusting'' layer of rice or wheat flour of at least 95 percent purity has been applied; (3) with the entire surface of the shrimp flesh thoroughly and evenly coated with the flour; (4) with the non-shrimp content of the end product constituting between four and 10 percent of the product's total weight after being dusted, but prior to being frozen; and (5) that is subjected to individually quick frozen (''IQF'') freezing immediately after application of the dusting layer. When dusted in accordance with the definition of dusting above, the battered shrimp product is also coated with a wet viscous layer containing egg and/or milk, and par-fried.

The products included in the scope of these investigations are currently classified under the following HTSUS subheadings: 0306.17.00.03, 0306.17.00.06, 0306.17.00.09, 0306.17.00.12, 0306.17.00.15, 0306.17.00.18, 0306.17.00.21, 0306.17.00.24, 0306.17.00.27, 0306.17.00.40, 1605.21.10.30 and 1605.29.10.10. These HTSUS subheadings are provided for convenience and for customs purposes only and are not dispositive, but rather the written description of the scope is dispositive.

[FR Doc. 2013–01579 Filed 1–24–13; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Proposed Information Collection; Comment Request; NOAA's Teacher at Sea Program

AGENCY: National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice.

SUMMARY: 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 take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3506(c)(2)(A)).

DATES: Written comments must be submitted on or before March 26, 2013.

ADDRESSES: Direct all written comments to Jennifer Jessup, Departmental Paperwork Clearance Officer, Department of Commerce, Room 6616, 14th and Constitution Avenue NW., Washington, DC 20230 (or via the Internet at *JJessup@doc.gov*).

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the information collection instrument and instructions should be directed to Jennifer Hammond, (301) 713–0353, or *jennifer.hammond@noaa.gov.*

SUPPLEMENTARY INFORMATION:

I. Abstract

This request is for extension of a current information collection.

NOAA provides educators an opportunity to gain first-hand experience with field research activities through the NOAA Teacher at Sea Program. Through this program, educators spend up to 4 weeks at sea on a NOAA research vessel, participating in an on-going research project with NOAA scientists. The application solicits information from interested educators: basic personal information, teaching experience and ideas for applying program experience in their classrooms, plus two recommendations and a NOAA Health Services Questionnaire required of anyone selected to participate in the program. Once educators are selected and participate on a cruise, they write a report detailing the events of the cruise and ideas for classroom activities based on what they learned while at sea. These materials are then made available to other educators so they may benefit from the experience, without actually going to sea themselves. NOAA does not collect information from this universe of respondents for any other purpose.

II. Method of Collection

Forms can be completed online and submitted electronically, and/or printed and mailed.

III. Data

OMB Control Number: 0648–0283.

Form Number: None.

Type of Review: Regular submission (extension of a current information collection).

Affected Public: Individuals or households.

Estimated Number of Respondents: 375.

Estimated Time per Response: 45 minutes to read and complete application, 15 minutes to complete a Health Services Questionnaire, 15 minutes to deliver and discuss recommendation forms to persons from whom recommendations are being requested, 15 minutes for those persons to complete a recommendation form, and 2 hours for a follow-up report.

Estimated Total Annual Burden Hours: 309.

Estimated Total Annual Cost to Public: $221.

IV. Request for 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 (including hours and cost) 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.

Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval of this information collection; they also will become a matter of public record.

Dated: January 22, 2013.

Gwellnar Banks,

Management Analyst, Office of the Chief Information Officer.

[FR Doc. 2013–01501 Filed 1–24–13; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XC459

Mid-Atlantic Fishery Management Council (MAFMC); Meetings

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

ACTION: Notice of public meeting.

SUMMARY: The Mid-Atlantic Fishery Management Council (Council) and its Ecosystem and Ocean Planning Committee will hold public meetings.

DATES: The meetings will be held February 12, 2013, through February 14, 2013. For specific dates, times, and agenda, see **SUPPLEMENTARY INFORMATION**.

ADDRESSES: Embassy Suites Hampton Roads, 1700 Coliseum Drive, Hampton, VA 23666; telephone: (757) 827–8200.

Council Address: Mid-Atlantic Fishery Management Council, 800 N. State St., Suite 201, Dover, DE 19901; telephone: 302–674–2331.

FOR FURTHER INFORMATION CONTACT: Christopher M. Moore, Ph.D. Executive

Director, Mid-Atlantic Fishery Management Council; telephone: 302–526–5255.

SUPPLEMENTARY INFORMATION:

Dates, Times, and Agenda

On Tuesday, February 12—The Ecosystem and Ocean Planning Committee will meet from 10 a.m. until 12 p.m. The Council will convene at 1 p.m. Amendment 15 to the Mackerel, Squid, and Butterfish Fishery Management Plan (FMP) will be reviewed from 1 p.m. until 2:30 p.m. A Butterfish and Climate Change presentation will be held from 2:30 p.m. until 3:30 p.m. The Standard Bycatch Reporting Methodology Report will be from 3:30 p.m. until 4:30 p.m. A Marine Recreation Information Program update will be held from 4:30 p.m. until 5 p.m. A Listening Session will be held from 5 p.m. until 6 p.m.

On Wednesday, February 13—The Council will convene at 9 a.m. From 9 a.m. until 10 a.m. there will be a North East Area Monitoring and Assessment Program presentation. Black Sea Bass Catch Limits for 2013 and 2014 will be discussed from 10 a.m. until 11:45 a.m. The Ricks E Savage Award will be presented from 11:45 a.m. until 12 p.m. The Omnibus Amendment for Recreational Accountability Measures will be discussed from 1 p.m. until 2:30 p.m. Special Management Zones (SMZs) will be discussed from 2:30 p.m. until 3:30 p.m. There will be a Bureau of Ocean Energy Management Presentation from 3:30 p.m. until 4 p.m. From 4 p.m. until 5 p.m. there will be a Scoping Hearing for the Deep Sea Corals Amendment.

On Thursday February 14—A presentation on the new Council Web site will be held from 9 a.m. until 9:30 a.m. The Council will hold its regular Business Session from 9 a.m. until 1 p.m. to approve the December 2012 minutes, receive Organizational Reports, the New England and South Atlantic Liaison Report, the Executive Director's Report, the Science Report; Committee Reports, and conduct any continuing and/or new business.

Agenda items by day for the Council's Committees and the Council itself are:

On Tuesday, February 12—The Ecosystem and Ocean Planning Committee will review the scoping document for Amendment 16 to the Mackerel, Squid, and Butterfish Fishery Management Plan (Deep Sea Corals Amendment) and review alternatives to be included in the Amendment. The Council will review the FMAT's progress and approach to alternative development for Amendment 15 to the Mackerel, Squid, and Butterfish Fishery Management Plan. A presentation will be provided to the Council on climate change, thermal habitat dynamics and systematic changes in habitat coverage bias in assessment surveys along with a case study of butterfish and some possible solutions. The Council will review and approve a draft environmental assessment for the Standard Bycatch Reporting Methodology Omnibus Amendment. The Council will receive an update on the Marine Recreational Information Program. The Council will hold a public listening session.

On Wednesday, February 13—The Council will hear a presentation regarding the North East Area Monitoring and Assessment Program. The Council will review the SSC Report in response to a Council request to clarify the 2013 and 2014 Black Sea Bass Acceptable Biological Catch and review the 2013 catch limits if appropriate and adopt 2014 catch limits. The Council will present the Ricks E Savage Award. The Council will review and approve alternatives to be included in the Omnibus Amendment regarding recreational accountability measures. The Council will review public hearings comments on options for designating Delaware's permitted reef sites in the EEZ and SMZs and develop recommendations to the Regional Administrator. The Council will receive a presentation from the Bureau of Ocean Energy Management. There will be a Public scoping hearing for Amendment 16 to the Mackerel, Squid, and Butterfish FMP (Deep Sea Corals).

On Thursday, February 14—The Council will hold its regular Business Session to approve the December 2012 minutes, receive Organizational Reports, the New England and South Atlantic Liaison Report; the Executive Director's Report, Science Report, Committee Reports, and conduct any continuing and/or new business.

Special Accommodations

This meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aid should be directed to M. Jan Saunders (302–526–5251) at least five days prior to the meeting date.

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

Dated: January 22, 2013.

Tracey L. Thompson,

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

[FR Doc. 2013–01504 Filed 1–24–13; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Telecommunications and Information Administration

First Responder Network Authority Board Meeting

AGENCY: National Telecommunications and Information Administration, U.S. Department of Commerce.

ACTION: Notice regarding public meeting.

SUMMARY: This notice provides additional information regarding the public meeting of the Board of the First Responder Network Authority (FirstNet) to be held on February 12, 2013.

DATES: The meeting will be held on February 12, 2013, from 9 a.m. to 12:30 p.m. Mountain Standard Time.

ADDRESSES: Board members will meet at the National Institute of Standards and Technology (NIST) Radio Building 1 (Room 1107), 325 Broadway, Boulder, CO 80305–3328.

FOR FURTHER INFORMATION CONTACT: Uzoma Onyeije, Secretary, FirstNet, U.S. Department of Commerce, 1401 Constitution Avenue NW., Washington, DC 20230, (202) 482–0016, *uzoma@firstnet.gov.* Please direct media inquiries to NTIA's Office of Public Affairs, (202) 482–7002.

SUPPLEMENTARY INFORMATION: On January 14, 2013, NTIA published a notice in the **Federal Register** announcing a public meeting of the FirstNet Board to be held on February 12, 2013 in Boulder, Colorado. 78 FR 2660 (Jan. 14, 2013). This Notice is intended to inform the public that the Board may, by a majority vote, close a portion of its February 12 meeting as necessary to preserve the confidentiality of commercial or financial information that is privileged or confidential, to discuss personnel matters, or to discuss legal matters affecting the First Responder Network Authority, including pending or potential litigation. *See* 47 U.S.C. 1424(e)(2).

Dated: January 22, 2013.

Kathy D. Smith,

Chief Counsel, National Telecommunications and Information Administration.

[FR Doc. 2013–01568 Filed 1–24–13; 8:45 am]

BILLING CODE 3510–60–P

COMMITTEE FOR PURCHASE FROM PEOPLE WHO ARE BLIND OR SEVERELY DISABLED

Procurement List; Proposed Additions

AGENCY: Committee for Purchase From People Who Are Blind or Severely Disabled.

ACTION: Proposed Additions to the Procurement List.

SUMMARY: The Committee is proposing to add products to the Procurement List that will be furnished by nonprofit agencies employing persons who are blind or have other severe disabilities.

Comments Must Be Received On or Before: 2/25/2013.

ADDRESSES: Committee for Purchase From People Who Are Blind or Severely Disabled, Jefferson Plaza 2, Suite 10800, 1421 Jefferson Davis Highway, Arlington, Virginia 22202–3259.

FOR FURTHER INFORMATION OR TO SUBMIT COMMENTS CONTACT: Barry S. Lineback, Telephone: (703) 603–7740, Fax: (703) 603–0655, or email *CMTEFedReg@AbilityOne.gov.*

SUPPLEMENTARY INFORMATION: This notice is published pursuant to 41 U.S.C. 8503(a)(2) and 41 CFR 51–2.3. Its purpose is to provide interested persons an opportunity to submit comments on the proposed actions.

Additions

If the Committee approves the proposed additions, the entities of the Federal Government identified in this notice will be required to procure the products listed below from nonprofit agencies employing persons who are blind or have other severe disabilities.

The following products are proposed for addition to the Procurement List for production by the nonprofit agencies listed:

Products

NSN: MR 1057—Butterfly Mop, Hybrid Sponge.
NSN: MR 1058—Refill, Hybrid Sponge Head, Blue.
NPA: L.C. Industries for the Blind, Inc., Durham, NC.
Contracting Activity: Military Resale-Defense Commissary Agency (DeCA), Fort Lee, VA.
Coverage: C-List for the requirements of military commissaries and exchanges as aggregated by the Defense Commissary Agency.

Coveralls, Breathable, Particulate Resistant Design

NSN: 8415–LL–L10–0002—Medium.
NSN: 8415–LL–L10–0003—Large.
NSN: 8415–LL–L10–0004—X-Large.
NSN: 8415–LL–L10–0005—2X-Large.
NSN: 8415–LL–L10–0006—3X-Large.
NSN: 8415–LL–L10–0007—4X-Large.
NPA: Northeastern Association of the Blind at Albany, Inc., Albany, NY.
Contracting Activity: Defense Logistics Agency Maritime—Norfolk, Portsmouth, VA.
Coverage: C-List for 100% of the requirement of the U.S. Navy, as aggregated by the Defense Logistics Agency Maritime—Norfolk, Portsmouth, VA.

Barry S. Lineback,
Director, Business Operations.

[FR Doc. 2013–01527 Filed 1–24–13; 8:45 am]
BILLING CODE 6353–01–P

COMMITTEE FOR PURCHASE FROM PEOPLE WHO ARE BLIND OR SEVERELY DISABLED

Procurement List; Additions

AGENCY: Committee for Purchase From People Who Are Blind or Severely Disabled.

ACTION: Additions to the Procurement List.

SUMMARY: This action adds products to the Procurement List that will be furnished by the nonprofit agency employing persons who are blind or have other severe disabilities.

DATES: *Effective Date:* 2/25/2013.

ADDRESSES: Committee for Purchase From People Who Are Blind or Severely Disabled, Jefferson Plaza 2, Suite 10800, 1421 Jefferson Davis Highway, Arlington, Virginia 22202–3259.

FOR FURTHER INFORMATION CONTACT: Barry S. Lineback, Telephone: (703) 603–7740, Fax: (703) 603–0655, or email *CMTEFedReg@AbilityOne.gov.*

SUPPLEMENTARY INFORMATION:

Additions

On 11/27/2012 (77 FR 70737–70738), the Committee for Purchase From People Who Are Blind or Severely Disabled published notice of proposed additions to the Procurement List.

After consideration of the material presented to it concerning capability of qualified nonprofit agency to furnish the products and impact of the addition on the current or most recent contractors, the Committee has determined that the products listed below are suitable for procurement by the Federal Government under 41 U.S.C. 8501–8506 and 41 CFR 51–2.4.

Regulatory Flexibility Act Certification

I certify that the following action will not have a significant impact on a substantial number of small entities. The major factors considered for this certification were:

1. The action will not result in any additional reporting, recordkeeping or other compliance requirements for small entities other than the small organization that will furnish the products to the Government.

2. The action will result in authorizing small entities to furnish the products to the Government.

3. There are no known regulatory alternatives which would accomplish the objectives of the Javits-Wagner-O'Day Act (41 U.S.C. 8501–8506) in connection with the products proposed for addition to the Procurement List.

End of Certification

Accordingly, the following products are added to the Procurement List:

Products

NSN: 8950–01–E61–0660—Spice, Oregano, Ground, 6/12 oz. Containers.
NSN: 8950–01–E62–0111—Spice, Cumin, Ground, 6/16 oz. Containers.
NSN: 8950–01–E60–9321—Spice, Pepper, White, Ground, 6/18 oz. Containers.
NSN: 8950–01–E62–0148—Spice, Bay Leaf, Whole, ⅜ oz. Containers.
NPA: CDS Monarch, Webster, NY.
Contracting Activity: Defense Logistics Agency Troop Support, Philadelphia, PA.
Coverage: C-List for 100% of the requirement of the Department of Defense, as aggregated by the Defense Logistics Agency Troop Support, Philadelphia, PA.

Barry S. Lineback,
Director, Business Operations.

[FR Doc. 2013–01528 Filed 1–24–13; 8:45 am]
BILLING CODE 6353–01–P

COMMODITY FUTURES TRADING COMMISSION

Sunshine Act Meetings

TIME AND DATE: 10:00 a.m., Friday February 22, 2013.

PLACE: 1155 21st St. NW., Washington, DC, 9th Floor Commission Conference Room.

STATUS: Closed.

MATTERS TO BE CONSIDERED: Surveillance and Enforcement Matters. I the event that the times or dates of these or any future meetings change, an announcement of the change, along with the new time and place of the meeting will be posted on the Commission's Web site at http://www.cftc.gov

CONTACT PERSON FOR MORE INFORMATION: Melissa Jurgens, 202–418–5516.

Stacy D. Yochum,
Counsel to the Executive Director.

[FR Doc. 2013–01734 Filed 1–23–13; 4:15 pm]
BILLING CODE 6351–01–P

COMMODITY FUTURES TRADING COMMISSION

Sunshine Act Meetings

TIME AND DATE: 10:00 a.m., Friday February 8, 2013.

PLACE: 1155 21st St. NW., Washington, DC, 9th Floor Commission Conference Room.

STATUS: Closed.

MATTERS TO BE CONSIDERED: Surveillance and Enforcement Matters. In the event that the times or dates of these or any future meetings change, an announcement of the change, along with the new time and place of the meeting will be posted on the Commission's Web site at *http://www.cftc.gov*.

CONTACT PERSON FOR MORE INFORMATION: Melissa Jurgens, 202–418–5516.

Stacy D. Yochum,

Counsel to the Executive Director.

[FR Doc. 2013–01731 Filed 1–23–13; 4:15 pm]

BILLING CODE 6351–01–P

COMMODITY FUTURES TRADING COMMISSION

Sunshine Act Meetings

TIME AND DATE: 10:00 a.m., Friday February 1, 2013.

PLACE: 1155 21st St. NW., Washington, DC, 9th Floor Commission Conference Room.

STATUS: Closed.

MATTERS TO BE CONSIDERED: Surveillance and Enforcement Matters. In the event that the times or dates of these or any future meetings change, an announcement of the change, along with the new time and place of the meeting will be posted on the Commission's Web site at *http://www.cftc.gov.*

CONTACT PERSON FOR MORE INFORMATION: Stacy Yochum, 202–418–5157.

Stacy D. Yochum,

Counsel to the Executive Director.

[FR Doc. 2013–01730 Filed 1–23–13; 4:15 pm]

BILLING CODE 6351–01–P

CONSUMER PRODUCT SAFETY COMMISSION

Sunshine Act Meetings, Cancellation

FEDERAL REGISTER CITATION OF PREVIOUS ANNOUNCEMENT: Vol. 77, No. 12, Thursday, January 17, 2013, page 3883.

ANNOUNCED TIME AND DATE OF MEETING: Thursday, January 23, 2013, 10 a.m.–11 a.m.

MATTER TO BE CONSIDERED: *Decisional Matter:* Section 1110 Certificates of Compliance—Notice of Proposed Rulemaking.

MEETING CANCELED: For a recorded message containing the latest agenda information, call (301) 504–7948.

CONTACT PERSON FOR ADDITIONAL INFORMATION: Todd A. Stevenson, Office of the Secretary, Consumer Product Safety Commission, 4330 East West Highway, Bethesda, MD 20814 (301) 504–7923.

Dated: January 23, 2013.

Todd A. Stevenson,

Secretary.

[FR Doc. 2013–01658 Filed 1–23–13; 4:15 pm]

BILLING CODE 6355–01–P

DEPARTMENT OF DEFENSE

Department of the Navy

Meeting of the U.S. Naval Academy Board of Visitors

AGENCY: Department of the Navy, DoD.

ACTION: Notice of Partially Closed Meeting.

SUMMARY: The U.S. Naval Academy Board of Visitors will meet to make such inquiry, as the Board shall deem necessary, into the state of morale and discipline, the curriculum, instruction, physical equipment, fiscal affairs, and academic methods of the Naval Academy. The executive session of this meeting from 11:00 a.m. to 12:00 p.m. on March 4, 2013, will include discussions of disciplinary matters and personnel issues at the Naval Academy; the disclosure of which would constitute a clearly unwarranted invasion of personal privacy. For this reason, the executive session of this meeting will be closed to the public.

DATES: The open session of the meeting will be held on March 4, 2013, from 8:30 a.m. to 11:00 a.m. The closed session of this meeting will be the executive session held from 11:00 a.m. to 12:00 p.m.

ADDRESSES: The meeting will be held in the Bo Coppedge Room at the Naval Academy in Annapolis, MD. The meeting will be handicap accessible.

FOR FURTHER INFORMATION CONTACT: Lieutenant Commander Travis Haire, USN, Executive Secretary to the Board of Visitors, Office of the Superintendent, U.S. Naval Academy, Annapolis, MD 21402–5000, 410–293–1503.

SUPPLEMENTARY INFORMATION: This notice of meeting is provided per the Federal Advisory Committee Act, as amended (5 U.S.C. App.). The executive session of the meeting from 11:00 a.m. to 12:00 p.m. on March 4, 2013, will consist of discussions of new and pending administrative/minor disciplinary infractions and non-judicial punishments involving the Midshipmen attending the Naval Academy to include but not limited to individual honor/conduct violations within the Brigade, and personnel issues. The discussion of such information cannot be adequately segregated from other topics, which precludes opening the executive session of this meeting to the public.

Accordingly, the Under Secretary of the Navy has determined in writing that the meeting shall be partially closed to the public because the discussions during the executive session from 11:00 a.m. to 12:00 p.m. will be concerned with matters coming under sections 552b(c)(5), (6), and (7) of title 5, United States Code.

Dated: January 17, 2013.

L.R. Almand,

Alternate Federal Register Liaison Officer, Office of the Judge Advocate General.

[FR Doc. 2013–01587 Filed 1–24–13; 8:45 am]

BILLING CODE P

DEPARTMENT OF EDUCATION

Applications for New Awards; Indian Education—Professional Development Grants Program

AGENCY: Office of Elementary and Secondary Education, Department of Education.

ACTION: Notice.

Overview Information

Indian Education—Professional Development Grants Program Notice inviting applications for new awards for fiscal year (FY) 2013.

Catalog of Federal Domestic Assistance (CFDA) Number: 84.299B.

DATES:

Applications Available: January 25, 2013.

Deadline for Transmittal of Applications: March 1, 2013.

Deadline for Intergovernmental Review: April 30, 2013.

Full Text of Announcement

I. Funding Opportunity Description

Purpose of Program: The purposes of the Indian Education Professional Development Grants program are to (1) Increase the number of qualified Indian individuals in professions that serve Indians; (2) provide training to qualified Indian individuals to become teachers, administrators, teacher aides, social workers, and ancillary educational

personnel; and (3) improve the skills of qualified Indian individuals who serve in the education field. Activities may include, but are not limited to, continuing education programs, symposia, workshops, conferences, and direct financial support.

Priorities: This competition contains three absolute priorities and two competitive preference priorities.

Absolute Priorities: Absolute Priority 1 is from the notice of final supplemental priorities and definitions for discretionary grant programs, published in the **Federal Register** on December 15, 2010 (75 FR 78486), and corrected on May 12, 2011 (76 FR 27637). In accordance with 34 CFR 75.105(b)(2)(ii), Absolute Priorities 2 and 3 are from the regulations for this program (34 CFR 263.5(c)). For FY 2013 and any subsequent year in which we make awards from the list of unfunded applicants from this competition, these priorities are absolute priorities. Under 34 CFR 75.105(c)(3), we consider only applications that meet Absolute Priority 1 and one or both of Absolute Priorities 2 and 3.

These priorities are:

Absolute Priority 1: Enabling More Data-Based Decision-Making

Projects that are designed to collect (or obtain), analyze, and use high-quality and timely data, including data on program participant outcomes, in accordance with privacy requirements (as defined in this notice), in the following priority area:

Improving postsecondary student outcomes relating to enrollment, persistence, and completion and leading to career success.

Absolute Priority 2: Pre-Service Training for Teachers

Projects that provide support and training to Indian individuals to complete a pre-service education program that enables these individuals to meet the requirements for full State certification or licensure as a teacher through—

(a)(1) Training that leads to a bachelor's degree in education before the end of the award period; or

(2) For States allowing a degree in a specific subject area, training that leads to a bachelor's degree in the subject area as long as the training meets the requirements for full State teacher certification or licensure; or

(3) Training in a current or new specialized teaching assignment that requires at least a bachelor's degree and in which a documented teacher shortage exists; and

(b) One-year induction services after graduation, certification, or licensure, provided during the award period to graduates of the pre-service program while they are completing their first year of work in schools with significant Indian populations.

Note: In working with various institutions of higher education and reviewing State certification and licensure requirements, we have found that States allowing a candidate for teacher certification to obtain a degree in a specific subject area (e.g., in a specialty area or in teaching at the secondary level) generally require a master's degree or fifth year of study before an individual can be certified or licensed as a teacher. These students would be eligible to participate so long as their training meets the requirements for full State certification or licensure as a teacher.

Absolute Priority 3: Pre-Service Administrator Training

A project that provides—

(1) Support and training to Indian individuals to complete a master's degree in education administration that is provided before the end of the award period and that allows participants to meet the requirements for State certification or licensure as an education administrator; and

(2) One year of induction services, during the award period, to participants after graduation, certification, or licensure, while they are completing their first year of work as administrators in schools with significant Indian student populations.

Competitive Preference Priorities: In accordance with 34 CFR 75.105(b)(2)(ii), the competitive preference priorities are from the regulations for this program (34 CFR 263.5(a) and (b)). For FY 2013 and any subsequent year in which we make awards from the list of unfunded applicants from this competition, these priorities are competitive preference priorities. Under 34 CFR 75.105(c)(2)(i) we award up to an additional 10 points to an application, depending on how well the application meets one or both of these priorities.

These priorities are:

Competitive Preference Priority One. (5 points)

We award five competitive preference points to an application submitted by an Indian tribe, Indian organization, or Indian institution of higher education that is eligible to participate in the Indian Education Professional Development program. A consortium application of eligible entities that meets the requirements of 34 CFR 75.127 through 75.129 of the Education Department General Administrative Regulations (EDGAR) and includes an Indian tribe, Indian organization, or Indian institution of higher education will be considered eligible to receive the five priority points. The consortium agreement, signed by all parties, must be submitted with the application in order to be considered as a consortium application.

Competitive Preference Priority Two. (5 points)

We award five competitive preference points to an application submitted by a consortium of eligible applicants that includes a tribal college or university and that designates that tribal college or university as the fiscal agent for the application. The consortium application of eligible entities must meet the requirements of 34 CFR 75.127 through 75.129 of EDGAR to be considered eligible to receive the five priority points. These competitive preference points are in addition to the five competitive preference points that may be given under Competitive Preference Priority One. The consortium agreement, signed by all parties, must be submitted with the application in order to be considered as a consortium application.

Definitions: The following definition is from the notice of supplemental priorities and definitions for discretionary grant programs, published in the **Federal Register** on December 15, 2010 (75 FR 78486), and corrected on May 12, 2011 (76 FR 27637), and applies to this competition. Additional definitions applicable to this program are found in the authorizing statute for this program at 20 U.S.C. 7442 and 7491, and in applicable regulations in 34 CFR parts 77 and 263, and will be included in the application package.

Privacy requirements means the requirements of the Family Educational Rights and Privacy Act (FERPA), 20 U.S.C. 1232g, and its implementing regulations in 34 CFR part 99, the Privacy Act, 5 U.S.C. 552a, as well as all applicable Federal, State and local requirements regarding privacy.

Program Authority: 20 U.S.C. 7442.

Applicable Regulations: (a) EDGAR in 34 CFR parts 74, 75, 77, 79, 80, 81, 82, 84, 86, 97, 98, and 99. (b) The Education Department suspension and debarment regulations in 2 CFR part 3485. (c) The regulations for this program in 34 CFR part 263. (d) The supplemental priorities and definitions for discretionary grant programs, published in the **Federal Register** on December 15, 2010 (75 FR 78486), and corrected on May 12, 2011 (76 FR 27637).

Note: The regulations in 34 CFR part 79 apply to all applicants except federally recognized Indian tribes.

Note: The regulations in 34 CFR part 86 apply to institutions of higher education only.

II. Award Information

Type of Award: Discretionary grants.

Estimated Available Funds: $2,347,789.

Contingent upon the availability of funds and the quality of applications, we may make additional awards in FY 2014 from the list of unfunded applicants from this competition.

Estimated Range of Awards: $300,000–$400,000.

Estimated Average Size of Awards: $370,000.

Maximum Award: We will reject any application that proposes a budget exceeding $400,000 for the first, second, or third 12-month budget period. The last 12-month budget period of a 48-month award will be limited to induction services only, at a cost not to exceed $90,000. The Assistant Secretary for Elementary and Secondary Education may change the maximum amount through a notice published in the **Federal Register**.

Estimated Number of Awards: 6.

Note: The Department is not bound by any estimates in this notice.

Project Period: Up to 48 months.

III. Eligibility Information

1. *Eligible Applicants:* Eligible applicants for this program are institutions of higher education, including Indian institutions of higher education; State educational agencies (SEAs) or local educational agencies (LEAs) in consortium with an institution of higher education; Indian tribes or organizations in consortium with an institution of higher education; and Department of the Interior/Bureau of Indian Education-funded schools in consortium with an institution of higher education. LEAs include charter schools that are considered LEAs under State law.

An application from a consortium of eligible entities must meet the requirements of 34 CFR 75.127 through 75.129. An application from a consortium of eligible entities must include a consortium agreement, signed by all parties, with the application. Letters of support do *not* meet the requirement for a consortium agreement.

In order to be considered an eligible entity, applicants, including institutions of higher education, must be eligible to provide the level and type of degree proposed in the application or must apply in a consortium with an institution of higher education that is eligible to grant the target degree.

Applicants applying in consortium with or as an Indian organization must demonstrate that they meet the definition of ''Indian organization'' in 34 CFR 263.3.

The term ''Indian institution of higher education'' means an accredited college or university within the United States cited in section 532 of the Equity in Educational Land-Grant Status Act of 1994 (7 U.S.C. 301 note), any other institution that qualifies for funding under the Tribally Controlled College or University Assistance Act of 1978 (25 U.S.C. 1801 et seq.), and Dine College (formerly Navajo Community College), authorized in the Navajo Community College Assistance Act of 1978 (25 U.S.C. 640a et seq.).

2. *Cost Sharing or Matching:* This program does not require cost sharing or matching.

3. *Other:* Projects funded under this competition are encouraged to budget for a two-day Project Directors' meeting in Washington, DC during each year of the project period. In addition, the Department strongly encourages grantees to begin to provide training by January 2014.

IV. Application and Submission Information

1. *Address to Request Application Package:* You can obtain an application package via the Internet or from the Education Publications Center (ED Pubs). To obtain a copy via the Internet, use the following address: *http://www.ed.gov/fund/grant/apply/grantapps/index.html.* To obtain a copy from ED Pubs, write, fax, or call the following: ED Pubs, U.S. Department of Education, P.O. Box 22207, Alexandria, VA 22304. Telephone, toll free: 1–877–433–7827. Fax: (703) 605–6794. If you use a telecommunications device for the deaf (TDD) or a text telephone (TTY), call the Federal Relay Service (FRS), toll free, at 1–800–877–8339.

You can contact ED Pubs at its Web site, also: *www.EDPubs.gov* or at its email address: *edpubs@inet.ed.gov.*

If you request an application from ED Pubs, be sure to identify this program or competition as follows: CFDA number 84.299B.

Individuals with disabilities can obtain a copy of the application package in an accessible format (e.g., braille, large print, audiotape, or compact disc) by contacting the person listed under *Accessible Format* in section VIII of this notice.

2. a. *Content and Form of Application Submission:* Requirements concerning the content of an application, together with the forms you must submit, are in the application package for this program.

Page Limit: The application narrative is where you, the applicant, address the selection criteria that reviewers use to evaluate your application. The suggested page limit for the application narrative is no more than 35 pages. The suggested standards for the narrative include:

- A page is 8.5″ x 11″, on one side only, with 1'' margins at the top, bottom, and both sides.
- Double space all text in the application narrative, including titles, headings, footnotes, quotations, references, and captions, as well as all text in charts, tables, figures, and graphs.
- Use a font that is either 12 point or larger or no smaller than 10 pitch (characters per inch).
- Use one of the following fonts: Times New Roman, Courier, Courier New, or Arial.

The suggested page limit does not apply to the cover sheet; the budget section, including the budget narrative justification; the assurances and certifications; or the abstract, table of contents, the resumes, the bibliography, letters of support, or the signed consortium agreement if applicable.

b. *Submission of Proprietary Information:*

Given the types of projects that may be proposed in applications for the Indian Education Professional Development Grant, an application may include business information that the applicant considers proprietary. The Department's regulations define ''business information'' in 34 CFR 5.11.

Because we plan to make successful applications available to the public, you may wish to request confidentiality of business information.

Consistent with Executive Order 12600, please designate in your application any information that you feel is exempt from disclosure under Exemption 4 of the Freedom of Information Act. In the appropriate Appendix section of your application, under ''Other Attachments Form,'' please list the page number or numbers on which we can find this information. For additional information please see 34 CFR 5.11(c).

3. *Submission Dates and Times:*

Applications Available: January 25, 2013.

Deadline for Transmittal of Applications: March 1, 2013.

Applications for grants under this competition must be submitted electronically using the Grants.gov Apply site (Grants.gov). For information (including dates and times) about how to submit your application electronically, or in paper format by mail or hand delivery if you qualify for an exception to the electronic submission requirement, please refer to section IV. 7. *Other Submission Requirements* of this notice.

We do not consider an application that does not comply with the deadline requirements.

Individuals with disabilities who need an accommodation or auxiliary aid in connection with the application process should contact the person listed under **FOR FURTHER INFORMATION CONTACT** in section VII of this notice. If the Department provides an accommodation or auxiliary aid to an individual with a disability in connection with the application process, the individual's application remains subject to all other requirements and limitations in this notice.

Deadline for Intergovernmental Review: April 30, 2013

4. *Intergovernmental Review:* This program is subject to Executive Order 12372 and the regulations in 34 CFR part 79. Information about Intergovernmental Review of Federal Programs under Executive Order 12372 is in the application package for this competition.

5. *Funding Restrictions:* We specify allowable costs in 34 CFR 263.4. A project funded under this program may include, as training costs, assistance to either fully finance a student's educational expenses or supplement other financial aid for meeting a student's educational expenses. For the payment of stipends to project participants receiving training, the Secretary expects to set the stipend maximum at $1,800 per month for full-time students and provide for a $300 allowance per month per dependent during an academic term. The terms ''stipend,'' ''full-time student,'' and ''dependent allowance'' are defined in 34 CFR 263.3. Stipends may be paid only to full-time students.

We reference additional regulations outlining funding restrictions in the *Applicable Regulations* section of this notice.

6. *Data Universal Numbering System Number, Taxpayer Identification Number, Central Contractor Registry, and System for Award Management:* To do business with the Department of Education, you must—

a. Have a Data Universal Numbering System (DUNS) number and a Taxpayer Identification Number (TIN);

b. Register both your DUNS number and TIN with the Central Contractor Registry (CCR)—and, after July 24, 2012, with the System for Award Management (SAM)—the Government's primary registrant database;

c. Provide your DUNS number and TIN on your application; and

d. Maintain an active CCR or SAM registration with current information while your application is under review by the Department and, if you are awarded a grant, during the project period.

You can obtain a DUNS number from Dun and Bradstreet. A DUNS number can be created within one business day.

If you are a corporate entity, agency, institution, or organization, you can obtain a TIN from the Internal Revenue Service. If you are an individual, you can obtain a TIN from the Internal Revenue Service or the Social Security Administration. If you need a new TIN, please allow 2–5 weeks for your TIN to become active.

The CCR or SAM registration process may take five or more business days to complete. If you are currently registered with the CCR, you may not need to make any changes. However, please make certain that the TIN associated with your DUNS number is correct. Also note that you will need to update your registration annually. This may take three or more business days to complete. Information about SAM is available at *SAM.gov.*

In addition, if you are submitting your application via Grants.gov, you must (1) be designated by your organization as an Authorized Organization Representative (AOR); and (2) register yourself with Grants.gov as an AOR. Details on these steps are outlined at the following Grants.gov Web page: *www.grants.gov/applicants/get_registered.jsp.*

7. *Other Submission Requirements:* Applications for grants under this competition must be submitted electronically unless you qualify for an exception to this requirement in accordance with the instructions in this section.

a. *Electronic Submission of Applications.*

Applications for grants under the Indian Education—Professional Development program, CFDA Number 84.299B, must be submitted electronically using the Governmentwide Grants.gov Apply site at *www.Grants.gov.* Through this site, you will be able to download a copy of the application package, complete it offline, and then upload and submit your application. You may not email an electronic copy of a grant application to us.

We will reject your application if you submit it in paper format unless, as described elsewhere in this section, you qualify for one of the exceptions to the electronic submission requirement *and* submit, no later than two weeks before the application deadline date, a written statement to the Department that you qualify for one of these exceptions. Further information regarding calculation of the date that is two weeks before the application deadline date is provided later in this section under *Exception to Electronic Submission Requirement.*

You may access the electronic grant application for the Indian Education—Professional Development program at *www.Grants.gov.* You must search for the downloadable application package for this program by the CFDA number. Do not include the CFDA number's alpha suffix in your search (e.g., search for 84.299, not 84.299B).

Please note the following:

- When you enter the Grants.gov site, you will find information about submitting an application electronically through the site, as well as the hours of operation.
- Applications received by Grants.gov are date and time stamped. Your application must be fully uploaded and submitted and must be date and time stamped by the Grants.gov system no later than 4:30:00 p.m., Washington, DC time, on the application deadline date. Except as otherwise noted in this section, we will not accept your application if it is received—that is, date and time stamped by the Grants.gov system—after 4:30:00 p.m., Washington, DC time, on the application deadline date. We do not consider an application that does not comply with the deadline requirements. When we retrieve your application from Grants.gov, we will notify you if we are rejecting your application because it was date and time stamped by the Grants.gov system after 4:30:00 p.m., Washington, DC time, on the application deadline date.
- The amount of time it can take to upload an application will vary depending on a variety of factors, including the size of the application and the speed of your Internet connection. Therefore, we strongly recommend that you do not wait until the application deadline date to begin the submission process through Grants.gov.
- You should review and follow the Education Submission Procedures for submitting an application through Grants.gov that are included in the application package for this program to

ensure that you submit your application in a timely manner to the Grants.gov system. You can also find the Education Submission Procedures pertaining to Grants.gov under News and Events on the Department's G5 system home page at *www.G5.gov.*

- You will not receive additional point value because you submit your application in electronic format, nor will we penalize you if you qualify for an exception to the electronic submission requirement, as described elsewhere in this section, and submit your application in paper format.
- You must submit all documents electronically, including all information you typically provide on the following forms: the Application for Federal Assistance (SF 424), the Department of Education Supplemental Information for SF 424, Budget Information—Non-Construction Programs (ED 524), and all necessary assurances and certifications.
- You must upload any narrative sections and all other attachments to your application as files in a PDF (Portable Document) read-only, non-modifiable format. Do not upload an interactive or fillable PDF file. If you upload a file type other than a read-only, non-modifiable PDF or submit a password-protected file, we will not review that material.
- Your electronic application must comply with any page-limit requirements described in this notice.
- After you electronically submit your application, you will receive from Grants.gov an automatic notification of receipt that contains a Grants.gov tracking number. (This notification indicates receipt by Grants.gov only, not receipt by the Department.) The Department then will retrieve your application from Grants.gov and send a second notification to you by email. This second notification indicates that the Department has received your application and has assigned your application a PR/Award number (an ED-specified identifying number unique to your application).
- We may request that you provide us original signatures on forms at a later date.

Application Deadline Date Extension in Case of Technical Issues with the Grants.gov System: If you are experiencing problems submitting your application through Grants.gov, please contact the Grants.gov Support Desk, toll free, at 1–800–518–4726. You must obtain a Grants.gov Support Desk Case Number and must keep a record of it.

If you are prevented from electronically submitting your application on the application deadline date because of technical problems with the Grants.gov system, we will grant you an extension until 4:30:00 p.m., Washington, DC time, the following business day to enable you to transmit your application electronically or by hand delivery. You also may mail your application by following the mailing instructions described elsewhere in this notice.

If you submit an application after 4:30:00 p.m., Washington, DC time, on the application deadline date, please contact the person listed under **FOR FURTHER INFORMATION CONTACT** in section VII of this notice and provide an explanation of the technical problem you experienced with Grants.gov, along with the Grants.gov Support Desk Case Number. We will accept your application if we can confirm that a technical problem occurred with the Grants.gov system and that that problem affected your ability to submit your application by 4:30:00 p.m., Washington, DC time, on the application deadline date. The Department will contact you after a determination is made on whether your application will be accepted.

Note: The extensions to which we refer in this section apply only to the unavailability of, or technical problems with, the Grants.gov system. We will not grant you an extension if you failed to fully register to submit your application to Grants.gov before the application deadline date and time or if the technical problem you experienced is unrelated to the Grants.gov system.

Exception to Electronic Submission Requirement: You qualify for an exception to the electronic submission requirement, and may submit your application in paper format, if you are unable to submit an application through the Grants.gov system because—

- You do not have access to the Internet; or
- You do not have the capacity to upload large documents to the Grants.gov system;

and

- No later than two weeks before the application deadline date (14 calendar days or, if the fourteenth calendar day before the application deadline date falls on a Federal holiday, the next business day following the Federal holiday), you mail or fax a written statement to the Department, explaining which of the two grounds for an exception prevent you from using the Internet to submit your application.

If you mail your written statement to the Department, it must be postmarked no later than two weeks before the application deadline date. If you fax your written statement to the Department, we must receive the faxed statement no later than two weeks before the application deadline date.

Address and mail or fax your statement to: Lana Shaughnessy, U.S. Department of Education, 400 Maryland Avenue SW., room number 3E231, Washington, DC 20202. Fax: (202) 260–7779.

Your paper application must be submitted in accordance with the mail or hand delivery instructions described in this notice.

b. *Submission of Paper Applications by Mail.*

If you qualify for an exception to the electronic submission requirement, you may mail (through the U.S. Postal Service or a commercial carrier) your application to the Department. You must mail the original and two copies of your application, on or before the application deadline date, to the Department at the following address:

U.S. Department of Education, Application Control Center, Attention: CFDA Number 84.299B, LBJ Basement Level 1, 400 Maryland Avenue SW., Washington, DC 20202–4260.

You must show proof of mailing consisting of one of the following:

(1) A legibly dated U.S. Postal Service postmark.

(2) A legible mail receipt with the date of mailing stamped by the U.S. Postal Service.

(3) A dated shipping label, invoice, or receipt from a commercial carrier.

(4) Any other proof of mailing acceptable to the Secretary of the U.S. Department of Education.

If you mail your application through the U.S. Postal Service, we do not accept either of the following as proof of mailing:

(1) A private metered postmark.

(2) A mail receipt that is not dated by the U.S. Postal Service.

If your application is postmarked after the application deadline date, we will not consider your application.

Note: The U.S. Postal Service does not uniformly provide a dated postmark. Before relying on this method, you should check with your local post office.

c. *Submission of Paper Applications by Hand Delivery.*

If you qualify for an exception to the electronic submission requirement, you (or a courier service) may deliver your paper application to the Department by hand. You must deliver the original and two copies of your application, by hand, on or before the application deadline date, to the Department at the following address: U.S. Department of Education, Application Control Center, Attention: (CFDA Number 84.299B), 550 12th Street SW., Room 7041, Potomac Center Plaza, Washington, DC 20202–4260.

The Application Control Center accepts hand deliveries daily between 8:00 a.m. and 4:30:00 p.m., Washington, DC time, except Saturdays, Sundays, and Federal holidays.

Note for Mail or Hand Delivery of Paper Applications: If you mail or hand deliver your application to the Department—

(1) You must indicate on the envelope and—if not provided by the Department—in Item 11 of the SF 424 the CFDA number, including suffix letter, if any, of the competition under which you are submitting your application; and

(2) The Application Control Center will mail to you a notification of receipt of your grant application. If you do not receive this notification within 15 business days from the application deadline date, you should call the U.S. Department of Education Application Control Center at (202) 245–6288.

V. Application Review Information

1. *Selection Criteria:* The selection criteria for this competition are from 34 CFR 263.6 and are listed in the application package.

2. *Review and Selection Process:* We remind potential applicants that in reviewing applications in any discretionary grant competition, the Secretary may consider, under 34 CFR 75.217(d)(3), the past performance of the applicant in carrying out a previous award, such as the applicant's use of funds, achievement of project objectives, and compliance with grant conditions. The Secretary may also consider whether the applicant failed to submit a timely performance report or submitted a report of unacceptable quality.

In addition, in making a competitive grant award, the Secretary also requires various assurances including those applicable to Federal civil rights laws that prohibit discrimination in programs or activities receiving Federal financial assistance from the Department of Education (34 CFR 100.4, 104.5, 106.4, 108.8, and 110.23).

3. *Special Conditions:* Under 34 CFR 74.14 and 80.12, the Secretary may impose special conditions on a grant if the applicant or grantee is not financially stable; has a history of unsatisfactory performance; has a financial or other management system that does not meet the standards in 34 CFR parts 74 or 80, as applicable; has not fulfilled the conditions of a prior grant; or is otherwise not responsible.

VI. Award Administration Information

1. *Award Notices:* If your application is successful, we notify your U.S. Representative and U.S. Senators and send you a Grant Award Notification (GAN); or we may send you an email containing a link to access an electronic version of your GAN. We may notify you informally, also.

If your application is not evaluated or not selected for funding, we notify you.

2. *Administrative and National Policy Requirements:* We identify administrative and national policy requirements in the application package and reference these and other requirements in the *Applicable Regulations* section of this notice.

We reference the regulations outlining the terms and conditions of an award in the *Applicable Regulations* section of this notice and include these and other specific conditions in the GAN. The GAN also incorporates your approved application as part of your binding commitments under the grant.

3. *Reporting:* (a) If you apply for a grant under this competition, you must ensure that you have in place the necessary processes and systems to comply with the reporting requirements in 2 CFR 170 should you receive funding under this competition. This does not apply if you have an exception under 2 CFR 170.110(b).

(b) At the end of your project period, you must submit a final performance report, including financial information, as directed by the Secretary. If you receive a multi-year award, you must submit an annual performance report that provides the most current performance and financial expenditure information as directed by the Secretary under 34 CFR 75.118. The Secretary may also require more frequent performance reports under 34 CFR 75.720(c). For specific requirements on reporting, please go to *http://www.ed.gov/fund/grant/apply/appforms/appforms.html.*

(c) During the entire performance period of the grant, you must submit information about participants and their status in the program, in the format provided by the Department. This information will include training costs, course of study, and length of training.

(d) You must submit to the Department a copy of each payback agreement signed by a participant in accordance with 34 CFR 263.8.

4. *Performance Measures:* Under the Government Performance and Results Act of 1993 (GPRA), the Department has established the following performance measures for measuring the overall effectiveness of the Indian Education Professional Development program: (1) The percentage of participants in administrator preparation projects who become principals, vice principals, or other school administrators in LEAs that enroll five percent or more American Indian and Alaska Native students; (2) The percentage of participants in teacher preparation projects who become teachers in LEAs that enroll five percent or more American Indian and Alaska Native students; (3) The percentage of program participants who meet the definition of ''Highly Qualified'' in section 9101(23) of the ESEA; (4) The percentage of program participants who complete their service requirement on schedule; (5) The cost per individual who successfully completes an administrator preparation program, takes a position in a school district with at least five percent American Indian/Alaska Native enrollment, and completes the service requirement in such a district; and (6) The cost per individual who successfully completes a teacher preparation program, takes a position in such a school district with at least five percent American Indian/Alaska Native enrollment, and completes the service requirement in such a district.

These measures constitute the Department's indicators of success for this program. Consequently, we advise an applicant for a grant under this program to give careful consideration to these measures in conceptualizing the approach and evaluation for its proposed project. Each grantee will be required to provide, in its annual performance and final reports, data about its progress in meeting these measures.

5. *Continuation Awards:* In making a continuation award, the Secretary may consider, under 34 CFR 75.253, the extent to which a grantee has made ''substantial progress toward meeting the objectives in its approved application.'' This consideration includes the review of a grantee's progress in meeting the targets and projected outcomes in its approved application, and documented in the required participant report and annual performance report, and whether the grantee has expended funds in a manner that is consistent with its approved application and budget. In general, the grantee will demonstrate progress to complete the recruiting and selection of participants in year one, will demonstrate progress in training of selected participants in years two and three, and implement induction services for all graduates in year four. In making a continuation grant, the Secretary also considers whether the grantee is operating in compliance with the assurances in its approved application, including those applicable to Federal civil rights laws that prohibit discrimination in programs or activities receiving Federal financial assistance

from the Department (34 CFR 100.4, 104.5, 106.4, 108.8, and 110.23).

VII. Agency Contact

FOR FURTHER INFORMATION CONTACT: Lana Shaughnessy, U.S. Department of Education, 400 Maryland Avenue SW., room 3E231, Washington, DC 20202–6335. Telephone: (202) 205–2528 or by email: *Lana.Shaughnessy@ed.gov.*

If you use a TDD or TTY, call the FRS, toll free, at 1–800–877–8339.

VIII. Other Information

Accessible Format: Individuals with disabilities can obtain this document and a copy of the application package in an accessible format (e.g., Braille, large print, audiotape, or compact disc) on request to the program contact person listed under **FOR FURTHER INFORMATION CONTACT** in section VII in this notice.

Electronic Access to This Document: The official version of this document is the document published in the **Federal Register**. Free Internet access to the official edition of the **Federal Register** and the Code of Federal Regulations is available via the Federal Digital System at: *www.gpo.gov/fdsys.* At this site you can view this document, as well as all other documents of this Department published in the **Federal Register**, in text or Adobe Portable Document Format (PDF). To use PDF you must have Adobe Acrobat Reader, which is available free at the site.

You may also access documents of the Department published in the **Federal Register** by using the article search feature at: *www.federalregister.gov.* Specifically, through the advanced search feature at this site, you can limit your search to documents published by the Department.

Dated: January 18, 2013.

Deborah Delisle,

Assistant Secretary for Elementary and Secondary Education.

[FR Doc. 2013–01424 Filed 1–24–13; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

Extension of Approval Period for Certain Tests Used in the National Reporting System for Adult Education

AGENCY: Office of Vocational and Adult Education, Department of Education.

ACTION: Extension of approval period.

SUMMARY: The Secretary announces an extension of the approval period for tests that were determined to be suitable for use in the National Reporting System for a period of three years, which would otherwise expire on February 2, 2013. The approval period for these tests is extended to September 30, 2013. This extension of the approval period will allow for the completion of the current National Reporting System assessment review cycle.

FOR FURTHER INFORMATION CONTACT: John LeMaster, Department of Education, 400 Maryland Avenue SW., Room 11159, PCP, Washington, DC 20202–7240. Telephone: (202) 245–6218 or by email: *John.LeMaster@ed.gov.*

If you use a telecommunications device for the deaf (TDD) or a text telephone (TTY), call the Federal Relay Service (FRS), toll free, at 1–800–877–8339.

SUPPLEMENTARY INFORMATION:

Background

On January 14, 2008, the Department published in the **Federal Register** final regulations for 34 CFR part 462, Measuring Educational Gain in the National Reporting System for Adult Education (NRS regulations) (73 FR 2306). The NRS regulations established the process that the Secretary uses to determine the suitability of tests for use in the NRS. We annually publish in the **Federal Register**, and post on the Internet at *www.nrsweb.org,* a list of the names of tests and the educational functioning levels the tests are suitable to measure in the NRS as required by 34 CFR 462.12(c)(2).

On April 16, 2008, we published in the **Federal Register** a notice providing test publishers an opportunity to submit tests for review under the NRS regulations (73 FR 20616) (April 2008 notice). On February 2, 2010, after completing a review of tests submitted in response to the April 2008 notice, we published in the **Federal Register** a notice (February 2010 notice) listing the tests and test forms that the Secretary determined to be suitable for use in the NRS (75 FR 5303). The Secretary determined tests and test forms to be suitable for a period of either seven or three years from the date of the February 2010 notice. A seven-year approval required no additional action on the part of the publisher, unless the information that the publisher submitted as a basis for the Secretary's review was inaccurate or unless the test was substantially revised. A three-year approval required a set of conditions to be met in order to gain a longer approval period. If the conditions were met, the Secretary would approve a period of time for which the test may continue to be used in the NRS. The three-year approvals expire on February 2, 2013.

On September 12, 2011, we published in the **Federal Register** (76 FR 56188) a notice (September 2011 notice) to update the list published on February 2, 2010 (75 FR 5303) and clarify and include suitable test delivery formats. On August 6, 2012, we published in the **Federal Register** (77 FR 46749) a notice (August 2012 notice) announcing the same list of test forms and computer delivery formats that continued to be suitable for use in the NRS, but also announcing a period during which States may sunset an expiring test and transition to other tests suitable for use in the NRS. Specifically, under the sunset provision, States may continue to use tests with three-year NRS approvals expiring on February 2, 2013, during a transition period ending on June 30, 2014. States may use the transition period to select new tests determined to be suitable by the Department, purchase appropriate inventories of assessment materials, and provide training to staff. Finally, on September 6, 2012, we announced in the **Federal Register** (77 FR 54904) the next NRS review cycle, inviting publishers to submit tests by October 1, 2012 so that the Department may determine their suitability for use in the NRS. The Department is currently conducting the assessment reviews.

Extension of Approval Period for Expiring Tests

As stated, the Department previously determined that certain tests were suitable for use in the NRS for a period of three years, beginning on February 2, 2010 and expiring on February 2, 2013. The expiration of the three-year approvals will occur during the Department's current NRS assessment reviews. To allow for the completion of the current NRS assessment review cycle, the Secretary is extending the approval period for these tests to September 30, 2013. Thus, all tests determined to be suitable for use in the NRS through February 2, 2013 may continue to be used in the NRS through September 30, 2013. This extension does not affect the sunset period for expiring tests provided in the August 2012 notice; the sunset period is available until it ends on June 30, 2014. (*Authority:* 34 CFR 462.14)

Accessible Format: Individuals with disabilities can obtain this document in an accessible format (e.g., braille, large print, audiotape, or compact disc) on request to the contact person listed under **FOR FURTHER INFORMATION CONTACT** in this notice.

Electronic Access to This Document: The official version of this document is the document published in the **Federal Register**. Free Internet access to the official edition of the **Federal Register** and the Code of Federal Regulations is

available via the Federal Digital System at: *www.gpo.gov/fdsys.* At this site you can view this document, as well as all other documents of this Department published in the **Federal Register**, in text or Adobe Portable Document Format (PDF). To use PDF you must have Adobe Acrobat Reader, which is available free at the site.

You may also access documents of the Department published in the **Federal Register** by using the article search feature at: *www.federalregister.gov.* Specifically, through the advanced search feature at this site, you can limit your search to documents published by the Department.

Program Authority: 20 U.S.C. 9212.

Dated: January 22, 2013.

Johan Uvin,

Deputy Assistant Secretary for Policy and Strategic Initiatives.

[FR Doc. 2013–01574 Filed 1–24–13; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

Annual Notice of Interest Rates of Federal Student Loans Made Under the William D. Ford Federal Direct Loan Program

AGENCY: Federal Student Aid, Department of Education.

ACTION: Notice.

Catalog of Federal Domestic Assistance (CFDA) Number: 84.268.

DATES: This notice is effective January 25, 2013.

SUMMARY: In accordance with by section 455(b)(9) of the Higher Education Act of 1965, as amended, the Chief Operating Officer for Federal Student Aid announces the interest rates for the period July 1, 2012, through June 30, 2013, for loans made under the William D. Ford Federal Direct Loan (Direct Loan) Program. The Chief Operating Officer takes this action to give notice of Direct Loan interest rates to the public.

FOR FURTHER INFORMATION CONTACT: Ian Foss, U.S. Department of Education, 830 First Street NE., room 114I1, Washington, DC 20202. Telephone: (202) 377–3681 or by email: *ian.foss@ed.gov.*

If you use a telecommunications device for the deaf (TDD) or a text telephone (TTY), call the Federal Relay Service (FRS), toll free, at 1–800–877–8339.

Individuals with disabilities can obtain this document in an accessible format (e.g., braille, large print, audiotape, or compact disc) on request to the contact person listed under **FOR FURTHER INFORMATION CONTACT**.

SUPPLEMENTARY INFORMATION: Section 455(b) of the Higher Education Act of 1965, as amended (HEA) (20 U.S.C. 1087e(b)), provides formulas for determining the interest rates charged to borrowers for loans made under the Direct Loan Program including: Federal Direct Subsidized Stafford Loans (Direct Subsidized Loans); Federal Direct Unsubsidized Stafford Loans (Direct Unsubsidized Loans); Federal Direct PLUS Loans (Direct PLUS Loans); and Federal Direct Consolidation Loans (Direct Consolidation Loans).

The Direct Loan Program includes loans with variable interest rates and loans with fixed interest rates. Most loans made under the Direct Loan Program before July 1, 2006, have variable interest rates that change each year. In most cases, the variable interest rate formula that applies to a particular loan depends on the date of the first disbursement of the loan. The variable rates are determined annually and are effective for each 12-month period beginning July 1 of one year and ending June 30 of the following year.

Under section 455(b) of the HEA, Direct Loans first disbursed on or after July 1, 2006, have a fixed interest rate.

In the case of some Direct Consolidation Loans, the interest rate is determined by the date on which the Direct Consolidation Loan application was received. Direct Consolidation Loans for which the application was received on or after February 1, 1999, have a fixed interest rate. This fixed rate is based on the weighted average of the loans that are consolidated, rounded up to the nearest higher ⅛ of one percent up to a maximum rate of 8.25 percent.

Under section 455(b) of the HEA, the Direct Loan variable interest rates are based on formulas that use the bond equivalent rates of the 91-day Treasury bills auctioned at the final auction held before June 1 of each year, plus a statutory add-on percentage. These formulas apply to all Direct Subsidized Loans and Direct Unsubsidized Loans; Direct Consolidation Loans for which the application was received on or after July 1, 1998, and before February 1, 1999; and Direct PLUS Loans disbursed on or after July 1, 1998. In each case, the calculated rate is capped by a maximum interest rate. The bond equivalent rate of the 91-day Treasury bills auctioned on May 29, 2012, which is used to calculate the interest rates on these loans, is 0.086 percent, which is rounded to 0.09 percent.

In addition, under section 455(b)(4) of the HEA, the interest rate for Direct PLUS Loans that were first disbursed on or after July 1, 1994, and before July 1, 1998, is based on the weekly average of the one-year constant maturity Treasury yield, as published by the Board of Governors of the Federal Reserve System on the last day of the calendar week ending on or before June 26 of each year, plus a statutory add-on percentage. The calculated rate is capped by a maximum interest rate. The weekly average of the one-year constant maturity Treasury yield published on June 22, 2012, which is used to calculate the interest rate on these loans, is 0.19 percent.

This notice includes five charts containing specific information on the calculation of the interest rates for loans made under the Direct Loan Program.

Chart 1 contains information on the interest rates for variable-rate Direct Subsidized and Direct Unsubsidized Loans.

Chart 2 contains information on the interest rates for variable-rate Direct PLUS Loans.

Chart 3 contains information on the interest rates for variable-rate Direct Subsidized Consolidation Loans and Direct Unsubsidized Consolidation Loans.

Chart 4 contains information on the interest rates for variable-rate Direct PLUS Consolidation Loans.

Chart 5 contains information on the interest rates for fixed-rate Direct Subsidized, Direct Unsubsidized, and Direct PLUS Loans.

CHART 1—VARIABLE-RATE DIRECT SUBSIDIZED AND DIRECT UNSUBSIDIZED LOANS

Cohort		Max. rate (percent)	Index rate	Margin		Total rate	
First disbursed on or after	First disbursed before		91-Day T-Bill rate (percent)	In-school, grace, deferment (percent)	All other periods (percent)	In-school, grace, deferment (percent)	All other periods (percent)
7/1/1994	7/1/1995	8.25	0.09	3.10	3.10	3.19	3.19

CHART 1—VARIABLE-RATE DIRECT SUBSIDIZED AND DIRECT UNSUBSIDIZED LOANS—Continued

Cohort		Max. rate (percent)	Index rate	Margin		Total rate	
First disbursed on or after	First disbursed before		91-Day T-Bill rate (percent)	In-school, grace, deferment (percent)	All other periods (percent)	In-school, grace, deferment (percent)	All other periods (percent)
7/1/1995	7/1/1998	8.25	0.09	2.50	3.10	2.59	3.19
7/1/1998	10/1/2006	8.25	0.09	1.70	2.30	1.79	2.39

CHART 2 —VARIABLE-RATE DIRECT PLUS LOANS

Cohort		Max. rate (percent)	Index rate		Margin (percent)	Total rate (percent)
First disbursed on or after	First disbursed before		91-Day T-Bill rate (percent)	1-Year constant treasury maturity (percent)		
7/1/1994	7/1/1998	9.00		0.19	3.10	3.29
7/1/1998	10/1/2006	8.25	0.09		3.10	3.19

In the remaining Charts 3 through 5, an asterisk following a date in a cohort field indicates that the trigger for the rate to apply is an application for a Direct Consolidation Loan being received either ''on or after'' or ''before'' the date in the cohort field. For example, the fourth row in Chart 3 describes the interest rate for Direct Subsidized and Unsubsidized Consolidation Loans for which the application was received before October 1, 1998, and that were first disbursed on or after October 1, 1998.

CHART 3—VARIABLE-RATE DIRECT SUBSIDIZED AND DIRECT UNSUBSIDIZED CONSOLIDATION LOANS

Cohort		Max. rate (percent)	Index rate	Margin		Total rate	
First disbursed on or after	First disbursed before		91-Day T-Bill rate (percent)	In-school, grace, deferment (percent)	All other periods (percent)	In-school, grace, deferment (percent)	All other periods
7/1/1994	7/1/1995	8.25	0.09	3.10	3.10	3.19	3.19
7/1/1995	7/1/1998	8.25	0.09	2.50	3.10	2.59	3.19
7/1/1998	10/1/1998	8.25	0.09	1.70	2.30	1.79	2.39
10/1/1998	10/1/1998*	8.25	0.09	1.70	2.30	1.79	2.39
10/1/1998*	2/1/1999*	8.25	0.09	2.30	2.30	2.39	2.39

CHART 4—VARIABLE-RATE DIRECT PLUS CONSOLIDATION LOANS

Cohort		Max. rate (percent)	Index rate		Margin		Total rate	
First disbursed on or after	First disbursed before		91-Day T-Bill rate (percent)	1-Year constant treasury maturity (percent)	In-school, grace, deferment (percent)	All other periods (percent)	In-school, grace, deferment (percent)	All other periods (percent)
7/1/1994	7/1/1998	9.00		0.19	3.10	3.10	3.29	3.29
7/1/1998	10/1/1998	9.00	0.09		3.10	3.10	3.19	3.19
10/1/1998	10/1/1998*	9.00	0.09		3.10	3.10	3.19	3.19
10/1/1998*	2/1/1999*	8.25	0.09		2.30	2.30	2.39	2.39

CHART 5—FIXED-RATE DIRECT SUBSIDIZED, DIRECT UNSUBSIDIZED, AND DIRECT PLUS LOANS

Loan type	Student grade level	First disbursed on or after	First disbursed before	Rate
Subsidized	Undergraduate Students	7/1/2006	7/1/2008	6.80
Subsidized	Undergraduate Students	7/1/2008	7/1/2009	6.00
Subsidized	Undergraduate Students	7/1/2009	7/1/2010	5.60
Subsidized	Undergraduate Students	7/1/2010	7/1/2011	4.50
Subsidized	Undergraduate Students	7/1/2011	7/1/2013	3.40
Subsidized	Graduate/Professional Students	7/1/2006	7/1/2012	6.80
Unsubsidized	All Students	7/1/2006	7/1/2013	6.80
PLUS	Parents and Graduate/Professional Students.	7/1/2006	7/1/2013	7.90

CHART 5—FIXED-RATE DIRECT SUBSIDIZED, DIRECT UNSUBSIDIZED, AND DIRECT PLUS LOANS—Continued

Loan type	Student grade level	First disbursed on or after	First disbursed before	Rate
Consolidation	All	2/1/1999	7/1/2013	Weighted average of rates on the loans included in the consolidation, rounded to ⅛ of 1 percent, up to 8.25 percent.

Note: Under the Budget Control Act of 2011 (Pub. L. 112–25) and effective for loan periods beginning on or after July 1, 2012, graduate and professional students are no longer eligible for Direct Subsidized Loans.

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You may also access documents of the Department published in the **Federal Register** by using the article search feature at: *www.federalregister.gov.* Specifically, through the advanced search feature at this site, you can limit your search to documents published by the Department.

Program Authority: 20 U.S.C. 1087 et seq.

Dated: January 18, 2013.

James W. Runcie,

Chief Operating Officer, Federal Student Aid.

[FR Doc. 2013–01421 Filed 1–24–13; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

Annual Notice of Interest Rates of Federal Student Loans Made Under the Federal Family Education Loan Program

AGENCY: Federal Student Aid, Department of Education.

ACTION: Notice.

Catalog of Federal Domestic Assistance (CFDA) Number: 84.032.

SUMMARY: In accordance with section 427A of the Higher Education Act of 1965, as amended, the Chief Operating Officer for Federal Student Aid announces the interest rates for the period July 1, 2012, through June 30, 2013, for certain loans made under the Federal Family Education Loan (FFEL) Program. The Chief Operating Officer takes this action to give notice of FFEL Program loan interest rates to the public.

DATES: This notice is effective January 25, 2013.

FOR FURTHER INFORMATION CONTACT: Ian Foss, U.S. Department of Education, 830 First Street NE., room 114I1, Washington, DC 20202. Telephone: (202) 377–3681 or by email: *ian.foss@ed.gov.*

If you use a telecommunications device for the deaf (TDD) or a text telephone (TTY), call the Federal Relay Service (FRS), toll free, at 1–800–877–8339.

Individuals with disabilities can obtain this document in an accessible format (e.g., braille, large print, audiotape, or compact disc) on request to the contact person listed under **FOR FURTHER INFORMATION CONTACT**.

SUPPLEMENTARY INFORMATION: Section 427A of the Higher Education Act of 1965, as amended (HEA) (20 U.S.C. Section 1077a), provides formulas for determining the interest rates charged to borrowers on loans made under the Federal Family Education Loan (FFEL) Program, including Federal Subsidized and Unsubsidized Stafford Loans, Federal PLUS Loans, and Federal Consolidation Loans.

The FFEL Program includes loans with variable interest rates and loans with fixed interest rates. Most loans made under the FFEL Program before July 1, 2006, have variable interest rates that change each year. In most cases, the variable interest rate formula that applies to a particular loan usually depends on the date of the first disbursement of the loan. The variable rates are determined annually and are effective for each 12-month period beginning July 1 of one year and ending June 30 of the following year.

Under section 427A(k) of the HEA, FFEL Program loans first disbursed on or after July 1, 2006, have a fixed interest rate.

In the case of some Federal Consolidation Loans, the interest rate is determined by the date on which the Federal Consolidation Loan application was received. Federal Consolidation Loans for which the application was received on or after October 1, 1998, have a fixed interest rate. This fixed rate is based on the weighted average of the loans that are consolidated, rounded up to the nearest higher ⅛ of one percent up to a maximum rate of 8.25 percent.

FFEL variable interest rates are based on formulas that use the bond equivalent rate of the 91-day Treasury bills auctioned at the final auction held before June 1 of each year plus a statutorily established add-on. These formulas apply to all Federal Subsidized and Unsubsidized Stafford Loans first disbursed before October 1, 1992, that have been converted to variable rate loans; all Federal Subsidized and Unsubsidized Stafford Loans first disbursed on or after October 1, 1992, and before July 1, 2006; Federal PLUS Loans first disbursed on or after July 1, 1998, and before July 1, 2006; and Federal Consolidation Loans for which the Federal Consolidation Loan application was received on or after November 13, 1997, and before October 1, 1998. In each case, the calculated rate is capped by a maximum interest rate. The bond equivalent rate of the 91-day Treasury bills auctioned on May 29, 2012, which is used to calculate the interest rates on these loans, is 0.086 percent, which is rounded to 0.09 percent.

For Federal PLUS loans first disbursed before July 1, 1998, the interest rate is based on the weekly average of the one-year constant maturity Treasury yield, as published by the Board of Governors of the Federal Reserve System on the last day of the calendar week ending on or before June 26 of each year, plus a statutory add-on percentage. The calculated rate is capped by a maximum interest rate. The weekly average of the one-year constant maturity Treasury yield published on June 22, 2012, which is used to calculate the interest rate on these loans, is 0.19 percent.

This notice includes five charts containing specific information on the calculation of interest rates for loans made under the FFEL Program:

Chart 1 contains information on the interest rates for Federal Subsidized and Unsubsidized Stafford Loans that were made as fixed-rate loans, but were subsequently converted to variable-rate loans.

Chart 2 contains information on the interest rates for variable-rate Federal Subsidized and Unsubsidized Stafford Loans.

Chart 3 contains information on the interest rates for variable-rate Federal PLUS Loans.

Chart 4 contains information on the interest rates for fixed-rate Federal Consolidation Loans.

Chart 5 contains information on the interest rates for fixed-rate Federal Subsidized and Unsubsidized Stafford and PLUS Loans.

CHART 1—''CONVERTED'' VARIABLE-RATE FEDERAL SUBSIDIZED AND UNSUBSIDIZED STAFFORD LOANS

Original fixed interest rate	Max. rate (percent)	91-Day T-Bill rate (percent)	Margin (percent)	Total rate (percent)
8.00, increasing to 10.00%	10.00	0.09	3.25	3.34
7.00%	7.00	0.09	3.25	3.34
8.00%	8.00	0.09	3.25	3.34
9.00%	9.00	0.09	3.25	3.34

In Charts 2 and 3, a dagger following a date in a cohort field indicates that the trigger for the rate to apply is a period of enrollment for which the loan was intended either ''ending before'' or ''beginning on or after'' the date in the cohort field.

CHART 2—VARIABLE-RATE FEDERAL SUBSIDIZED AND UNSUBSIDIZED STAFFORD LOANS

Cohort		Max. rate (percent)	91-Day T-Bill rate (percent)	Margin		Total rate	
First disbursed on or after	First disbursed before			In-school, grace, deferment (percent)	All other periods (percent)	In-school, grace, deferment (percent)	All other periods (percent)
10/1/1992	7/1/1994	9.00	0.09	3.10	3.10	3.19	3.19
7/1/1994	7/1/1994†	8.25	0.09	3.10	3.10	3.19	3.19
7/1/1994	7/1/1995	8.25	0.09	3.10	3.10	3.19	3.19
7/1/1995	7/1/1998	8.25	0.09	2.50	3.10	2.59	3.19
7/1/1998	7/1/2006	8.25	0.09	1.70	2.30	1.79	2.39

Note: The FFEL Program loans represented in the first row in Chart 2 were only made to ''new borrowers'' on or after October 1, 1992. The FFEL Program loans represented in the second row in Chart 2 were only made to ''new borrowers'' on or after July 1, 1994. The FFEL Program loans represented in the third row in Chart 2 must—in addition to having been first disbursed on or after July 1, 1994, and before July 1, 1995—have been made for a period of enrollment that began on or included July 1, 1994.

In Charts 3 and 4, an asterisk following a date in a cohort field indicates that the relevant trigger is an application for a Federal Consolidation Loan being received either ''on or after'' or ''before'' the date in the cohort field. For example, the sixth row in Chart 3 describes the interest rate for a Federal Consolidation Loan for which the application was received on or after November 13, 1997, but before October 1, 1998.

CHART 3—VARIABLE-RATE FEDERAL PLUS, SLS, AND CONSOLIDATION LOANS

Loan type	Cohort		Max. rate (percent)	Index rate		Margin (percent)	Total rate (percent)
	First disbursed on or after	First disbursed before		91-Day T-Bill rate (percent)	1-Year Constant Treasury Maturity (percent)		
PLUS and SLS		10/1/1992	12.00		0.19	3.25	3.44
SLS	10/1/1992	7/1/1994†	11.00		0.19	3.10	3.29
PLUS	10/1/1992	7/1/1994	10.00		0.19	3.10	3.29
PLUS	7/1/1994	7/1/1998	9.00		0.19	3.10	3.29
PLUS	7/1/1998	7/1/2006	9.00	0.09		3.10	3.19
Consolidation	11/13/1997*	10/1/1998*	8.25	0.09		3.10	3.19
HHS Portion of Consolidation				0.09		3.00	3.09

The last row in Chart 3 refers to portions of Federal Consolidation Loans attributable to loans made by the U.S. Department of Health and Human Services under subpart I of part A of title VII of the Public Health Service Act.

CHART 4—FIXED-RATE CONSOLIDATION LOANS

First disbursed on or after	First disbursed before	Max. rate (percent)	Rate
	7/1/1994	.....	Weighted average of rates on the loans included in the consolidation, rounded to nearest whole percent, but not less than 9.00%.
7/1/1994	11/13/1997*	.....	Weighted average of rates on the loans included in the consolidation, rounded upward to nearest whole percent.
10/1/1998	7/1/2010	8.25	Weighted average of rates on the loans included in the consolidation, rounded to the nearest higher ⅛ of 1 percent.

CHART 5—FIXED-RATE FEDERAL SUBSIDIZED AND UNSUBSIDIZED STAFFORD AND PLUS LOANS

Loan type	Student grade level	First disbursed on or after	First disbursed before	Rate (percent)
Subsidized	Undergraduate Students	7/1/2006	7/1/2008	6.80
Subsidized	Undergraduate Students	7/1/2008	7/1/2009	6.00
Subsidized	Undergraduate Students	7/1/2009	7/1/2010	5.60
Subsidized	Graduate/Professional Students	7/1/2006	7/1/2010	6.80
Unsubsidized	All Students	7/1/2006	7/1/2010	6.80
PLUS	Parents and Graduate/Professional Students	7/1/2006	7/1/2010	8.50

Note: No new loans have been made under the FFEL Program since June 30, 2010.

Electronic Access to This Document: The official version of this document is the document published in the **Federal Register**. Free Internet access to the official edition of the **Federal Register** and the Code of Federal Regulations is available via the Federal Digital System at: *www.gpo.gov/fdsys.* At this site you can view this document, as well as all other documents of this Department published in the **Federal Register**, in text or Adobe Portable Document Format (PDF). To use PDF you must have Adobe Acrobat Reader, which is available free at the site.

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Program Authority: 20 U.S.C. 1071 et seq.

Dated: January 18, 2013.

James W. Runcie,

Chief Operating Officer Federal Student Aid.

[FR Doc. 2013–01423 Filed 1–24–13; 8:45 am]

BILLING CODE 4000–01–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: RP13–448–000.

Applicants: Great Lakes Gas Transmission Limited Par.

Description: Great Lakes Gas Transmission Limited Partnership Revenue Subject to Sharing True-Up Report.

Filed Date: 1/15/13.

Accession Number: 20130115–5083.

Comments Due: 5 p.m. ET 1/28/13.

Docket Numbers: RP13–449–000.

Applicants: Natural Gas Pipeline Company of America.

Description: Natural Gas Pipeline Company of America LLC submits tariff filing per 154.204: Tenaska Amendmemt Filing to be effective 1/16/2013.

Filed Date: 1/16/13.

Accession Number: 20130116–5022.

Comments Due: 5 p.m. ET 1/28/13.

Docket Numbers: RP13–450–000.

Applicants: Natural Gas Pipeline Company of America.

Description: Natural Gas Pipeline Company of America LLC submits tariff filing per 154.204: Tenaska Neg Filing to be effective 1/16/2013.

Filed Date: 1/16/13.

Accession Number: 20130116–5023.

Comments Due: 5 p.m. ET 1/28/13.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

Dated: January 16, 2013.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2013–01508 Filed 1–24–13; 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: EC13–63–000.

Applicants: Dynegy Roseton, L.L.C., CCI Roseton LLC.

Description: Joint Application for Approval under Section 203 of the Federal Power Act and Request for Expedited Consideration of Dynegy Roseton, L.L.C. and CCI Roseton LLC.

Filed Date: 1/16/13.

Accession Number: 20130116–5132.

Comments Due: 5 p.m. ET 2/6/13.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER10–1569–001; ER12–21–005; ER10–2783–003; ER10–2784–003; ER11–2855–004; ER10–2791–003; ER10–2792–003; ER10–1564–002; ER10–1565–002; ER10–2795–003; ER10–2798–003; ER10–1575–001; ER10–2799–003; ER10–2801–003 ER11–3727–002; ER10–1566–002; ER12–2413–001; ER11–2062–002; ER10–2812–002; ER10–1291–003; ER10–2843–001 ER11–4307–002; ER12–1711–002; ER10–2846–003; ER12–261–001; ER10–2871–001; ER10–2875–003; ER10–1568–002 ER10–1581–004; ER10–2876–003; ER10–2878–003; ER10–

2879–003; ER10–2880–003; ER10–2888–003; ER10–2896–003 ER10–2913–003; ER10–2914–003; ER10–2916–003; ER10–2915–003; ER12–1525–002; ER12–2019–001; ER12–2398–001 ER10–1582–001; ER11–3459–001; ER10–2931–003; ER10–2969–003; ER11–4308–002; ER10–1580–004; ER11–2856–004; ER11–2857–004; ER10–2947–003; ER11–2504–001; ER11–2505–001; ER11–2864–001; ER11–2506–001; ER11–2508–001; ER12–2137–001; ER11–2510–001; ER12–2545–001; ER11–2863–001; ER11–2854–001; ER11–2513–001; ER11–2515–001; ER11–2742–001; ER11–2784–001; ER11–2805–001; ER10–3143–003.

Applicants: NRG Power Marketing LLC, Agua Caliente Solar, LLC, Arthur Kill Power LLC, Astoria Gas Turbine Power, Avenal Park LLC, Bayou Cove Peaking Power LLC, Big Cajun I Peaking Power LLC, Cabrillo Power I LLC, Cabrillo Power II LLC, Conemaugh Power LLC, Connecticut Jet Power LLC, Cottonwood Energy Company, LP, Devon Power LLC, Dunkirk Power LLC, El Segundo Energy Center LLC, El Segundo Power LLC, Energy Alternatives Wholesale, LLC, Energy Plus Holdings LLC, GenCon Devon LLC, GenCon Energy LLC, GenCon Middletown LLC, Green Mountain Energy Company, High Plains Ranch II, LLC, Huntley Power LLC, Independence Energy LLC, Indian River Power LLC, Keystone Power LLC, Long Beach Generation LLC, Long Beach Peakers LLC, Louisiana Generating LLC, Middletown Power LLC, Montville Power LLC, NEO Freehold LLC, Norwalk Power LLC, NRG Energy Center Dover LLC, NRG Energy Center Paxton LLC, NRG New Jersey Energy Sales LLC, NRG Rockford LLC, NRG Rockford II LLC, NRG Solar Alpine LL, NRG Solar Avra Valley LLC, NRG Solar Borrego I LLC, NRG Solar Blythe LLC, NRG Solar Roadrunner LLC, NRG Sterlington Power LLC, Oswego Harbor Power LLC, Reliant Energy Northeast LLC, Saguaro Power Company LP, San Drag LLC, Sun City Project, Vienna Power LLC, GenOn Bowline, LLC, GenOn Canal, LLC, GenOn Chalk Point, LLC, GenOn Delta, LLC, GenOn Energy Management, LLC, GenOn Florida, LP, GenOn Kendall, LLC, GenOn Marsh Landing, LLC, GenOn Mid-Atlantic, LLC, GenOn Potomac River, LLC, GenOn Power Midwest, LP, GenOn REMA, LLC, GenOn West, LP, GenOn Wholesale Generation, LP, RRI Energy Services, LLC, Sabine Cogen, LP.

Description: Notice of Non-Material Change in Status of NRG Power Marketing LLC, et al.

Filed Date: 1/14/13.

Accession Number: 20130114–5241.

Comments Due: 5 p.m. ET 2/4/13.

Docket Numbers: ER13–768–000.

Applicants: Northern States Power Company, a Minnesota corporation.

Description: Northern States Power Company, a Minnesota Corporation submits tariff filing per 35.13(a)(2)(iii: 2013–01–16_MSHL TOP Agrmt-539 to be effective 12/1/2012.

Filed Date: 1/16/13.

Accession Number: 20130116–5113.

Comments Due: 5 p.m. ET 2/6/13.

Docket Numbers: ER13–769–000.

Applicants: Entergy Mississippi, Inc.

Description: Entergy Mississippi, Inc. submits tariff filing per 35.13(a)(2)(iii: EMI–EAI Splmntl Trns Upgrades Cost Agreement to be effective 12/18/2013.

Filed Date: 1/16/13.

Accession Number: 20130116–5126.

Comments Due: 5 p.m. ET 2/6/13.

Docket Numbers: ER13–770–000.

Applicants: Entergy Louisiana, LLC.

Description: Entergy Louisiana, LLC submits tariff filing per 35.13(a)(2)(iii: ELL–EAI Ouachita Splmnt Trns Cost Agrmnt to be effective 12/18/2013.

Filed Date: 1/16/13.

Accession Number: 20130116–5127.

Comments Due: 5 p.m. ET 2/6/13.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: January 17, 2013.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2013–01506 Filed 1–24–13; 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: ER12–1204–004.

Applicants: PJM Interconnection, L.L.C.

Description: PJM Interconnection, L.L.C. submits Compliance Filing per 11/16/2012 Order in ''ER12–1204'' & ER12–2391 eff. 10/1/2012 to be effective 10/1/2012.

Filed Date: 1/15/13.

Accession Number: 20130115–5119.

Comments Due: 5 p.m. ET 2/5/13.

Docket Numbers: ER12–2391–003.

Applicants: PJM Interconnection, L.L.C.

Description: PJM Interconnection, L.L.C. submits Compliance Filing per 11/16/2012 Order in ER12–1204 & ''ER12–2391'' eff 12/1/2012 to be effective 12/1/2012.

Filed Date: 1/15/13.

Accession Number: 20130115–5120.

Comments Due: 5 p.m. ET 2/5/13.

Docket Numbers: ER13–290–000.

Applicants: Michigan Power Limited Partnership.

Description: Michigan Power Limited Partnership submits Supplement to 11/01/2012 Revision to Market-Based Rate Tariff.

Filed Date: 12/13/12.

Accession Number: 20121213–5135.

Comments Due: 5 p.m. ET 1/25/13.

Docket Numbers: ER13–765–000.

Applicants: New Mexico Green Initiatives, LLC.

Description: New Mexico Green Initiatives, LLC submits tariff filing per 35.15: Tariff Cancellation to be effective 1/16/2013.

Filed Date: 1/16/13.

Accession Number: 20130116–5000.

Comments Due: 5 p.m. ET 2/6/13.

Docket Numbers: ER13–766–000.

Applicants: Smoky Mountain Transmission LLC.

Description: Smoky Mountain Transmission LLC submits tariff filing per 35.13(a)(2)(iii: Tariff filing to be effective 1–16–2013 to be effective 1/16/2013.

Filed Date: 1/16/13.

Accession Number: 20130116–5098.

Comments Due: 5 p.m. ET 2/6/13.

Docket Numbers: ER13–767–000.

Applicants: Badger Windpower, LLC.

Description: Badger Windpower, LLC submits tariff filing per 35.15: Badger Windpower Tariff Cancellation to be effective 12/21/2012.

Filed Date: 1/16/13.

Accession Number: 20130116–5102.

Comments Due: 5 p.m. ET 2/6/13.

Take notice that the Commission received the following qualifying facility filings:

Docket Numbers: QF12–174–000.

Applicants: Winona County Wind, LLC.

Description: Refund Report of Winona County Wind, LLC.
Filed Date: 01/15/2013.
Accession Number: 20130115–5123.
Comment Date: 5 p.m. ET 2/5/13.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: January 16, 2013.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2013–01509 Filed 1–24–13; 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: RP13–451–000.
Applicants: Gulf Crossing Pipeline Company LLC.
Description: IT Discount Filing to be effective 2/17/2013.
Filed Date: 1/17/13.
Accession Number: 20130117–5026.
Comments Due: 5 p.m. ET 1/29/13.

Docket Numbers: RP13–452–000.
Applicants: Gulf South Pipeline Company, LP.
Description: IT Discount Filing to be effective 2/17/2013.
Filed Date: 1/17/13.
Accession Number: 20130117–5027.
Comments Due: 5 p.m. ET 1/29/13.

Docket Numbers: RP13–453–000.
Applicants: Texas Gas Transmission, LLC.
Description: IT Discount Filing to be effective 2/17/2013.
Filed Date: 1/17/13.
Accession Number: 20130117–5028.
Comments Due: 5 p.m. ET 1/29/13.

Docket Numbers: RP13–454–000.
Applicants: Petal Gas Storage, L.L.C.
Description: IT Discount Filing to be effective 2/17/2013.
Filed Date: 1/17/13.
Accession Number: 20130117–5029.
Comments Due: 5 p.m. ET 1/29/13.

Docket Numbers: RP13–455–000.
Applicants: Ozark Gas Transmission, L.L.C.
Description: Jan 2013 Cleanup Filing to Capitalize Defined Terms to be effective 2/17/2013.
Filed Date: 1/17/13.
Accession Number: 20130117–5030.
Comments Due: 5 p.m. ET 1/29/13.

Docket Numbers: RP13–456–000.
Applicants: Big Sandy Pipeline, LLC.
Description: Jan 2013 Cleanup Filing to Capitalize Defined Terms to be effective 2/17/2013.
Filed Date: 1/17/13.
Accession Number: 20130117–5049.
Comments Due: 5 p.m. ET 1/29/13.

Docket Numbers: RP13–457–000.
Applicants: Kinder Morgan Illinois Pipeline LLC.
Description: Penalty Revenue Crediting Report of Kinder Morgan Illinois Pipeline LLC.
Filed Date: 1/17/13.
Accession Number: 20130117–5104.
Comments Due: 5 p.m. ET 1/29/13.

Docket Numbers: CP13–29–000.
Applicants: Columbia Gas of Ohio, Inc.
Description: Columbia Gas of Ohio, Inc. application for a limited jurisdiction blanket certificate of public convenience and necessity, pursuant to Section 284.224 of the Commission.
File Date: 1/17/13.
Comments Due: 5 p.m. ET 1/28/13.

Docket Numbers: RP13–458–000.
Applicants: Trailblazer Pipeline Company LLC.
Description: Cancel 5th Revised Volume to be effective 2/18/2013.
Filed Date: 1/18/13.
Accession Number: 20130118–5001.
Comments Due: 5 p.m. ET 1/30/13.

Docket Numbers: RP13–459–000.
Applicants: Trailblazer Pipeline Company LLC.
Description: Trailblazer Baseline to Section based to be effective 2/18/2013.
Filed Date: 1/18/13.
Accession Number: 20130118–5002.
Comments Due: 5 p.m. ET 1/30/13.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

Filings in Existing Proceedings

Docket Numbers: RP13–81–003.
Applicants: Caledonia Energy Partners, L.L.C.
Description: Caledonia Energy Partners, L.L.C. submits tariff filing per 154.203: Caledonia Correction to FERC Gas Tariff to Comply with FERC Order No. 587–V to be effective 12/1/2012.
Filed Date: 1/17/13.
Accession Number: 20130117–5145.
Comments Due: 5 p.m. ET 1/29/13.

Docket Numbers: RP12–813–001.
Applicants: Gulf South Pipeline Company, LP.
Description: Gulf South Pipeline Company, LP submits tariff filing per 154.203: Compliance Filing in RP12–813 to be effective 1/1/2013.
Filed Date: 01/18/2013.
Accession Number: 20130118–5138.
Comments Due: 5 p.m. ET 1/30/13.

Docket Numbers: RP12–814–001.
Applicants: Gulf Crossing Pipeline Company LLC.
Description: Gulf Crossing Pipeline Company LLC submits tariff filing per 154.203: Compliance filing in Docket No. RP12–814 to be effective 1/1/2013.
Filed Date: 1/18/13.
Accession Number: 20130118–5137.
Comments Due: 5 p.m. ET 1/30/13.

Docket Numbers: RP12–820–001.
Applicants: Texas Gas Transmission, LLC.
Description: Texas Gas Transmission, LLC submits tariff filing per 154.203: Compliance filing in Docket No. RP12–820 to be effective 1/1/2013.
Filed Date: 1/18/13.
Accession Number: 20130118–5139.
Comments Due: 5 p.m. ET 1/30/13.

Any person desiring to protest in any the above proceedings must file in accordance with Rule 211 of the Commission's Regulations (18 CFR 385.211) on or before 5:00 p.m. Eastern time on the specified comment date.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, and service can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: January 18, 2013.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2013–01505 Filed 1–24–13; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. TS04–277–001]

Green Mountain Power Corporation; Notice of Filing

Take notice that on July 27, 2012, Green Mountain Power Corporation filed a notice of material change in facts and request for continued waiver of Standards of Conduct.

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 email notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please email *FERCOnlineSupport@ferc.gov,* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Comment Date: 5:00 p.m. Eastern Time on February 7, 2013.

Dated: January 17, 2013.

Kimberly D. Bose,

Secretary.

[FR Doc. 2013–01453 Filed 1–24–13; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

National Nuclear Security Administration

Proposed Agency Information Collection

AGENCY: National Nuclear Security Administration, U.S. Department of Energy.

ACTION: Notice and request for comments.

SUMMARY: The Department of Energy (DOE) invites public comment on a proposed collection of information that DOE is developing for submission to the Office of Management and Budget (OMB) pursuant to the Paperwork Reduction Act of 1995. This proposed collection would be for use of the American Assured Fuel Supply. Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; 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.

DATES: Comments regarding this proposed information collection must be received on or before March 26, 2013. If you anticipate difficulty in submitting comments within that period, contact the person listed in **ADDRESSES** as soon as possible.

ADDRESSES: Written comments may be sent to Rich Goorevich, Senior Policy Advisor, Office of Nonproliferation and International Security, National Nuclear Security Administration, U.S. Department of Energy, 1000 Independence Ave. SW., Washington DC 20585, or by fax at 202–586–1348, or by email at *Richard.Goorevich@NNSA.DOE.GOV.*

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the information collection instrument and instructions should also be directed to Rich Goorevich, Senior Policy Advisor, Office of Nonproliferation and International Security, National Nuclear Security Administration, U.S. Department of Energy, 1000 Independence Ave. SW., Washington DC 20585, or by fax at 202–586–1348, or by email at *Richard.Goorevich@NNSA.DOE.GOV.*

SUPPLEMENTARY INFORMATION: This information collection request contains: (1) *OMB No.* {''New''}; (2) *Information Collection Request Title:* The American Assured Fuel Supply Program; (3) *Type of Request:* New; (4) *Purpose:* The U.S. Department of Energy (DOE) created the American Assured Fuel Supply (AFS), a reserve of low enriched uranium (LEU) to serve as a backup fuel supply for foreign recipients to be supplied through U.S. persons or for domestic recipients, in the event of a fuel supply disruption. DOE is committed to making the AFS available to eligible recipients in the case of supply disruptions in the nuclear fuel market. This effort supports the United States Government's nuclear nonproliferation objectives by supporting civilian nuclear energy development while minimizing proliferation risks. DOE published a Notice of Availability for the AFS on August 18, 2011, and now needs to publish an application to clarify the information that must be provided in a request to access the material in the AFS as set forth in the Notice of Availability. 76 FR 51357, 51358. This application form is necessary in order for DOE to identify if applicants meet basic requirements for use of the AFS and implement this important nonproliferation initiative; (5) *Annual Estimated Number of Respondents:* 10; (6) *Annual Estimated Number of Total Responses:* 1; (7) *Annual Estimated Number of Burden Hours:* 8; (8) *Annual Estimated Reporting and Recordkeeping Cost Burden:* $1,600.

Statutory Authority: The Secretary of Energy is authorized pursuant to the Atomic Energy Act of 1954, as amended (Pub. L. 83–703), and the Nuclear Non-Proliferation Act of 1978 (NNPA) (Pub. L. 95–242) to encourage the widespread use of atomic energy for peaceful purposes, and to enter into and distribute nuclear material in cooperation with other nations where appropriate safeguard measures are in place to ensure the material is properly controlled and used for peaceful purposes. In 2005, DOE set aside a portion of its LEU inventory to be used to support the International Atomic Energy Agency's (IAEA) International Nuclear Fuel Bank (INFB) initiative, which is envisioned as an LEU reserve that will be administered by the IAEA and that will serve as a back-up for global supply disruptions. Congress later appropriated $49,540,000 in the Consolidated Appropriations Act, 2008 (Pub. L. 110–161) to fund a portion of

the INFB. Congress, in the Explanatory Statement accompanying the House Appropriations Committee Print (which in this Act was given the same effect as a joint explanatory statement), noted that the INFB freed up DOE's LEU set-aside, and recommended DOE also ''allow U.S. interests to purchase uranium fuel from the Reliable Fuel Supply [now the AFS] in the event of supply disruption.'' (H. Approp. Cmte. Print at 592.)

The sale of LEU from the AFS will be conducted consistent with applicable law, the policies and guidance in the ''Secretary of Energy's 2008 Policy Statement on Management of Department of Energy's Excess Uranium Inventory'' (March 11, 2008), and the DOE Excess Uranium Inventory Management Plan.

Issued in Washington, DC, on January 15, 2013.

Andrew Bieniawski,

Acting Principal Assistant Deputy Administrator, Defense Nuclear Nonproliferation, National Nuclear Security Administration, U.S. Department of Energy.

[FR Doc. 2013–01525 Filed 1–24–13; 8:45 am]

BILLING CODE 6450–01–P

ENVIRONMENTAL PROTECTION AGENCY

[ER–FRL–9007–3]

Environmental Impacts Statements; Notice of Availability

Responsible Agency: Office of Federal Activities, General Information (202) 564–7146 or *http://www.epa.gov/compliance/nepa/.*

Weekly receipt of Environmental Impact Statements

Filed 01/14/2013 Through 01/18/2013

Pursuant to 40 CFR 1506.9

Notice

Section 309(a) of the Clean Air Act requires that EPA make public its comments on EISs issued by other Federal agencies. EPA's comment letters on EISs are available at: *http://www.epa.gov/compliance/nepa/eisdata.html.*

SUPPLEMENTARY INFORMATION: As of October 1, 2012, EPA will not accept paper copies or CDs of EISs for filing purposes; all submissions on or after October 1, 2012 must be made through e-NEPA.

While this system eliminates the need to submit paper or CD copies to EPA to meet filing requirements, electronic submission does not change requirements for distribution of EISs for public review and comment. To begin using e-NEPA, you must first register with EPA's electronic reporting site—*https://cdx.epa.gov/epa_home.asp*

EIS No. 20130009, Final EIS, NPS, HI, Hawaii Volcanoes National Park Project, Protecting and Restoring Native Ecosystems by Managing Non-Native Ungulates, Hawaii County, HI, Review Period Ends: 02/25/2013, Contact: Rhonda Loh 808–986–6098.

EIS No. 20130010, Draft EIS, BLM, CO, Grand Junction Field Office Resource Management Plan, Mesa, Garfield, Montrose and Rio Blanco Counties, CO, Comment Period Ends: 04/25/2013, Contact: Collin Ewing 970–244–3627.

EIS No. 20130011, Draft EIS, NPS, TX, Lake Meredith National Recreation Area, Off-Road Management Plan, TX, Comment Period Ends: 03/26/2013, Contact: Arlene Wimer 806–857–0300.

EIS No. 20130012, Draft EIS, USFS, MT, Blackfoot Travel Plan, Lincoln Ranger District, Helena National Forest, Lewis and Clark and Powell Counties, MT, Comment Period Ends: 03/11/2013, Contact: Amber Kamps 406–362–7002.

EIS No. 20130013, Final EIS, USFS, ID, Scriver Creek Integrated Restoration Project, Emmett Ranger District, Boise National Forest, Boise and Valley Counties, ID, Review Period Ends: 03/12/2013, Contact: Randal Hayman 208–373–4157.

EIS No. 20130014, Final EIS, FHWA, 00, Illiana Corridor Project Tier One Transportation System Improvements, Will and Kankakee Counties, IL and Lake County, IN, Contact: J. Michael Bowen 217–492–4600.

EIS No. 20130015, Draft Supplement, FHWA, CA, Mid County Parkway, a new Freeway from the City of Perris to the City of San Jacinto, Riverside County, CA, Comment Period Ends: 03/11/2013, Contact: Larry Vinzant 916–498–5040.

Amended Notices

EIS No. 20090231, Draft EIS, BIA, CA, Point Molate Mixed-Use Tribal Destination Resort and Casino, Proposed Project is to Strengthen the Tribal Government and Improve the Social Economic Status, Guidiville Band of Pomo Indian of the Guidiville Rancheria (Tribe), City of Richmond, Contra Costa County, CA, Comment Period Ends: 10/23/2009, Contact: Larry Blevin 916–978–6037. Revision to FR Notice Published 10/09/2009; The U.S. Department of the Interior's Bureau of Indian Affairs has Officially Cancelled the above project.

EIS No. 20120369, Draft EIS, NOAA, CA, Authorization of Incidental Take and Implementation of the Mendocino Redwood Habitat Conservation Plan/Natural Community Conservation and Timber Management Plan, Mendocino County, CA, Comment Period Ends: 04/22/2013, Contact: Eric Shott 707–575–6089. Revision to FR Notice Published 11/23/2012; Extending Comment Period from 02/21/2013 to 04/22/2013.

EIS No. 20120383, Draft EIS, USACE, CA, Gregory Canyon Landfill, Application for Permit Authorizing Discharge of Fill in U.S. Waters, San Diego County, CA, Comment Period Ends: 04/15/2013, Contact: William H. Miller 602–230–6954. Revision to FR Notice Published 11/23/2012; Extending Comment Period from 02/21/2013 to 04/22/2013.

Dated: January 22, 2013.

Cliff Rader,

Director, NEPA Compliance Division, Office of Federal Activities.

[FR Doc. 2013–01586 Filed 1–24–13; 8:45 am]

BILLING CODE 6560–50–P

EXPORT-IMPORT BANK

[Public Notice 2013–0105]

Application for Final Commitment for a Long-Term Loan or Financial Guarantee in Excess of $100 Million: AP087734XX

AGENCY: Export-Import Bank of the United States.

ACTION: Notice.

SUMMARY: This Notice is to inform the public, in accordance with Section 3(c)(10) of the Charter of the Export-Import Bank of the United States (''Ex-Im Bank''), that Ex-Im Bank has received an application for final commitment for a long-term loan or financial guarantee in excess of $100 million (as calculated in accordance with Section 3(c)(10) of the Charter). Comments received within the comment period specified below will be presented to the Ex-Im Bank Board of Directors prior to final action on this Transaction.

Reference: AP087734XX.

Purpose and Use: Brief description of the purpose of the transaction:

To support the export of U.S. manufactured commercial aircraft to Turkey.

Brief non-proprietary description of the anticipated use of the items being exported:

To be used for short- and medium-haul passenger air service within Turkey and between Turkey and other countries.

To the extent that Ex-Im Bank is reasonably aware, the item(s) being exported are not expected to produce exports or provide services in competition with the exportation of goods or provision of services by a United States industry.

Parties: Principal Supplier: The Boeing Company.

Obligor: Turk Hava Yollari A.O.

Guarantor(s): N/A.

Description of Items Being Exported: Boeing 737 aircraft.

Information on Decision: Information on the final decision for this transaction will be available in the ''Summary Minutes of Meetings of Board of Directors'' on *http://www.exim.gov/articles.cfm/board%20minute.*

Confidential Information: Please note that this notice does not include confidential or proprietary business information; information which, if disclosed, would violate the Trade Secrets Act; or information which would jeopardize jobs in the United States by supplying information that competitors could use to compete with companies in the United States.

DATES: Comments must be received on or before February 19, 2013 to be assured of consideration before final consideration of the transaction by the Board of Directors of Ex-Im Bank.

ADDRESSES: Comments may be submitted through Regulations.gov at *www.regulations.gov.* To submit a comment, enter EIB–2013–0004 under the heading ''Enter Keyword or ID'' and select Search. Follow the instructions provided at the Submit a Comment screen. Please include your name, company name (if any) and EIB–2013–0004 on any attached document.

Koro Nuri,

Deputy General Counsel (Acting).

[FR Doc. 2013–01520 Filed 1–24–13; 8:45 am]

BILLING CODE 6690–01–P

FEDERAL ELECTION COMMISSION

Sunshine Act Notice

AGENCY: Federal Election Commission.

DATE AND TIME: *Tuesday, January 29, 2013 at 10:00 a.m. and its continuation on January 31, 2013 after the open meeting.*

PLACE: 999 E Street NW., Washington, DC.

STATUS: This meeting will be closed to the public.

ITEMS TO BE DISCUSSED: Compliance matters pursuant to 2 U.S.C. 437g.

Audits conducted pursuant to 2 U.S.C. 437g, 438(b), and Title 26, U.S.C.

Matters concerning participation in civil actions or proceedings or arbitration.

Internal personnel rules and procedures or matters affecting a particular employee.

Investigatory records compiled for law enforcement purposes, or information which if written would be contained in such records.

Information the premature disclosure of which would be likely to have a considerable adverse effect on the implementation of a proposed Commission action.

* * * * *

PERSON TO CONTACT FOR INFORMATION: Judith Ingram, Press Officer, Telephone: (202) 694–1220.

Shelley E. Garr,

Deputy Secretary of the Commission.

[FR Doc. 2013–01615 Filed 1–23–13; 11:15 am]

BILLING CODE 6715–01–P

FEDERAL MARITIME COMMISSION

Notice of Agreements Filed

The Commission hereby gives notice of the filing of the following agreements under the Shipping Act of 1984. Interested parties may submit comments on the agreements to the Secretary, Federal Maritime Commission, Washington, DC 20573, within ten days of the date this notice appears in the **Federal Register**. Copies of the agreements are available through the Commission's Web site (www.fmc.gov) or by contacting the Office of Agreements at (202)–523–5793 or *tradeanalysis@fmc.gov.*

Agreement No.: 010099–057.

Title: International Council of Containership Operators.

Parties: A.P. Moller-Maersk A/S; China Shipping Container Lines Co., Ltd.; CMA CGM, S.A.; Compañía Chilena de Navegación Interoceánica S.A.; Compania Sud Americana de Vapores S.A.; COSCO Container Lines Co. Ltd; Crowley Maritime Corporation; Evergreen Marine Corporation (Taiwan), Ltd.; Hamburg-Süd KG; Hanjin Shipping Co., Ltd.; Hapag-Lloyd AG; Hyundai Merchant Marine Co., Ltd.; Kawasaki Kisen Kaisha, Ltd.; Mediterranean Shipping Co. S.A.; Mitsui O.S.K. Lines, Ltd.; Neptune Orient Lines, Ltd.; Nippon Yusen Kaisha; Orient Overseas Container Line, Ltd.; Pacific International Lines (Pte) Ltd.; United Arab Shipping Company (S.A.G.); Wan Hai Lines Ltd.; Yang Ming Transport Marine Corp.; and Zim Integrated Shipping Services Ltd.

Filing Party: John Longstreth, Esq.; K & L Gates LLP; 1601 K Street NW.; Washington, DC 20006–1600.

Synopsis: The amendment deletes Safmarine Container Lines N.V. as a subsidiary of A.P. Moller-Maersk A/S.

Agreement No.: 011275–035.

Title: Australia and New Zealand-United States Discussion Agreement.

Parties: A.P. Moller-Maersk AS, trading under the name Maersk Line; CMA CGM, S.A./ANL Singapore Pte Ltd. (acting as a single party); Hamburg-Süd KG; Hapag-Lloyd AG; and Mediterranean Shipping Company S.A.

Filing Party: Wayne R. Rohde, Esq.; Cozen O'Connor LLP; 1627 I Street NW.; Suite 1100; Washington, DC 20006–4007.

Synopsis: The amendment would update Appendix B and update references to the Australian statute which governs the agreement in Australia.

Agreement No.: 201219.

Title: The Los Angeles and Long Beach Port Infrastructure and Environmental Programs Cooperative Working Agreement.

Parties: City of Los Angeles and City of Long Beach.

Filing Party: Heather M. McCloskey, Deputy City Attorney; Los Angeles City Attorney's Office; 425 S. Palos Verdes Street; San Pedro, CA 90731.

Synopsis: The agreement would authorize the Ports of Los Angeles and Long Beach to discuss and agree upon joint programs and strategies to improve port transportation infrastructure and decrease port-related pollution emissions. The parties requested expedited review.

By Order of the Federal Maritime Commission.

Dated: January 18, 2013.

Rachel E. Dickon,

Assistant Secretary.

[FR Doc. 2013–01429 Filed 1–24–13; 8:45 am]

BILLING CODE P

FEDERAL MARITIME COMMISSION

Ocean Transportation Intermediary License Revocations

The Commission gives notice that the following Ocean Transportation Intermediary licenses have been revoked pursuant to section 19 of the Shipping Act of 1984 (46 U.S.C. 40101) effective on the date shown.

License No.: 3549NF.

Name: Demetrios Air Freight Company, Inc.

Address: 215 Salem Street, Woburn, MA 01801.

Date Revoked: December 14, 2012.
Reason: Failed to maintain valid bonds.

License No.: 004191NF.
Name: Genesis Forwarding Group USA, Inc. dba Genesis Container Lines.
Address: 800 Hindry Avenue, Units B–D, Inglewood, CA 90301.
Date Revoked: December 17, 2012.
Reason: Failed to maintain valid bonds.

License No.: 8504N.
Name: Hyun Dae Trucking Co., Inc.
Address: 3022 S. Western Avenue, Los Angeles, CA 90018.
Date Revoked: December 1, 2012.
Reason: Failed to maintain a valid bond.

License No.: 12472N.
Name: Delta Express Freight Service, Inc.
Address: 550 W. Patrice Place, Suite A, Gardena, CA 90248.
Date Revoked: November 14, 2012.
Reason: Failed to maintain a valid bond.

License No.: 17642N.
Name: Direct Shipping, Corp. dba Direct Shipping Line.
Address: 1371 South Santa Fe Avenue, Compton, CA 90221.
Date Revoked: November 26, 2012.
Reason: Failed to maintain a valid bond.

License No.: 017663N.
Name: Data Cargo Co., Inc.
Address: 11801 NW 100th Road, Suite 13, Medley, FL 33178.
Date Revoked: November 14, 2012.
Reason: Failed to maintain a valid bond.

License No.: 019791N.
Name: Ruky International Company.
Address: 100 Menlo Park Drive, Suite 310, Edison, NJ 08837.
Date Revoked: December 26, 2012.
Reason: Voluntary Surrender of License.

License No.: 020201F.
Name: Genesis Forwarding Services CA, Inc. dba Genesis Container Lines.
Address: 800 Hindry Avenue, Units B–D, Inglewood, CA 90301.
Date Revoked: November 15, 2012.
Reason: Failed to maintain a valid bond.

License No.: 020202F.
Name: Genesis Freight Forwarding Services, Inc. dba Genesis Container Lines.
Address: 2700 Greens Road, Suite 300, Houston, TX 77032.
Date Revoked: November 15, 2012.
Reason: Failed to maintain a valid bond.

License No.: 020203F.
Name: Genesis Forwarding Services IL, Inc. dba Genesis Container Lines.
Address: 2601–2605 Greenleaf Avenue, Elk Grove Village, IL 60007.
Date Revoked: November 15, 2012.
Reason: Failed to maintain a valid bond.

License No.: 020204F.
Name: Genesis Forwarding Services NY, Inc. dba Genesis Container Lines.
Address: 145 Hook Creek Blvd., Bldg. B–1, Valley Stream, NY 11581.
Date Revoked: November 15, 2012.
Reason: Failed to maintain a valid bond.

License No.: 020252N.
Name: Sobe Enterprises, Inc. dba Sobe Export Services.
Address: 150 NW 176th Street, Unit C, Miami Gardens, FL 33169.
Date Revoked: November 15, 2012.
Reason: Failed to maintain a valid bond.

License No.: 020445F.
Name: Freight It, Inc.
Address: 11222 La Cienega Blvd., Suite 555, Inglewood, CA 90304.
Date Revoked: December 7, 2012.
Reason: Failed to maintain a valid bond.

License No.: 022246N.
Name: Pelham Services, Inc.
Address: 5413 NW 72nd Avenue, Miami, FL 33166.
Date Revoked: December 23, 2012.
Reason: Failed to maintain a valid bond.

License No.: 022299N.
Name: KLS Logistics Group LLC
Address: 1563 NW 82nd Avenue, Miami, FL 33126.
Date Revoked: December 1, 2012.
Reason: Failed to maintain a valid bond.

License No.: 022877NF.
Name: Twenty Two Global Transport, LP.
Address: 1110 Henderson Street, Houston, TX 77007.
Date Revoked: December 12, 2012.
Reason: Failed to maintain valid bonds.

License No.: 023045F.
Name: First America Metal Corporation.
Address: 113 Industrial Drive, Minooka, IL 60447.
Date Revoked: November 12, 2012.
Reason: Failed to maintain a valid bond.

License No.: 023500N.
Name: IMAC International Corp.
Address: 527 Albert Street, East Meadow, NY 11554.
Date Revoked: December 10, 2012.
Reason: Voluntary Surrender of License.

Vern W. Hill,
Director, Bureau of Certification and Licensing.

[FR Doc. 2013–01516 Filed 1–24–13; 8:45 am]
BILLING CODE 6730–01–P

FEDERAL MARITIME COMMISSION

Ocean Transportation Intermediary License Applicants

The Commission gives notice that the following applicants have filed an application for an Ocean Transportation Intermediary (OTI) license as a Non-Vessel-Operating Common Carrier (NVO) and/or Ocean Freight Forwarder (OFF) pursuant to section 19 of the Shipping Act of 1984 (46 U.S.C. 40101). Notice is also given of the filing of applications to amend an existing OTI license or the Qualifying Individual (QI) for a licensee.

Interested persons may contact the Office of Ocean Transportation Intermediaries, Federal Maritime Commission, Washington, DC 20573, by telephone at (202) 523–5843 or by email at *OTI@fmc.gov.*

Advantex Express Inc. (OFF), 4402 Theiss Road, Humble, TX 77338, Officers: Gary C. Cockrell, Assistant Vice President for Regulatory Affairs (QI), Greg Richard, President, Application Type: New OFF License.

Amerifreight (N.A.), Inc. dba Freight Team (NVO & OFF), 218 Machlin Court, Walnut, CA 91789, Officer: Lionel Bao, President (QI), Application Type: Add Trade Name iGlobal US.

Blue Cargo Group, LLC (NVO & OFF), 177–15 149th Road, 2nd Floor, Jamaica, NY 11434, Officers: Khalid Aziz, Manager (QI), Steven Perlman, Manager, Application Type: Add Trade Name Blu Logistics.

Brutos International Corp. (NVO & OFF), 428 S. Atlantic Blvd., Suite 203, Monterey Park, CA 91754, Officers: Janet Li, Secretary (QI), Jesse Wu, CEO/CFO, Application Type: New NVO & OFF License.

Durard Timothy Gruelle dba D.T. Gruelle Company (NVO & OFF), 301 Moon Clinton Road, Coraopolis, PA 15108, Officers: Durard T. Gruelle, President (QI), Matteo A. Gruelle, Manager (QI), Application Type: License Transfer to D.T. Gruelle Company Group, LLC & QI Change.

Em-Lines Limited (NVO), 21/F Gloucester Tower, The Landmark Queen's Road, Central Hong Kong, China, Officers: Robin B. Finke, President (QI), Olen D. Woods, Director, Application Type: New NVO License.

Global Logistics New Jersey, LLC (NVO & OFF), 275 Veterans Blvd., Rutherford, NJ 07070, Officers: Ohmoon Kwon, Manager (QI), Jihyuk Lim, Treasurer, Application Type: Add Trade Name Hyundai Glovis New Jersey, LLC.

Harris International Freight Forwarders, Inc. (OFF), 2033 Second Avenue, Suite 1510, Seattle, WA 98121, Officers: Irmgard H. Harris, Secretary (QI), Michael W. Harris, President (QI), Application Type: QI Change.

Jawed Salim dba Continents Shipping & Trading (OFF), 18062 FM 529 Road, Suite 172, Cypress, TX 77433, Officer: Jawed Salim, Sole Proprietor (QI), Application Type: New OFF License.

JT Freight Solutions (NVO & OFF), 438 Lafayette Street, San Gabriel, CA 91776, Officer: Jeremy Tran, President (QI), Application Type: New NVO & OFF License.

OceanLink Shipping Logistics (NVO & OFF), 3070 East Frontere Street, Suite 210, Anaheim, CA 92806, Officers: Nevine G. Shehata, CEO (QI), Amer Eid, CFO, Application Type: New NVO & OFF License.

Veco Logistics Miami, Inc. (NVO & OFF), 7270 NW 35 Ter, Suite 101, Miami, FL 33122, Officers: Patricia E. Puga, Vice President (QI), Zoraida E. Sorrano, President, Application Type: QI Change & Add OFF Service.

World Link Logistics Inc. (NVO & OFF), 17022 De Groot Place, Cerritos, CA 90703, Officer: Syed M. Ali, President (QI), Application Type: New NVO & OFF License.

By the Commission.

Dated: January 18, 2013.

Rachel E. Dickon,

Assistant Secretary.

[FR Doc. 2013–01521 Filed 1–24–13; 8:45 am]

BILLING CODE 6730–01–P

FEDERAL MARITIME COMMISSION

Ocean Transportation Intermediary License Reissuances

The Commission gives notice that the following Ocean Transportation Intermediary license has been reissued pursuant to section 19 of the Shipping Act of 1984 (46 U.S.C. 40101) effective on the date shown.

License No.: 020445N.

Name: Freight It, Inc.

Address: 11222 La Cienega Blvd., Suite 555, Inglewood, CA 90304.

Date Reissued: December 7, 2012.

Vern W. Hill,

Director, Bureau of Certification and Licensing.

[FR Doc. 2013–01519 Filed 1–24–13; 8:45 am]

BILLING CODE 6730–01–P

FEDERAL RESERVE SYSTEM

Change in Bank Control Notices; Acquisitions of Shares of a Bank or Bank Holding Company

The notificants listed below have applied under the Change in Bank Control Act (12 U.S.C. 1817(j)) and § 225.41 of the Board's Regulation Y (12 CFR 225.41) to acquire shares of a bank or bank holding company. The factors that are considered in acting on the notices are set forth in paragraph 7 of the Act (12 U.S.C. 1817(j)(7)).

The notices are available for immediate inspection at the Federal Reserve Bank indicated. The notices also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing to the Reserve Bank indicated for that notice or to the offices of the Board of Governors. Comments must be received not later than February 11, 2013.

A. Federal Reserve Bank of Minneapolis (Jacqueline G. King, Community Affairs Officer) 90 Hennepin Avenue, Minneapolis, Minnesota 55480–0291:

1. *Kellen M. Shebeck,* Underwood, Minnesota, and Meegan S. Heiderbrink, Adrian, Minnesota; to retain voting shares of Underwood Bancshares, Inc., and thereby indirectly retain voting shares of Farmers State Bank of Underwood, both in Underwood, Minnesota.

Board of Governors of the Federal Reserve System, January 22, 2013.

Margaret McCloskey Shanks,

Deputy Secretary of the Board.

[FR Doc. 2013–01543 Filed 1–24–13; 8:45 am]

BILLING CODE 6210–01–P

FEDERAL RESERVE SYSTEM

Change in Bank Control Notices; Acquisitions of Shares of a Bank or Bank Holding Company

The notificants listed below have applied under the Change in Bank Control Act (12 U.S.C. 1817(j)) and § 225.41 of the Board's Regulation Y (12 CFR 225.41) to acquire shares of a bank or bank holding company. The factors that are considered in acting on the notices are set forth in paragraph 7 of the Act (12 U.S.C. 1817(j)(7)).

The notices are available for immediate inspection at the Federal Reserve Bank indicated. The notices also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing to the Reserve Bank indicated for that notice or to the offices of the Board of Governors. Comments must be received not later than February 7, 2013.

A. Federal Reserve Bank of Chicago (Colette A. Fried, Assistant Vice President) 230 South LaSalle Street, Chicago, Illinois 60690–1414:

1. *Palen Trust for Descendents and Edward Palen, as trustee of the Palen Trust for Descendents,* individually, and together as a group acting in concert with the Palen Marital Trust, Edward Palen, Lorraine Palen, and Joseph Palen, individually and as co-trustees of the Palen Marital Trust, Elizabeth Dray and Judith Somers, all of Forrest, Illinois; Marie King, Piper City, Illinois; and Leona Pacheco, Springfield, Illinois;, to retain voting shares of Forrest Bancshares, Inc., and thereby indirectly retain voting shares of First State Bank of Forrest, both in Forrest, Illinois.

Board of Governors of the Federal Reserve System, January 18, 2013.

Robert deV. Frierson,

Secretary of the Board.

[FR Doc. 2013–01466 Filed 1–24–13; 8:45 am]

BILLING CODE 6210–01–P

FEDERAL RESERVE SYSTEM

Formations of, Acquisitions by, and Mergers of Bank Holding Companies

The companies listed in this notice have applied to the Board for approval, pursuant to the Bank Holding Company Act of 1956 (12 U.S.C. 1841 *et seq.*) (BHC Act), Regulation Y (12 CFR part 225), and all other applicable statutes and regulations to become a bank holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a bank or bank holding company and all of the banks and nonbanking companies owned by the bank holding company, including the companies listed below.

The applications listed below, as well as other related filings required by the Board, are available for immediate inspection at the Federal Reserve Bank indicated. The applications will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the standards enumerated in the BHC Act (12 U.S.C. 1842(c)). If the proposal also involves the acquisition of a nonbanking company, the review also includes whether the acquisition of the nonbanking company complies with the standards in section 4 of the BHC Act (12 U.S.C. 1843). Unless otherwise noted, nonbanking activities will be conducted throughout the United States.

Unless otherwise noted, comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than February 21, 2013.

A. Federal Reserve Bank of Minneapolis (Jacqueline G. King, Community Affairs Officer) 90

Hennepin Avenue, Minneapolis, Minnesota 55480–0291:

1. State Bankshares, Inc., Fargo, North Dakota; to acquire 100 percent of the voting shares of Business Bancorporation, Inc., and thereby indirectly acquire voting shares of The Business Bank, both in Minnetonka, Minnesota.

B. Federal Reserve Bank of San Francisco (Kenneth Binning, Vice President, Applications and Enforcement) 101 Market Street, San Francisco, California 94105–1579:

1. *Columbia Banking System, Inc.,* Tacoma, Washington; to merge with West Coast Bancorp, and thereby indirectly acquire West Coast Bank, both in Lake Oswego, Oregon.

In connection with this application, Applicant also has applied to acquire West Coast Trust Company, Portland, Oregon, and thereby engage in trust company activities, pursuant to section 225.28(b)(5).

Board of Governors of the Federal Reserve System, January 22, 2013.

Margaret McCloskey Shanks,

Deputy Secretary of the Board.

[FR Doc. 2013–01542 Filed 1–24–13; 8:45 am]

BILLING CODE 6210–01–P

FEDERAL TRADE COMMISSION

Agency Information Collection Activities; Submission for OMB Review; Comment Request

AGENCY: Federal Trade Commission.

ACTION: Notice and request for comment.

SUMMARY: In compliance with the Paperwork Reduction Act (PRA) of 1995, the FTC is seeking public comments on its request to OMB for a three-year extension of the current PRA clearance for the information collection requirements contained in the Mail or Telephone Order Merchandise Trade Regulation Rule. That clearance expires on February 28, 2013 (OMB Control No. 3084–0106).

DATES: Comments must be received by February 25, 2013.

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.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the proposed information requirements should be addressed to Jock Chung, Attorney, Division of Enforcement, Bureau of Consumer Protection, Federal Trade Commission, 600 Pennsylvania Avenue NW., Washington, DC 20580, (202) 326–2984.

SUPPLEMENTARY INFORMATION:

Title: Mail or Telephone Order Merchandise Trade Regulation Rule (MTOR or Rule), 16 CFR Part 435.

OMB Control Number: 3084–0106.

Type of Review: Extension of a currently approved collection.

Abstract: Generally, the MTOR requires a merchant to: (1) Have a reasonable basis for any express or implied shipment representation made in soliciting the sale (if no express time period is promised, the implied shipment representation is 30 days); (2) notify the consumer and obtain the consumer's consent to any delay in shipment; and (3) make prompt and full refunds when the consumer exercises a cancellation option or the merchant is unable to meet the Rule's other requirements.

The notice provisions in the Rule require a merchant who is unable to ship within the promised shipment time or 30 days to notify the consumer of a revised date and his or her right to cancel the order and obtain a prompt refund. Delays beyond the revised shipment date also trigger a notification requirement to consumers. When the MTOR requires the merchant to make a refund and the consumer has paid by credit card, the Rule also requires the merchant to notify the consumer either that any charge to the consumer's charge account will be reversed or that the merchant will take no action that will result in a charge.

On October 24, 2012, the Commission sought comment on the information collection requirements in MTOR. See 77 FR 64994. No comments were received. As required by OMB regulations, 5 CFR Part 1320, the FTC is providing this second opportunity for public comment.

Likely Respondents: Businesses engaged in the sale of merchandise by mail or by telephone.

Estimated Annual Hours Burden: 1,764,390 hours.

Third Party Disclosure: [(29,478 established businesses × 50 hours) + (1,263 new entrants × 230 hours) = 1,764,390 hours.

Estimated Annual Cost Burden: $31,830,000 (rounded to the nearest thousand), which is derived from 1,764,390 hours × $18.04/hour.[1]

[1] This is the mean hourly income for workers in sales and related occupations according to the latest figures from the Department of Commerce's Bureau of Labor Statistics. *See* Table 1, National employment and wage data from the Occupational Employment Statistics survey by occupation, May 2011, at *http://www.bls.gov/news.release/pdf/ocwage.pdf.*

Request for Comment: You can file a comment online or on paper. For the Commission to consider your comment, we must receive it on or before February 25, 2013. Write ''Mail or Telephone Order Merchandise Trade Regulation Rule: FTC File No. R511929'' 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 does not 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 does not include any sensitive health information, like medical records or other individually identifiable health information. In addition, do not include any ''[t]rade secret or any commercial or financial information which is * * * privileged or confidential,'' as discussed 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). In particular, do not include competitively sensitive information such as costs, sales statistics, inventories, formulas, patterns, devices, manufacturing processes, or customer names.

If you want the Commission to give your comment confidential treatment, you must file it in paper form, with a request for confidential treatment, and you have to follow the procedure explained in FTC Rule 4.9(c), 16 CFR 4.9(c). Your comment will be kept confidential only if the FTC General Counsel, in his or her sole discretion, grants your request in accordance with the law and the public interest.

Postal mail addressed to the Commission is subject to delay due to heightened security screening. As a result, we encourage you to submit your comments online, or to send them to the Commission by courier or overnight service. To make sure that the Commission considers your online comment, you must file it at *https://ftcpublic.commentworks.com/ftc/MTORpra2,* by following the instructions on the web-based form. If

this Notice appears at *http://www.regulations.gov,* you also may file a comment through that Web site.

If you file your comment on paper, write ''Mail or Telephone Order Merchandise Trade Regulation Rule: FTC File No. R511929'' on your comment and on the envelope, and mail or deliver it to the following address: Federal Trade Commission, Office of the Secretary, Room H–113 (Annex J), 600 Pennsylvania Avenue NW., Washington, DC 20580. If possible, submit your paper comment to the Commission by courier or overnight service.

Visit the Commission Web site at *http://www.ftc.gov* to read this Notice. 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 February 25, 2013. 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.shtm.*

Comments on the information collection requirements subject to review under the PRA should also be submitted to OMB. If sent by U.S. mail, address comments 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.

David C. Shonka,

Acting General Counsel.

[FR Doc. 2013–01523 Filed 1–24–13; 8:45 am]

BILLING CODE 6750–01–P

DEPARTMENT OF DEFENSE

GENERAL SERVICES ADMINISTRATION

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[Docket 2012–0076; Sequence 41; OMB Control No. 9000–0070]

Submission for OMB Review; Payments

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

ACTION: Notice of request for comments regarding the extension of a previously existing OMB clearance.

SUMMARY: Under the provisions of the Paperwork Reduction Act, the Regulatory Secretariat will be submitting to the Office of Management and Budget (OMB) a request to review and approve an extension of a previously approved information collection requirement concerning Payments. A notice was published in the **Federal Register** at 77 FR 43080, on July 23, 2012. One respondent submitted comments.

Public comments are particularly invited on: Whether this collection of information is necessary for the proper performance of functions of the Federal Acquisition Regulations (FAR), and whether it will have practical utility; whether our estimate of the public burden of this collection of information is accurate, and based on valid assumptions and methodology; ways to enhance the quality, utility, and clarity of the information to be collected; and ways in which we can minimize the burden of the collection of information on those who are to respond, through the use of appropriate technological collection techniques or other forms of information technology.

DATES: Submit comments on or before February 25, 2013.

ADDRESSES: Submit comments identified by Information Collection 9000–0070, Payments, by any of the following methods:

- *Regulations.gov: http://www.regulations.gov.*

Submit comments via the Federal eRulemaking portal by searching the OMB control number. Select the link ''Submit a Comment'' that corresponds with ''Information Collection 9000–0070, Payments''. Follow the instructions provided at the ''Submit a Comment'' screen. Please include your name, company name (if any), and ''Information Collection 9000–0070, Payments'' on your attached document.

- *Fax:* 202–501–4067.
- *Mail:* General Services Administration, Regulatory Secretariat (MVCB), 1275 First Street NE., Washington, DC 20417. ATTN: Hada Flowers/IC 9000–0070, Payments.

Instructions: Please submit comments only and cite Information Collection 9000–0070, Payments, in all correspondence related to this collection. All comments received will be posted without change to *http://www.regulations.gov,* including any personal and/or business confidential information provided.

FOR FURTHER INFORMATION CONTACT: Edward Chambers, Procurement Analyst, Office of Acquisition Policy, GSA at (202) 501–3221 or Email at *Edward.chambers@gsa.gov.*

SUPPLEMENTARY INFORMATION:

A. Purpose

Firms performing under Federal contracts must provide adequate documentation to support requests for payment under these contracts. The documentation may range from a simple invoice to detailed cost data. The information is usually submitted once, at the end of the contract period or upon delivery of the supplies, but could be submitted more often depending on the payment schedule established under the contract (see FAR 52.232–1 through 52.232–4, and FAR 52.232–6 through 52.232–11). The information is used to determine the proper amount of payments to Federal contractors.

B. Analysis of Public Comments

One respondent submitted public comments on the extension of the previously approved information collection. The analysis of the public comments is summarized as follows:

Comment: The respondent commented that the extension of the information collection would violate the fundamental purposes of the Paperwork Reduction Act because of the burden it puts on the entity submitting the information and the agency collecting the information.

Response: In accordance with the Paperwork Reduction Act (PRA), agencies can request OMB approval of an existing information collection. The PRA requires that agencies use the **Federal Register** notice and comment process, to extend OMB's approval, at least every three years. This extension, to a previously approved information collection, pertains to documentation necessary to support requests for payment under Government contracts. The documentation may range from a simple invoice to detailed cost data. The information is usually submitted once, at the end of the contract period or upon delivery of the supplies, but could be submitted more often depending on the payment schedule established under the contract (see FAR 52.232–1 through 52.232–11). The information is used to determine the proper amount of payments to Federal contractors. Absent this documentation, which serves as the basis for contract payments, the Government would be prevented from making such payments.

Comment: The respondent commented that the agency did not accurately estimate the public burden challenging that the agency's methodology for calculating it is insufficient and inadequate and does not reflect the total burden. The respondent stated the estimate of 120 responses per respondent is understated, and proposed that the number of responses for many respondents, particularly large government contractors, exceeds 1,000 responses per year. Additionally, the respondent stated that the estimate of .025 hours of burden per response is unrealistically low given the level of documentation required to support requests for payment, especially on certain contracts, and proposed that contractors will expend an amount of effort more than 100 times the estimate of .025 hours. For this reason, the respondent provided that the agency should reassess the estimated total burden hours and revise the estimate upwards to be more accurate, as was done in FAR Case 2007–006. The same respondent also provided that the burden of compliance with the information collection requirement greatly exceeds the agency's estimate and outweighs any potential utility of the extension.

Response: Serious consideration is given, during the open comment period, to all comments received and adjustments are made to the paperwork burden estimate based on reasonable considerations provided by the public. This is evidenced, as the respondent notes, in FAR Case 2007–006 where an adjustment was made from the total preparation hours from three to 60. This change was made considering particularly the hours that would be required for review within the company, prior to release to the Government.

The burden is prepared taking into consideration the necessary criteria in OMB guidance for estimating the paperwork burden put on the entity submitting the information. For example, consideration is given to an entity reviewing instructions; using technology to collect, process, and disclose information; adjusting existing practices to comply with requirements; searching data sources; completing and reviewing the response; and transmitting or disclosing information. The estimated burden hours for a collection are based on an average between the hours that a simple disclosure by a very small business might require and the much higher numbers that might be required for a very complex disclosure by a major corporation. Also, the estimated burden hours should only include projected hours for those actions which a company would not undertake in the normal course of business. Careful consideration went into assessing the estimated burden hours for this collection, and although, the respondent provided estimates of responses and burden hours, the estimates cannot be confirmed with any degree of certainty to totally rely on the information. However, it is determined that an upward adjustment is warranted at this time based upon consideration of the information provided in the public comment. The information collection requirement has been revised to reflect an overall increase in the total public burden hours.

C. Annual Reporting Burden

Respondents: 80,000.
Responses per Respondent: 120.
Total Responses: 9,600,000.
Hours per Response: .25.
Total Burden Hours: 2,400,000.
Obtaining Copies of Proposals: Requesters may obtain a copy of the information collection documents from the General Services Administration, Regulatory Secretariat (MVCB), 1275 First Street NE., Washington, DC 20417, telephone (202) 501–4755. Please cite OMB Control No. 9000–0070, Payments, in all correspondence.

Dated: January 17, 2013.

William Clark,

Acting Director, Federal Acquisition Policy Division, Office of Governmentwide Acquisition Policy, Office of Acquisition Policy, Office of Governmentwide Policy.

[FR Doc. 2013–01438 Filed 1–24–13; 8:45 am]

BILLING CODE 6820–EP–P

DEPARTMENT OF DEFENSE

GENERAL SERVICES ADMINISTRATION

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[Docket 2012–0076; Sequence 48; OMB Control No. 9000–0101]

Federal Acquisition Regulation; Submission for OMB Review; Drug-Free Workplace (FAR 52.223–6)

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

ACTION: Notice of request for public comments regarding an extension of an existing OMB clearance.

SUMMARY: Under the provisions of the Paperwork Reduction Act, the Regulatory Secretariat will be submitting to the Office of Management and Budget (OMB) a request to review and approve an extension of a previously approved information collection requirement concerning drug-free workplace. A notice was published in the **Federal Register** at 77 FR 52696, on August 30, 2012. No comments were received.

Public comments are particularly invited on: Whether this collection of information is necessary for the proper performance of functions of the Federal Acquisition Regulations (FAR), and whether it will have practical utility; whether our estimate of the public burden of this collection of information is accurate, and based on valid assumptions and methodology; ways to enhance the quality, utility, and clarity of the information to be collected; and ways in which we can minimize the burden of the collection of information on those who are to respond, through the use of appropriate technological collection techniques or other forms of information technology.

DATES: Submit comments on or before February 25, 2013.

ADDRESSES: Submit comments identified by Information Collection 9000–0101, Drug-Free Workplace, by any of the following methods:

- *Regulations.gov: http://www.regulations.gov.*

Submit comments via the Federal eRulemaking portal by searching the OMB control number. Select the link ''Submit a Comment'' that corresponds with ''Information Collection 9000–0101, Drug-Free Workplace''. Follow the instructions provided at the ''Submit a Comment'' screen. Please include your name, company name (if any), and ''Information Collection 9000–0101, Drug-Free Workplace'' on your attached document.

- *Fax:* 202–501–4067.
- *Mail:* General Services Administration, Regulatory Secretariat (MVCB), 1275 First Street NE., Washington, DC 20417. ATTN: Hada Flowers/IC 9000–0101, Drug-Free Workplace.

Instructions: Please submit comments only and cite Information Collection 9000–0101, Drug-Free Workplace, in all correspondence related to this collection. All comments received will be posted without change to *http://www.regulations.gov,* including any personal and/or business confidential information provided.

FOR FURTHER INFORMATION CONTACT: Ms. Marissa Petrusek, Procurement Analyst, Office of Acquisition Policy, GSA (202)

501–0136 or email *marissa.petrusek@gsa.gov.*

SUPPLEMENTARY INFORMATION:

A. Purpose

FAR clause 52.223–6, Drug-Free Workplace, requires (1) contractor employees to notify their employer of any criminal drug statute conviction for a violation occurring in the workplace; and (2) Government contractors, after receiving notice of such conviction, to notify the contracting officer. The clause is not applicable to commercial items, contracts at or below simplified acquisition threshold (unless awarded to an individual), and contracts performed outside the United States or by law enforcement agencies. The clause implements the Drug-Free Workplace Act of 1988 (Pub. L. 100–690).

The information provided to the Government is used to determine contractor compliance with the statutory requirements to maintain a drug-free workplace.

B. Annual Reporting Burden

Based on Fiscal Year 2011 (FY11) data from the Federal Procurement Data System (FPDS), statistical information from other sources, and historical knowledge of the information collection, the estimated total burden is as follows:

Respondents: 598.

Responses per Respondent: 1.

Annual Responses: 598.

Hours per Response: .5.

Total Burden Hours: 299.

Obtaining Copies of Proposals: Requesters may obtain a copy of the information collection documents from the General Services Administration, Regulatory Secretariat (MVCB), 1275 First Street NE., Washington, DC 20417, telephone (202) 501–4755. Please cite OMB Control No. 9000–0101, Drug-Free Workplace, in all correspondence.

Dated: January 18, 2013.

William Clark,

Acting Director, Federal Acquisition Policy Division, Office of Governmentwide Acquisition Policy, Office of Acquisition Policy, Office of Governmentwide Policy.

[FR Doc. 2013–01452 Filed 1–24–13; 8:45 am]

BILLING CODE 6820–EP–P

DEPARTMENT OF DEFENSE

GENERAL SERVICES ADMINISTRATION

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[Docket 2012–0076; Sequence 42; OMB Control No. 9000–0071]

Federal Acquisition Regulation; Submission for OMB Review; Price Redetermination

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

ACTION: Notice of request for public comments regarding an extension of an existing OMB clearance.

SUMMARY: Under the provisions of the Paperwork Reduction Act, the Regulatory Secretariat will be submitting to the Office of Management and Budget (OMB) a request to review and approve an extension of a previously approved information collection requirement concerning Price Redetermination. A notice was published in the **Federal Register** at 77 FR 51784, on August 27, 2012. One respondent submitted comments.

Public comments are particularly invited on: Whether this collection of information is necessary; whether it will have practical utility; whether our estimate of the public burden of this collection of information is accurate, and based on valid assumptions and methodology; ways to enhance the quality, utility, and clarity of the information to be collected; and ways in which we can minimize the burden of the collection of information on those who are to respond, through the use of appropriate technological collection techniques or other forms of information technology.

DATES: Submit comments on or before February 25, 2013.

ADDRESSES: Submit comments identified by Information Collection 9000–0071, Price Redetermination, by any of the following methods:

- *Regulations.gov: http://www.regulations.gov.* Submit comments via the Federal eRulemaking portal by searching the OMB control number. Select the link ''Submit a Comment'' that corresponds with ''Information Collection 9000–0071, Price Redetermination''. Follow the instructions provided at the ''Submit a Comment'' screen. Please include your name, company name (if any), and ''Information Collection 9000–0071, Price Redetermination'' on your attached document.
- *Fax:* 202–501–4067.
- *Mail:* General Services Administration, Regulatory Secretariat (MVCB), 1275 First Street NE., Washington, DC 20417. ATTN: Hada Flowers/IC 9000–0071, Price Redetermination.

Instructions: Please submit comments only and cite Information Collection 9000–0071, Price Redetermination, in all correspondence related to this collection. All comments received will be posted without change to *http://www.regulations.gov,* including any personal and/or business confidential information provided.

FOR FURTHER INFORMATION CONTACT: Mr. Curtis E. Glover, Sr., Procurement Analyst, Office of Governmentwide Acquisition Policy, GSA, (202) 501–1448 or email *curtis.glover@gsa.gov.*

SUPPLEMENTARY INFORMATION:

I. Purpose

FAR 16.205, Fixed-price contracts with prospective price redetermination, provides for firm fixed prices for an initial period of the contract with prospective redetermination at stated times during performance. FAR 16.206, Fixed price contracts with retroactive price redetermination, provides for a fixed ceiling price and retroactive price redetermination within the ceiling after completion of the contract. In order for the amounts of price adjustments to be determined, the firms performing under these contracts must provide information to the Government regarding their expenditures and anticipated costs.

II. Discussion and Analysis

One respondent submitted public comments on the extension of the previously approved information collection. The analysis of the public comments is summarized as follows:

Comment: The respondent commented that the extension of the information collection would violate the fundamental purposes of the Paperwork Reduction Act because of the burden it puts on the entity submitting the information and the agency collecting the information.

Response: In accordance with the Paperwork Reduction Act (PRA), agencies can request an OMB approval of an existing information collection. The PRA requires that agencies use the **Federal Register** notice and comment process, to extend the OMB's approval, at least every three years. This extension, to a previously approved information collection, pertains to FAR

16.206, Fixed price contracts with retroactive price redetermination. The FAR section allows an agency to award a contract with a fixed ceiling price and retroactively redetermine the price within the ceiling after completion of the contract. In order for the amounts of price adjustments to be determined, the firms performing under these contracts must provide information to the Government regarding their expenditures and anticipated costs. The Government uses this information to establish fair price adjustments to Federal contracts. Not granting this extension would consequently eliminate the Government's ability to negotiate a fair and reasonable firm-fixed price after the initial period.

Comment: The respondent commented that the agency did not accurately estimate the public burden an extension of this information collection requirement would create. The respondent offers that the obligations imposed by the clause under a fixed-price contract with prospective price redetermination are onerous, and will require a contractor to implement accounting systems that are equipped to account for allowable costs substantially the same as a cost reimbursement contract. The respondent believes a more reasonable estimate of hours per response would be in the range of 40 to 80 hours.

Response: It is expected and anticipated that potential contractors seeking to do business with the Government under a fixed-price contract with prospective price redetermination would have accounting systems that allow for collecting, tracking, monitoring and reporting the type of information required for this collection. Generally, the information requested under this collection is generated in the normal course of doing business, available electronically and organized similar to the format requested. However, considering the public comment and given the extent a company may not provide for accounting the information as previously discussed, the Government has adjusted the hours per response for this information collection to 8 hours.

Comment: The respondent commented that the collective burden of compliance with the information collection requirement greatly exceeds the agencies estimate and outweighs any potential utility of the extension.

Response: The respondents concern is addressed within the framework of OMB review and approval of this information collection requirement and its associated regulation, as required by the Paperwork Reduction Act (PRA) and Executive Order 12866. The PRA requires Federal agencies to take specific steps before requiring or requesting information from the public. These steps include (1) seeking public comment on proposed information collections and (2) submitting proposed collections for review and approval by OMB. A central goal of OMB review is to help agencies strike a balance between collecting information necessary to fulfill their statutory missions and guarding against unnecessary or duplicative information that imposes unjustified costs on the American public. In this regard, OMB evaluates whether the collection of information by the agency: is necessary for the proper performance of the functions of the agency, including whether the information has practical utility; minimizes the Federal information collection burden, with particular emphasis on those individuals and entities most adversely affected; and maximizes the practical utility of and public benefit from information collected by or for the Federal Government.

The OMB review process under Executive Order 12866 seeks to ensure that agencies, to the extent permitted by law, comply with the regulatory principles stated in the Executive Order and that the President's policies and priorities are reflected in agency rules. Such review also helps to promote adequate interagency review of draft proposed and final regulatory actions, so that such actions are coordinated with other agencies to avoid inconsistent, incompatible, or duplicative policies. OMB review helps to ensure that agencies carefully consider the consequences of rules (including both benefits and costs) before they proceed.

Comment: The respondent commented that the Government's response to the Paperwork Reduction Act waiver for FAR Case 2007–006 is instructive on the total burden for respondents.

Response: Serious consideration is given, during the open comment period, to all comments received and adjustments are made to the paperwork burden estimate based on reasonable considerations provided by the public. This is evidenced, as the respondent notes, in FAR Case 2007–006 where an adjustment was made from the total preparation hours from three to 60. This change was made considering particularly the hours that would be required for review within the company, prior to release to the Government.

The burden is prepared taking into consideration the necessary criteria in OMB guidance for estimating the paperwork burden put on the entity submitting the information. For example, consideration is given to an entity reviewing instructions; using technology to collect, process, and disclose information; adjusting existing practices to comply with requirements; searching data sources; completing and reviewing the response; and transmitting or disclosing information. The estimated burden hours for a collection are based on an average between the hours that a simple disclosure by a very small business might require and the much higher numbers that might be required for a very complex disclosure by a major corporation. Also, the estimated burden hours should only include projected hours for those actions which a company would not undertake in the normal course of business. Careful consideration went into assessing the estimated burden hours for this collection, and it is determined that an upward adjustment is reasonable at this time.

III. Annual Reporting Burden

Based on Fiscal Year 2011 information from the Federal Procurement Data System, an estimated 230 unique contractors were awarded 1,970 fixed-price redetermination contracts. Thus, each vendor responded on average 8.6 times a year (rounded up to 9). The hours per response is increased to 8 hours after a reassessment of the time required to prepare and report the information.

Respondents: 230.

Responses per Respondent: 9.

Annual Responses: 2,070.

Hours per Response: 8.

Total Burden Hours: 16,560.

Obtaining Copies of Proposals: Requesters may obtain a copy of the information collection documents from the General Services Administration, Regulatory Secretariat (MVCB), 1275 First Street NE., Washington, DC 20417, telephone (202) 501–4755. Please cite OMB Control No. 9000–0071, Price Redetermination, in all correspondence.

Dated: January 17, 2013.

William Clark,

Acting Director, Federal Acquisition Policy Division, Office of Governmentwide Acquisition Policy, Office of Acquisition Policy, Office of Governmentwide Policy.

[FR Doc. 2013–01476 Filed 1–24–13; 8:45 am]

BILLING CODE 6820–EP–P

DEPARTMENT OF DEFENSE

GENERAL SERVICES ADMINISTRATION

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[Docket 2012–0076; Sequence 45; OMB Control No. 9000–0082]

Federal Acquisition Regulation; Submission for OMB Review; Economic Purchase Quantity—Supplies

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

ACTION: Notice of request for public comments regarding an extension to an existing OMB clearance.

SUMMARY: Under the provisions of the Paperwork Reduction Act, the Regulatory Secretariat will be submitting to the Office of Management and Budget (OMB) a request to review and approve an extension of a previously approved information collection requirement concerning Economic Purchase Quantity—Supplies. A notice was published in the **Federal Register** at 77 FR 43077, on July 23, 2012. One respondent submitted comments.

Public comments are particularly invited on: Whether this collection of information is necessary for the proper performance of functions of the Federal Acquisition Regulation (FAR), and whether it will have practical utility; whether our estimate of the public burden of this collection of information is accurate, and based on valid assumptions and methodology; ways to enhance the quality, utility, and clarity of the information to be collected; and ways in which we can minimize the burden of the collection of information on those who are to respond, through the use of appropriate technological collection techniques or other forms of information technology.

DATES: Submit comments on or before February 25, 2013.

ADDRESSES: Submit comments identified by Information Collection 9000–0082, Economic Purchase Quantity—Supplies, by any of the following methods:

- *Regulations.gov: http://www.regulations.gov.*

Submit comments via the Federal eRulemaking portal by searching the OMB control number. Select the link ''Submit a Comment'' that corresponds with ''Information Collection 9000–0082 Economic Purchase Quantity—Supplies''. Follow the instructions provided at the ''Submit a Comment'' screen. Please include your name, company name (if any), and ''Information Collection 9000–0082 Economic Purchase Quantity—Supplies'' on your attached document.

- *Fax:* 202–501–4067.
- *Mail:* General Services Administration, Regulatory Secretariat (MVCB), 1275 First Street NE., Washington, DC 20417. ATTN: Hada Flowers/IC 9000–0082, Economic Purchase Quantity—Supplies.

Instructions: Please submit comments only and cite Information Collection 9000–0082, Economic Purchase Quantity—Supplies, in all correspondence related to this collection. All comments received will be posted without change to *http://www.regulations.gov,* including any personal and/or business confidential information provided.

FOR FURTHER INFORMATION CONTACT: Mr. Michael O. Jackson, Procurement Analyst, Office of Governmentwide Acquisition Policy, (202) 208–4949 or email *michaelo.jackson@gsa.gov.*

SUPPLEMENTARY INFORMATION:

A. Purpose

The provision at 52.207–4, Economic Purchase Quantity—Supplies, invites offerors to state an opinion on whether the quantity of supplies on which bids, proposals, or quotes are requested in solicitations is economically advantageous to the Government. Each offeror who believes that acquisitions in different quantities would be more advantageous is invited to (1) recommend an economic purchase quantity, showing a recommended unit and total price, and (2) identify the different quantity points where significant price breaks occur. This information is required by Public Law 98–577 and Public Law 98–525.

B. Discussion and Analysis

One respondent submitted public comments on the extension of the previously approved information collection. The analysis of the public comments is summarized as follows:

Comment: The respondent commented that the extension of the information collection would violate the fundamental purposes of the Paperwork Reduction Act because of the burden it puts on the entity submitting the information and the agency collecting the information. The respondent opposes granting the extension of the information collection requirement.

Response: In accordance with the Paperwork Reduction Act (PRA), agencies can request an OMB approval of an existing information collection. The PRA requires that agencies use the **Federal Register** notice and comment process, to extend the OMB's approval, at least every three years. This extension, to a previously approved information collection, pertains to the provision at FAR 52.207–4, Economic Purchase Quantity—Supplies, which invites offerors to state an opinion on whether the quantity of supplies on which bids, proposals, or quotes are requested in solicitations is economically advantageous to the Government. Each offeror who believes that acquisitions in different quantities would be more advantageous is invited to (1) recommend an economic purchase quantity, showing a recommended unit and total price, and (2) identify the different quantity points where significant price breaks occur. This information is required by Public Law 98–577 and Public Law 98–525. Not granting this extension would consequently eliminate FAR clauses that provide a benefit to the public and the agency collecting the information.

Comment: The respondent commented that the agency did not accurately estimate the public burden challenging that the agency's methodology for calculating it is insufficient and inadequate and does not reflect the total burden. For this reason, the respondent provided that the agency should reassess the estimated total burden hours and revise the estimate upwards to be more accurate, as was done in FAR Case 2007–006. The same respondent also provided that the burden of compliance with the information collection requirement greatly exceeds the agency's estimate and outweighs any potential utility of the extension.

Response: Serious consideration is given, during the open comment period, to all comments received and adjustments are made to the paperwork burden estimate based on reasonable considerations provided by the public. This is evidenced, as the respondent notes, in FAR Case 2007–006 where an adjustment was made from the total preparation hours from three to 60. This change was made considering particularly the hours that would be required for review within the company, prior to release to the Government.

The burden is prepared taking into consideration the necessary criteria in OMB guidance for estimating the paperwork burden put on the entity submitting the information. For example, consideration is given to an entity reviewing instructions; using technology to collect, process, and

disclose information; adjusting existing practices to comply with requirements; searching data sources; completing and reviewing the response; and transmitting or disclosing information. The estimated burden hours for a collection are based on an average between the hours that a simple disclosure by a very small business might require and the much higher numbers that might be required for a very complex disclosure by a major corporation. Also, the estimated burden hours should only include projected hours for those actions which a company would not undertake in the normal course of business.

Careful consideration went into assessing the burden for this collection. There is no centralized database for the collection of the information associated with this requirement. The solicitation provision of this information collection is not required to be inserted in contracts for the General Services Administration multiple award schedule contract program where numerous agencies place orders for supplies. In addition, a contracting officer can determine not to include the provision in a solicitation for supplies under certain circumstances. Further, the FAR requirements to conduct market research significantly reduced the applicability of the provision because Government quantities are more in line with industry practices. However, based on the information submitted by the respondent an adjustment is made to the estimated burden. At any point, members of the public may submit comments for further consideration, and are encouraged to provide data to support their request for an adjustment.

C. Annual Reporting Burden

Respondents: 3,000.

Responses Per Respondent: 25.

Annual Responses: 75,000.

Hours per Response: 1.

Total Burden Hours: 75,000.

Obtaining Copies of Proposals: Requesters may obtain a copy of the information collection documents from the General Services Administration, Regulatory Secretariat (MVCB), 1275 First Street NE., Washington, DC 20417, telephone (202) 501–4755. Please cite OMB Control No. 9000–0082, Economic Purchase Quantity—Supplies, in all correspondence.

Dated: January 18, 2013.

William Clark,

Acting Director, Federal Acquisition Policy Division, Office of Governmentwide Acquisition Policy, Office of Acquisition Policy, Office of Governmentwide Policy.

[FR Doc. 2013–01451 Filed 1–24–13; 8:45 am]

BILLING CODE 6820–EP–P

DEPARTMENT OF DEFENSE

GENERAL SERVICES ADMINISTRATION

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[Docket 2012–0076; Sequence 43; OMB Control No. 9000–0073]

Federal Acquisition Regulation; Submission of OMB Review; Advance Payments

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

ACTION: Notice of request for public comments regarding an extension to an existing OMB clearance.

SUMMARY: Under the provisions of the Paperwork Reduction Act, the Regulatory Secretariat will be submitting to the Office of Management and Budget (OMB) a request to review and approve an extension of a previously approved information collection requirement concerning advance payments. A notice was published in the **Federal Register** at 77 FR 43083, on July 23, 2012. One comment was received.

Public comments are particularly invited on: Whether this collection of information is necessary for the proper performance of functions of the Federal Acquisition Regulations (FAR), and whether it will have practical utility; whether our estimate of the public burden of this collection of information is accurate, and based on valid assumptions and methodology; ways to enhance the quality, utility, and clarity of the information to be collected; and ways in which we can minimize the burden of the collection of information on those who are to respond, through the use of appropriate technological collection techniques or other forms of information technology.

DATES: Submit comments on or before February 25, 2013.

ADDRESSES: Submit comments identified by Information Collection 9000–0073 Advance Payments by any of the following methods:

- *Regulations.gov: http://www.regulations.gov.*

Submit comments via the Federal eRulemaking portal by searching the OMB control number. Select the link ''Submit a Comment'' that corresponds with ''Information Collection 9000–0073, Advance Payments''. Follow the instructions provided at the ''Submit a Comment'' screen. Please include your name, company name (if any), and ''Information Collection 9000–0073, Advance Payments'' on your attached document.

- *Fax:* 202–501–4067.
- *Mail:* General Services Administration, Regulatory Secretariat (MVCB), 1275 First Street NE., Washington, DC 20417. ATTN: Hada Flowers/IC 9000–0073, Advance Payments.

Instructions: Please submit comments only and cite Information Collection 9000–0073, Advance Payments, in all correspondence related to this collection. All comments received will be posted without change to *http://www.regulations.gov,* including any personal and/or business confidential information provided.

FOR FURTHER INFORMATION CONTACT: Mr. Edward Chambers, Procurement Analyst, Office of Governmentwide Acquisition Policy, GSA (202) 501–3221 or email *edward.chambers@gsa.gov.*

SUPPLEMENTARY INFORMATION:

A. Purpose

Advance payments may be authorized under Federal contracts and subcontracts. Advance payments are the least preferred method of contract financing and require special determinations by the agency head or designee. Specific financial information about the contractor is required before determinations by the agency head or designee. Specific financial information about the contractor is required before such payments can be authorized (see FAR 32.4 and 52.232–12). The information is used to determine if advance payments should be provided to the contractor.

B. Analysis of Public Comments

One respondent submitted public comments on the extension of the previously approved information collection. The analysis of the public comments is summarized as follows:

Comment: The respondent commented that the extension of the information collection would violate the fundamental purposes of the Paperwork Reduction Act because of the burden it puts on the entity submitting the information and the agency collecting the information.

Response: In accordance with the Paperwork Reduction Act (PRA), agencies can request OMB approval of an existing information collection. The PRA requires that agencies use the **Federal Register** notice and comment process, to extend OMB's approval, at least every three years. This extension, to a previously approved information collection, pertains to documentation necessary to support requests for advance payments. Specific financial information about the contractor is required before such payments can be authorized (see FAR 32.4 and 52.232–12). The information serves as the basis for advance payments. Absent this information the suitability of the contractor to receive advance payments could not be ascertained, and would prevent the Government from making such payments.

Comment: The respondent commented that the agency did not accurately estimate the public burden challenging that the agency's methodology for calculating it is insufficient and inadequate and does not reflect the total burden. For this reason, the respondent provided that the agency should reassess the estimated total burden hours and revise the estimate upwards to be more accurate, as was done in FAR Case 2007–006. The same respondent also provided that the burden of compliance with the information collection requirement greatly exceeds the agency's estimate and outweighs any potential utility of the extension.

Response: Serious consideration is given, during the open comment period, to all comments received and adjustments are made to the paperwork burden estimate based on reasonable considerations provided by the public. This is evidenced, as the respondent notes, in FAR Case 2007–006 where an adjustment was made from the total preparation hours from three to 60. This change was made considering particularly the hours that would be required for review within the company, prior to release to the Government.

The burden is prepared taking into consideration the necessary criteria in OMB guidance for estimating the paperwork burden put on the entity submitting the information. For example, consideration is given to an entity reviewing instructions; using technology to collect, process, and disclose information; adjusting existing practices to comply with requirements; searching data sources; completing and reviewing the response; and transmitting or disclosing information. The estimated burden hours for a collection are based on an average between the hours that a simple disclosure by a very small business might require and the much higher numbers that might be required for a very complex disclosure by a major corporation. Also, the estimated burden hours should only include projected hours for those actions which a company would not undertake in the normal course of business. Careful consideration went into assessing the estimated burden hours for this collection, and it is determined that an upward adjustment is not required at this time. However, at any point, members of the public may submit comments for further consideration, and are encouraged to provide data to support their request for an adjustment.

C. Annual Reporting Burden

Respondents: 500.
Responses per Respondent: 1.
Annual Responses: 500.
Hours per Response: 1.
Total Burden Hours: 500.

Obtaining Copies of Proposals: Requesters may obtain a copy of the information collection documents from the General Services Administration, Regulatory Secretariat (MVCB), 1275 First Street NE., Washington, DC 20417, telephone (202) 501–4755. Please cite OMB Control No. 9000–0073, Advance Payments, in all correspondence.

Dated: January 17, 2013.

William Clark,

Acting Director, Federal Acquisition Policy Division, Office of Governmentwide Acquisition Policy, Office of Acquisition Policy, Office of Governmentwide Policy.

[FR Doc. 2013–01465 Filed 1–24–13; 8:45 am]

BILLING CODE 6820–EP–P

DEPARTMENT OF DEFENSE

GENERAL SERVICES ADMINISTRATION

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[Docket 2012–0076; Sequence 49; OMB Control No. 9000–0102]

Information Collection; Prompt Payment

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

ACTION: Notice of request for public comments regarding an extension to an existing OMB clearance.

SUMMARY: Under the provisions of the Paperwork Reduction Act, the Regulatory Secretariat will be submitting to the Office of Management and Budget (OMB) a request to review and approve an extension to a previously approved information collection requirement concerning prompt payment.

DATES: Submit comments on or before March 26, 2013.

ADDRESSES: Submit comments identified by Information Collection 9000–0102, Prompt Payment, by any of the following methods:

- *Regulations.gov: http://www.regulations.gov.* Submit comments via the Federal eRulemaking portal by searching the OMB control number. Select the link ''Submit a Comment'' that corresponds with ''Information Collection 9000–0102, Prompt Payment''. Follow the instructions provided at the ''Submit a Comment'' screen. Please include your name, company name (if any), and ''Information Collection 9000–0102, Prompt Payment'' on your attached document.
- *Fax:* 202–501–4067.
- *Mail:* General Services Administration, Regulatory Secretariat (MVCB), 1275 First Street NE., Washington, DC 20417. ATTN: Hada Flowers/IC 9000–0102, Prompt Payment.

Instructions: Please submit comments only and cite Information Collection 9000–0102, Prompt Payment, in all correspondence related to this collection. All comments received will be posted without change to *http://www.regulations.gov,* including any personal and/or business confidential information provided.

FOR FURTHER INFORMATION CONTACT: Mr. Edward Chambers, Procurement Analyst, Office of Acquisition Policy, GSA, (202) 501–3221 or email *Edward.chambers@gsa.gov.*

SUPPLEMENTARY INFORMATION:

A. Purpose

Part 32 of the FAR and the clause at FAR 52.232–5, Payments Under Fixed-Price Construction Contracts, require that contractors under fixed-price construction contracts certify, for every progress payment request, that payments to subcontractors/suppliers have been made from previous payments received under the contract and timely payments will be made from the proceeds of the payment covered by the certification, and that this payment request does not include any amount which the contractor intends to withhold from a subcontractor/supplier. Part 32 of the FAR and the clause at 52.232–27, Prompt Payment for Construction Contracts, further require

that contractors on construction contracts—

(a) Notify subcontractors/suppliers of any amounts to be withheld and furnish a copy of the notification to the contracting officer;

(b) Pay interest to subcontractors/suppliers if payment is not made by 7 days after receipt of payment from the Government, or within 7 days after correction of previously identified deficiencies;

(c) Pay interest to the Government if amounts are withheld from subcontractors/suppliers after the Government has paid the contractor the amounts subsequently withheld, or if the Government has inadvertently paid the contractor for nonconforming performance; and

(d) Include a payment clause in each subcontract which obligates the contractor to pay the subcontractor for satisfactory performance under its subcontract not later than 7 days after such amounts are paid to the contractor, include an interest penalty clause which obligates the contractor to pay the subcontractor an interest penalty if payments are not made in a timely manner, and include a clause requiring each subcontractor to include these clauses in each of its subcontractors and to require each of its subcontractors to include similar clauses in their subcontracts.

These requirements are imposed by Public Law 100–496, the Prompt Payment Act Amendments of 1988.

Contracting officers will be notified if the contractor withholds amounts from subcontractors/suppliers after the Government has already paid the contractor the amounts withheld. The contracting officer must then charge the contractor interest on the amounts withheld from subcontractors/suppliers. Federal agencies could not comply with the requirements of the law if this information were not collected.

B. Annual Reporting and Recordkeeping Burden

Data from the Federal Procurement Data System (FPDS) regarding fixed price construction contracts for Fiscal Year (FY) 2011 revealed that the number of affected contracts and, therefore, respondents has been reduced from the previously approved information collection. Time required to assemble and prepare notification or certification regarding withhold is estimated at .11 hours per notice. This estimate is based on the assumption that some construction contractors will be required to notify the Government of withholding and others will have to provide their payment certification, and that 2,679 contractors under a total of 4,450 contracts will have to notify the Government 11 times per year. This estimate assumes automation of contractor records. The recordkeeping burden is based on the revised number of contracts for FY11 and the estimated hours from the previously approved collection.

Annual Reporting Burden

Respondents: 2,679.
Responses per Respondent: 18.27.
Total Responses: 48,950.
Hours per Response: .11.
Total Burden Hours: 5,384.

Annual Recordkeeping Burden

Recordkeepers: 4,450.
Hours per Recordkeeper: 18.
Total Recordkeeping Burden Hours: 80,100.

Obtaining Copies of Proposals: Requesters may obtain a copy of the information collection documents from the General Services Administration, Regulatory Secretariat (MVCB), 1275 First Street NE., Washington, DC 20417, telephone (202) 501–4755. Please cite OMB Control No. 9000–0102, Prompt Payment, in all correspondence.

Dated: January 18, 2013.

William Clark,

Acting Director, Federal Acquisition Policy Division, Office of Governmentwide Acquisition Policy, Office of Governmentwide Policy.

[FR Doc. 2013–01565 Filed 1–24–13; 8:45 am]

BILLING CODE 6820–EP–P

DEPARTMENT OF DEFENSE

GENERAL SERVICES ADMINISTRATION

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[Docket 2012–0076; Sequence 39; OMB Control No. 9000–0053]

Federal Acquisition Regulation; Submission for OMB Review; Permits, Authorities, or Franchises

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

ACTION: Notice of request for public comments regarding an extension of a previously existing OMB clearance.

SUMMARY: Under the provisions of the Paperwork Reduction Act, the Regulatory Secretariat will be submitting to the Office of Management and Budget (OMB) a request to review and approve an extension of a previously approved information collection requirement concerning permits, authorities, or franchises for regulated transportation. A notice was published in the **Federal Register** at 77 FR 55475, on September 10, 2012. One respondent submitted comments.

Public comments are particularly invited on: Whether this collection of information is necessary for the proper performance of functions of the Federal Acquisition Regulations (FAR), and whether it will have practical utility; whether our estimate of the public burden of this collection of information is accurate, and based on valid assumptions and methodology; ways to enhance the quality, utility, and clarity of the information to be collected; and ways in which we can minimize the burden of the collection of information on those who are to respond, through the use of appropriate technological collection techniques or other forms of information technology.

DATES: Submit comments on or before February 25, 2013.

ADDRESSES: Submit comments identified by Information Collection 9000–0053, Permits, Authorities, or Franchises, by any of the following methods:

- *Regulations.gov: http://www.regulations.gov.* Submit comments via the Federal eRulemaking portal by searching the OMB control number. Select the link ''Submit a Comment'' that corresponds with ''Information Collection 9000–0053, Permits, Authorities, or Franchises''. Follow the instructions provided at the ''Submit a Comment'' screen. Please include your name, company name (if any), and ''Information Collection 9000–0053, Permits, Authorities, or Franchises'' on your attached document.
- *Fax:* 202–501–4067.
- *Mail:* General Services Administration, Regulatory Secretariat (MVCB), 1275 First Street NE., Washington, DC 20417. ATTN: Hada Flowers/IC 9000–0053, Permits, Authorities, or Franchises.

Instructions: Please submit comments only and cite Information Collection 9000–0053, Permits, Authorities, or Franchises, in all correspondence related to this collection. All comments received will be posted without change to *http://www.regulations.gov,* including any personal and/or business confidential information provided.

FOR FURTHER INFORMATION CONTACT: Mr. Michael O. Jackson, Procurement Analyst, Office of Governmentwide Acquisition Policy, GSA (202) 208–4949 or email *michaelo.jackson@gsa.gov.*

SUPPLEMENTARY INFORMATION:

I. Purpose

The FAR requires insertion of clause 52.247–2, Permits, Authorities, or Franchises, when regulated transportation is involved. The clause requires the contractor to indicate whether it has the proper authorization from the Federal Highway Administration (or other cognizant regulatory body) to move material. The contractor may be required to provide copies of the authorization before moving material under the contract. The clause also requires the contractor, at its expense, to obtain and maintain any permits, franchises, licenses, and other authorities issued by State and local governments. The Government may request to review the documents to ensure that the contractor has complied with all regulatory requirements.

II. Discussion and Analysis

One respondent submitted a comment related to the submission of medical errors. The comment is not within the scope of this information collection requirement.

III. Annual Reporting Burden

The estimated annual reporting burden has decreased from what was published in the **Federal Register** at 74 FR 56640, on November 2, 2009. The decrease is based on a revised estimate of the number of respondents, responses per year and response time per response. According to Fiscal Year 2011 Federal Procurement Data System (FPDS) data, 3,877 contracts were awarded to 1021 unique vendors under the North American Industry Classification System (NAICS) code 484 for trucking, where the requirements for this collection would apply. It is estimated that a maximum of 25%, or 255 of these vendors would be required to provide the information required by the clause. The information need only be gathered and submitted on an exception basis. We estimate that any respondent will be required to submit supporting information only one time annually. In addition, we think that it will take the contractor only one half hour to pull existing franchises or permits from the files.

Respondents: 255.

Responses per Respondent: 1.

Annual Responses: 255.

Hours per Response: 0.5.

Total Burden Hours: 128.

Obtaining Copies of Proposals: Requesters may obtain a copy of the information collection documents from the General Services Administration, Regulatory Secretariat (MVCB), 1275 First Street NE., Washington, DC 20417, telephone (202) 501–4755. Please cite OMB Control No. 9000–0053, Permits, Authorities, or Franchises, in all correspondence.

Dated: January 17, 2013.

William Clark,

Acting Director, Federal Acquisition Policy Division, Office of Governmentwide Acquisition Policy, Office of Acquisition Policy, Office of Governmentwide Policy.

[FR Doc. 2013–01475 Filed 1–24–13; 8:45 am]

BILLING CODE 6820–EP–P

DEPARTMENT OF DEFENSE

GENERAL SERVICES ADMINISTRATION

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[Docket 2012–0076; Sequence 46; OMB Control No. 9000–0083]

Federal Acquisition Regulation; Submission for OMB Review; Qualification Requirements

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

ACTION: Notice of reinstatement request for an information collection requirement regarding an existing OMB clearance.

SUMMARY: Under the provisions of the Paperwork Reduction Act, the Regulatory Secretariat will be submitting to the Office of Management and Budget (OMB) a request to review and approve an extension of a previously approved information collection requirement concerning Qualification Requirements. A notice was published in the **Federal Register** at 77 FR 51784, on August 27, 2012. One respondent submitted comments.

DATES: Submit comments on or before February 25, 2013.

ADDRESSES: Submit comments identified by Information Collection 9000–0083, Qualification Requirements, by any of the following methods:

- *Regulations.gov: http://www.regulations.gov.* Submit comments via the Federal eRulemaking portal by searching the OMB control number. Select the link ''Submit a Comment'' that corresponds with ''Information Collection 9000–0083, Qualification Requirements''. Follow the instructions provided at the ''Submit a Comment'' screen. Please include your name, company name (if any), and ''Information Collection 9000–0083, Qualification Requirements'' on your attached document.
- *Fax:* 202–501–4067.
- *Mail:* General Services Administration, Regulatory Secretariat (MVCB), 1275 First Street NE., Washington, DC 20417. ATTN: Hada Flowers/IC 9000–0083, Qualification Requirements.

Instructions: Please submit comments only and cite Information Collection 9000–0083, Qualification Requirements, in all correspondence related to this collection. All comments received will be posted without change to *http://www.regulations.gov,* including any personal and/or business confidential information provided.

FOR FURTHER INFORMATION CONTACT: Ms. Patricia Corrigan, Procurement Analyst, Office of Governmentwide Acquisition Policy, GSA, (202) 208–1963 or *patricia.corrigan@gsa.gov.*

SUPPLEMENTARY INFORMATION:

A. Purpose

FAR subpart 9.2 and the associated clause at FAR 52.209–1, implement the statutory requirements of 10 U.S.C. 2319 and 41 U.S.C. 3311, which allow an agency to establish a qualification requirement for testing or other quality assurance demonstration that must be completed by an offeror before award of a contract. Under the qualification requirements, an end item, or a component thereof, may be required to be prequalified. The clause at FAR 52.209–1, Qualification Requirements, requires offerors who have met the qualification requirements to identify the offeror's name, the manufacturer's name, source's name, the item name, service identification, and test number (to the extent known). This eliminates the need for an offeror to provide new information when the offeror, manufacturer, source, product or service covered by qualification requirement has already met the standards specified by an agency in a solicitation.

The contracting officer uses the information to determine eligibility for award when the clause at 52.209–1 is included in the solicitation. Alternatively, items not yet listed may be considered for award upon the submission of evidence of qualification with the offer.

B. Analysis of Public Comments

One respondent submitted public comments on the extension of the previously approved information collection. The analysis of the public comments is summarized as follows:

Comment: The respondent commented that the extension of the information collection would violate the fundamental purposes of the Paperwork

Reduction Act because of the burden it puts on the entity submitting the information and the agency collecting the information.

Response: In accordance with the Paperwork Reduction Act (PRA), agencies can request an OMB approval of an existing information collection. The PRA requires that agencies use the **Federal Register** notice and comment process, to extend the OMB's approval, at least every three years. This extension, to a previously approved information collection, pertains to FAR subpart 9.2 and the associated clause at FAR 52.209–1. This information collection, which implements the statutory requirements of 10 U.S.C. 2319 and 41 U.S.C. 3311, which allows an agency to establish a qualification requirement for testing or other quality assurance demonstration that must be completed by an offeror before award of a contract. Under the qualification requirements, an end item, or a component thereof, may be required to be prequalified. The clause at FAR 52.209–1, Qualification Requirements, requires offerors who have met the qualification requirements to identify the offeror's name, the manufacturer's name, source's name, the item name, service identification, and test number (to the extent known). This eliminates the need for an offeror to provide new information when the offeror, manufacturer, source, product or service covered by qualification requirement has already met the standards specified by an agency in a solicitation. The contracting officer uses the information to determine eligibility for award when the clause at 52.209–1 is included in the solicitation.

Comment: The respondent commented that the agency did not accurately estimate the public burden challenging that the agency's methodology for calculating it is insufficient and inadequate and does not reflect the total burden. The respondent stated that ''the Agencies estimate that only 2,207 respondents will be subject to this requirement annually * * * we respectfully submit that this is greatly understated.'' The respondent also took issue with the ''number of responses annually per respondent. The Agencies have reduced the prior estimate by 95% without any explanation. The current estimate of five responses per year is entirely unrealistic.'' Further, the respondent found the estimate of 15 minutes per response to be ''unrealistic'' indicating that ''a reasonable estimate would be in the range of at least two to three hours per response''. For this reason, the respondent provided that the agency should reassess the estimated total burden hours and revise the estimate upwards to be more accurate. The same respondent provided that the burden of compliance with the information collection requirement greatly exceeds the agency's estimate and outweighs any potential utility of the extension.

Response: Serious consideration is given, during the open comment period, to all comments received and adjustments are made to the paperwork burden estimate based on reasonable considerations provided by the public. This is evidenced, as the respondent notes, in FAR Case 2007–006 where an adjustment was made from the total preparation hours from three to 60. This change was made considering particularly the hours that would be required for review within the company, prior to release to the Government.

The burden is prepared taking into consideration the necessary criteria in OMB guidance for estimating the paperwork burden put on the entity submitting the information. For example, consideration is given to an entity reviewing instructions; using technology to collect, process, and disclose information; adjusting existing practices to comply with requirements; searching data sources; completing and reviewing the response; and transmitting or disclosing information. The estimated burden hours for a collection are based on an average between the hours that a simple disclosure by a very small business might require and the much higher numbers that might be required for a very complex disclosure by a major corporation. Also, the estimated burden hours should only include projected hours for those actions which a company would not undertake in the normal course of business.

Following careful consideration of both the estimated number of respondents and the time needed to respond to the information required by the clause at FAR 52.209–1, it is determined that an upward adjustment is required.

In response to the respondent's concern that ''the Agencies' estimate that only 2,207 respondents will be subject to this requirement annually'' was ''greatly understated'', it should be noted that the clause at FAR 52.209–1, Qualification Requirements, is used in relatively limited circumstances. The clause is prescribed for solicitations and contracts only when the acquisition is subject to a qualification requirement, which should be rare because of the statutory requirement favoring the acquisition of commercial items. Further, offerors are only required to provide information in paragraph (c) of the clause in cases where the offeror, manufacturer, source, product or service covered by a qualification requirement has already met the standards specified in the solicitation. Given these limiting circumstances and absent receipt of additional data to support the respondent's comments, the estimated number of respondents is revised from the previous 2,207 to 5 percent or 9,693 of the 193,859 unique vendors awarded contracts during Fiscal Year 2011. It is estimated that 5 percent of the 193,859 vendors would have received awards for solicitations in which the clause at FAR 52.209–1 was used and contained one or more qualification requirements.

The respondent also commented on the estimated number of responses annually, stating that ''the Agencies have reduced the prior estimate by 95% without any explanation. The current estimate of five responses per year is entirely unrealistic.'' The estimated number of responses annually contained in the currently approved information collection is changed from 100, which was based on an estimated number of qualification requirements contained in each solicitation, to an estimated average of 5 responses per respondent. The estimated number of responses refers to the average number of offers received annually per respondent for the type of information associated with this collection, despite the number of qualification requirements contained in a solicitation.

Lastly, based on the previous explanation of the limited circumstances of which this collection applies and the respondent's comments, the estimated responses time is revised from 15 minutes to one hour. The estimate is an average time for an offeror to complete six brief responses of what should be readily available qualification documentation regarding one to four qualified products per solicitation.

C. Annual Reporting Burden

There is no Governmentwide data collection process or system, e.g., Federal Procurement Data System (FPDS) which respondents has been raised from 2,207 to 9,693 reflecting an estimate of 5 percent of the 193,859 new contracts awarded in Fiscal Year 2011. Lastly, the estimated Hours per Response is raised from 15 minutes to one hour to accommodate an information collection on multiple qualified products in each solicitation.

Respondents: 9,693.
Responses per Respondent: 5.
Annual Responses: 48,465.
Hours per Response: 1.0.
Total Burden Hours: 48,465.

Obtaining Copies of Proposals: Requesters may obtain a copy of the information collection documents from the General Services Administration, Regulatory Secretariat (MVCB), 1275 First Street NE., Washington, DC 20417, telephone (202) 501–4755. Please cite OMB Control No. 9000–0083, Qualification Requirements, in all correspondences.

Dated: January 18, 2013.

William Clark,

Acting Director, Federal Acquisition Policy Division, Office of Governmentwide Acquisition Policy, Office of Acquisition Policy, Office of Governmentwide Policy.

[FR Doc. 2013–01557 Filed 1–24–13; 8:45 am]

BILLING CODE 6820–EP–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Findings of Research Misconduct

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: Notice is hereby given that the Office of Research Integrity (ORI) has taken final action in the following case:

Rao M. Adibhatla, Ph.D., University of Wisconsin: Based on the report of an investigation conducted by the University of Wisconsin (UW) and additional analysis conducted by ORI in its oversight review, ORI found that Dr. Rao M. Adibhatla, Assistant Professor, Department of Neurological Surgery, UW, engaged in research misconduct by falsifying results in two publications supported by National Institute of Neurological Diseases and Stroke (NINDS), National Institutes of Health (NIH), grant R01 NS042008 and in three unfunded applications that Dr. Adibhatla submitted to NINDS, NIH, as R01 NS042008–05, –05A1, and –05A2. The questioned papers are:

1. Adibhatla, R.M., Hatcher, J.F., Larsen E.C. *et al.* ''CDP-choline Significantly Restores Phoshatidylcholine Levels by Differentially Affecting Phospholipase A_2 and CTP:Phosphocholine Cytidylyltransferase after Stroke.'' *J. Biol. Chem.* 281:6718–6725, 2006 (hereafter referred to as the ''*JBC* paper''), as the $sPLA_2$-IIA, CCTα, and PLD2 data in Figures 1B, 2A, and 3A, respectively
2. Adibhatla, R.M., & Hatcher, J.F. ''Secretory phospholipase A2 IIA is Up-regulated by TNF-α and IL-1α/β after Transient Focal Cerebral Ischemia in Rat.'' *Brain Research* 1134:199–205, 2007 (hereafter referred to as the ''*Brain Research* paper''), as the $sPLA_2$-IIA data in Figures 2A and 2C.

ORI found that Respondent committed research misconduct by falsifying Western blot images as well as quantitative and statistical data obtained from purported scans of the films. The research studied the effect of cerebral ischemia on phospholipid homeostasis in an experimental animal model (SHR rat) of stroke during the course of reperfusion of the ischemic cortex. The falsified Western blot images and derivative quantitative data describe changes in levels of $sPLA_2$-IIAA, CCTα, and of PLD2 during reperfusion in the ischemic cortex.

Specifically, the Respondent:

- Falsified the Western blot data demonstrating $sPLA_2$ expression in a time course after ischemia in Figure 1B of the *JBC* paper and Figure 2A and 2C of the *Brain Research* paper by rearranging the bands such that the labels do not accurately portray what is in the lanes. He perpetuated the falsification by presenting the quantification of the single falsified Western blot in a bar graph as the average of five (5) replicate Western blots. The result in the paper cannot be substantiated by the actual experiments.
- Falsified the Western blot data demonstrating CCTα expression in a time course assay after ischemia in Figure 2A of the *JBC* paper by rearranging the bands such that the labels do not accurately portray what is in the lanes. He perpetuated the falsification by presenting the quantification of the single falsified Western blot in a bar graph as the average of four (4) replicate Western blots and the six (6) hour time point was further falsified to make the results look better. The result in the paper cannot be substantiated by the actual experiments.
- Falsified the quantification of a Western blot demonstrating PLD2 expression in a time course after ischemia in Figure 3A of the *JBC* paper by claiming a bar graph quantifying a single Western blot is the average of four Western blots.
- Submitted the same falsified Western blot images and bar graph data in three unfunded grant applications: NS042008–05, NS042008–05A1, and NS042008–05A2. Specifically:

< the falsified $sPLA_2$-IIA data were submitted as Figures 3, 8, and 12 in the respective NS042008–05, –05A1, and –05A2 applications

< the falsified CCTα data appeared as Figures 10, 15, and 16 in the respective –05, –05A1, and –05A2 applications

< The falsified PLD2 bar graph data and associated statistical claims appeared as Figures 8 and 13 in the –05 and –05A1 applications respectively.

Dr. Adibhatla has entered into a Voluntary Exclusion Agreement and has voluntarily agreed:

(1) To exclude himself voluntarily for a period of two (2) years from the effective date of the Agreement from any contracting or subcontracting with any agency of the United States Government and from eligibility or involvement in nonprocurement programs of the United States pursuant to HHS' Implementation (2 CFR part 376 *et seq.*) of OMB Guidelines to Agencies on Governmentwide Debarment and Suspension, 2 CFR Part 180 (collectively the ''Debarment Regulations'');

(2) To exclude himself voluntarily from serving in any advisory capacity to PHS including, but not limited to, service on any PHS advisory committee, board, and/or peer review committee, or as a consultant for a period of three (3) years beginning on December 18, 2012; and

(3) To request retraction of the following papers:

- *J. Biol. Chem.* 281:6718–6725, 2006
- *Brain Research* 1134:199–205, 2007.

FOR FURTHER INFORMATION CONTACT: Director, Office of Research Integrity, 1101 Wootton Parkway, Suite 750, Rockville, MD 20852, (240) 453–8200.

David E. Wright,

Director, Office of Research Integrity.

[FR Doc. 2013–01454 Filed 1–24–13; 8:45 am]

BILLING CODE 4150–31–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Solicitation of Nominations for Organizations To Serve as Non-Voting Liaison Representatives to the Chronic Fatigue Syndrome Advisory Committee (CFSAC)

AGENCY: Office of the Assistant Secretary for Health, Office of the Secretary, Department of Health and Human Services.

ACTION: Notice.

Authority: 42 U.S.C. 217a, section 222 of the Public Health Service (PHS) Act, as amended. The committee is governed by the provisions of the Federal Advisory Committee Act, as amended (5 U.S.C. App 2), which sets forth standards for the formation and use of advisory committees.

SUMMARY: The Office of the Assistant Secretary for Health (OASH), within the Department of Health and Human Services (HHS), is soliciting nominations from qualified organizations to be considered for non-voting liaison representative positions

on the Chronic Fatigue Syndrome Advisory Committee (CFSAC). CFSAC provides advice and recommendations to the Secretary of HHS, through the Assistant Secretary for Health (ASH), on a broad range of issues and topics related to myalgic encephalomyelitis/chronic fatigue syndrome (ME/CFS). The issues can include factors affecting access and care for persons with ME/CFS; the science and definition of ME/CFS; and public health, clinical, research, and educational issues related to ME/CFS. These three non-voting liaison representative positions will be occupied by individuals who are selected by their organizations to serve as representatives of organizations concerned with ME/CFS. Organizations will be designated to occupy the positions for a two-year term to commence during the 2013 calendar year. Nominations of qualified organizations are being sought for these three non-voting liaison representative positions. The organizations chosen for representation on CFSAC will be selected by the Designated Federal Officer (DFO) or designee during the 2013 calendar year. Details of nomination requirements are provided below.

DATES: Nominations must be received no later than 5 p.m. EDT on February 22, 2013, at the address listed below.

ADDRESSES: All nominations should be mailed or delivered to Nancy C. Lee, M.D., Designated Federal Officer, Chronic Fatigue Syndrome Advisory Committee, Office on Women's Health, Department of Health and Human Services, 200 Independence Ave. SW., Room 712E, Washington, DC 20201. Nomination materials, including attachments, may be submitted electronically to *cfsac@hhs.gov.*

FOR FURTHER INFORMATION CONTACT: Nancy C. Lee, M.D., Designated Federal Officer, Chronic Fatigue Syndrome Advisory Committee, Office on Women's Health, Department of Health and Human Services, 200 Independence Ave. SW., Room 712E, Washington, DC 20201. Inquiries can be sent to *cfsac@hhs.gov.*

SUPPLEMENTARY INFORMATION: CFSAC was established on September 5, 2002. The purpose of the CFSAC is to provide advice and recommendations to the Secretary of HHS, through the ASH, on issues related to ME/CFS. CFSAC advises and makes recommendations on a broad range of topics including: (1) The current state of knowledge and research; the relevant gaps in knowledge and research about the epidemiology, etiologies, biomarkers and risk factors relating to ME/CFS; and potential opportunities in these areas; (2) impact and implications of current and proposed diagnostic and treatment methods for ME/CFS; (3) development and implementation of programs to inform the public, health care professionals, and the biomedical research communities about ME/CFS advances; and (4) strategies to improve the quality of life of ME/CFS patients. Management and support services for Committee activities are provided by staff from the HHS Office on Women's Health, within the OASH. The CFSAC charter is available at *http://www.hhs.gov/advcomcfs/charter/index.html.*

CFSAC meetings are held not less than two times per year. The CFSAC membership consists of 11 voting members, including the Chair. The voting members are composed of seven biomedical research scientists, and four individuals with expertise in health insurance, health care delivery, private health care services, or representatives of voluntary organizations concerned with the problems of individuals with ME/CFS. CFSAC also includes seven non-voting *ex officio* member representatives from the Agency for Healthcare Research and Quality, Centers for Disease Control and Prevention, Centers for Medicare and Medicaid Services, Food and Drug Administration, Health Resources and Services Administration, National Institutes of Health, and Social Security Administration.

The CFSAC structure has been expanded to include three non-voting liaison representative positions. Authorization was given for the Committee structure to include the three non-voting liaison representative positions when the charter was renewed on September 5, 2012. These positions will be occupied by individuals who are selected by their organizations to serve as the official representative for organizations that are concerned with ME/CFS. Organizations will occupy these representative positions for a two-year term.

Nominations

The OASH is requesting nominations of organizations to fill three non-voting liaison representative positions for the CFSAC. The represented organizations will be selected by the DFO or designee during the 2013 calendar year.

Selection of organizations that will serve as non-voting liaison representatives will be based on the organization's qualifications to contribute to the accomplishment of the CFSAC mission, as described in the Committee charter. In selecting organizations to be considered for these positions, the OASH will give close attention to equitable geographic distribution and give priority to U.S.-chartered 501(c)(3) organizations that operate within the United States and have membership with demonstrated expertise in ME/CFS and related research, clinical services, or advocacy and outreach on issues concerning ME/CFS.

The individual designated to serve as the official non-voting liaison representative will perform the associated duties without compensation, and will not receive per diem or reimbursement for travel expenses. The organizations that are selected to be represented will cover expenses for the designated representative to attend, at a minimum, one in-person CFSAC meeting per year during the designated term of appointment.

To qualify for consideration of selection to the Committee, an organization should submit the following items:

(1) A statement of the organization's history, mission, and focus, including information that demonstrates the organization's experience and expertise in ME/CFS and related research, clinical services, or advocacy and outreach on issues of ME/CFS, as well as expert knowledge of the broad issues and topics pertinent to ME/CFS. This information should demonstrate the organization's proven ability to work and communicate with the ME/CFS patient and advocacy community, and other public/private organizations concerned with ME/CFS, including public health agencies at the federal, state, and local levels.

(2) One to three letters of recommendation that clearly state why the organization is qualified to serve on CFSAC in a representative position. These letters should be from individuals who are not part of the organization's leadership.

(3) A statement that the organization is willing to serve as a non-voting liaison representative of the Committee and will cover expenses for an individual representative to attend in-person, at a minimum, one CFSAC meeting per year in Washington, DC during the designated term of appointment.

(4) A current financial disclosure statement (or annual report) demonstrating the organization's ability to cover expenses for an individual to attend, at a minimum, one CFSAC meeting per year in Washington, DC, during the term of appointment.

Submitted nominations must include these critical elements in order for the organization to be considered for one of the non-voting liaison representative positions.

Nomination materials should be typewritten, 12-point type and double-spaced. All nomination materials should be submitted (postmarked or received) by February 22, 2013.

Electronic submissions: Nomination materials, including attachments, may be submitted electronically to *cfsac@hhs.gov.*

Telephone and facsimile submissions cannot be accepted.

Regular, Express, or Overnight Mail: Written documents may be submitted to the following addressee only: Nancy C. Lee, Designated Federal Officer, CFSAC, Office on Women's Health, Department of Health and Human Services, 200 Independence Ave. SW., Room 712E, Washington, DC 20201.

HHS makes every effort to ensure that the membership of Federal advisory committees is fairly balanced in terms of points of view represented. Every effort is made to ensure that a broad representation of geographic areas, sex, ethnic and minority groups, and people with disabilities are given consideration for membership on Federal advisory committees. Selection of the represented organizations shall be made without discrimination against the composition of an organization's membership on the basis of age, sex, race, ethnicity, sexual orientation, disability, and cultural, religious, or socioeconomic status.

Dated: January 18, 2013.

Nancy C. Lee,

Designated Federal Officer, Chronic Fatigue Syndrome Advisory Committee.

[FR Doc. 2013–01456 Filed 1–24–13; 8:45 am]

BILLING CODE 4150–42–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day-13–0841]

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) 639–7570 or send an email 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

Management Information System for Comprehensive Cancer Control Programs—Revision (OMB No. 0920–0841, exp. 1/31/2013)—National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Through the National Comprehensive Cancer Control Program (NCCCP), CDC currently provides cooperative agreement funding and technical assistance to 65 entities: all 50 states, the District of Columbia, seven tribes/tribal organizations, and seven territories/U.S. Pacific Island jurisdictions. Since January 2010, NCCCP awardees have submitted progress and activity information to CDC twice per year using an electronic information system (''Management Information System for Comprehensive Cancer Control Programs,'' OMB No. 0920–0841, exp. 1/31/2013). The program director for each awardee is responsible for overseeing activities and submitting the required reports to CDC.

New cooperative agreements were awarded to all NCCCP programs in 2012 (''Cancer Prevention and Control Program for State, Territorial and Tribal Organizations,'' Funding Opportunity Announcement (FOA) DP12–1205). The new cooperative agreements place increased emphasis on policy and environmental approaches to cancer prevention and control.

CDC seeks OMB approval to continue using MIS-based reporting for the NCCCP awardees. Minor changes to the existing core cancer prevention and control data elements will be implemented to reflect the FOA's new performance requirements.

Thirteen of the 65 NCCCP awardees received additional funding for related but distinct cooperative agreements (''Demonstrating the Capacity of Comprehensive Cancer Control Programs to Implement Policy and Environmental Cancer Control Interventions,'' FOA DP10–1017). The demonstration program is aimed at accelerating the development of policy and environmental approaches to cancer control for awardees that are poised to move forward rapidly. Demonstration program activities will be aligned with the existing comprehensive cancer control program in a manner that minimizes duplication, capitalizes on existing activities, and fosters rapid implementation. Similar semi-annual progress reports are required to monitor activities conducted under the demonstration program. A state- or territory-based policy task force coordinator will be responsible for submitting the required reports to CDC.

CDC proposes to use the same MIS-based methodology for all reporting. Due to the distinct objectives, resources, and activities associated with each cooperative agreement, separate reports will be required from the program director and the task force coordinator.

CDC's Revision request utilizes a modified method of estimating respondent burden which distinguishes between (i) the initial burden of populating the MIS, and (ii) routine MIS maintenance and report generation. In the initial OMB approval period (2010–2013), respondent burden was based on a long-term average burden per response.

For the 65 state- and territory-based cancer prevention and control programs, CDC estimates the initial burden of populating the MIS at four hours per response. Some of the information entered into the MIS during the previous cooperative agreement period will be downloaded to minimize respondent burden in the new funding period, but awardees will be responsible for verifying this information and entering new objectives. After completing these steps, the estimated burden for ongoing system maintenance and semi-annual reporting is three hours per response.

For the 13 states and territories that are also participating in the demonstration program, the initial burden of populating the MIS is estimated to be six hours per response. Awardees will be responsible for entering information about the new objectives, staff, and other resources for demonstration program activities. Thereafter, the estimated burden for ongoing system maintenance and semi-annual reporting is estimated at three hours per response.

OMB approval is requested for three years. Information will be reported electronically twice per year. CDC will use the reports to identify training and technical assistance needs, monitor compliance with cooperative agreement requirements, evaluate progress made in achieving program-specific goals, and obtain information needed to respond to inquiries. There are no costs to respondents other than their time. The total estimated annualized burden hours are 586.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Burden per response (in hr)
Program Director for State- or Territory-Based Cancer Prevention and Control Program.	Data Elements for All CPC Programs: Initial MIS Population.	22	1	4
	Data Elements for All CPC Programs: Semi-annual Reporting.	65	2	3
State- or Territory-Based Policy Task Force Coordinator.	Data Elements for CPC Demonstration Program: Initial MIS Population.	5	1	6
	Data Elements for CPC Demonstration Program: Semi-annual Reporting.	13	2	3

Dated: January 17, 2013.

Ron A. Otten,

Director, Office of Scientific Integrity (OSI), Office of the Associate Director for Science (OADS), Office of the Director, Centers for Disease Control and Prevention.

[FR Doc. 2013–01448 Filed 1–24–13; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–10401]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Centers for Medicare & Medicaid Services (CMS) is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

1. *Type of Information Collection Request:* Revision of a currently approved collection. *Title of Information Collection:* Standards Related to Reinsurnace, Risk Corridors and Risk Adjustment; *Use:* Section 1341 of the Affordable Care Act provides that each State must establish a transitional reinsurance program to help stabilize premiums for coverage in the individual market during the first three years of Exchange operation. Section 1342 provides for the establishment of a temporary risk corridors program that will apply to qualified health plans in the individual and small group markets for the first three years of Exchange operation. Section 1343 provides for a program of risk adjustment for all non-grandfathered plans in the individual and small group market both inside and outside of the Exchange. These risk-spreading programs, which will be implemented by HHS, states, or both HHS and states, are designed to mitigate adverse selection and provide stability for health insurance issuers in the individual and small group markets as market reforms and Exchanges are implemented. Section 1321(a) also provides broad authority for the Secretary to establish standards and regulations to implement the statutory requirements related to Exchanges, reinsurance, risk adjustment, and other components of title I of the Affordable Care Act. The data collection and reporting requirements described in this information collection request will enable states, HHS, or both states and HHS to implement the aforementioned programs, which will mitigate the impact of adverse selection in the individual and small group markets both inside and outside the Exchange. *Form Number:* CMS–10401 (OCN 0938–1155). *Frequency:* Occasionally; *Affected Public:* Private Sector (business or other for-profit and not-for-profit institutions). *Number of Respondents:* 5,071; *Total Annual Responses:* 9,000,574,542; *Total Annual Hours:* 10,774,789; (For policy questions regarding this collection contact Jaya Ghildiyal at 410–786–6573. For all other issues call 410–786–1326.)

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS' Web Site address at *http://www.cms.hhs.gov/PaperworkReductionActof1995,* or email your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov,* or call the Reports Clearance Office on 410–786–1326.

In commenting on the proposed information collections please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in one of the following ways by March 26, 2013.

1. *Electronically.* You may submit your comments electronically to *http://www.regulations.gov.* Follow the instructions for ''Comment or Submission'' or ''More Search Options'' to find the information collection document(s) accepting comments.

2. *By regular mail.* You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: Document Identifier/OMB Control Number _____, Room C4–26–05, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

Dated: January 22, 2013.

Martique Jones,

Deputy Director, Regulations Development Group, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2013–01570 Filed 1–24–13; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–4172–NC]

Medicare Program; Request for Information To Aid in the Design and Development of a Survey Regarding Patient and Family Member/Friend Experiences With Hospice Care

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

ACTION: Request for information.

SUMMARY: This document is a request for information regarding patient and family member or close friend experiences with hospice care.

DATES: The information solicited in this notice must be received at the address provided below by March 26, 2013.

ADDRESSES: In responding to this solicitation please reply via email to *HospiceSurvey@cms.hhs.gov* or by postal mail at Centers for Medicare and Medicaid Services, Attention: Debra Dean-Whittaker, Mailstop C1–25–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

FOR FURTHER INFORMATION CONTACT: Debra Dean-Whittaker, 410–786–0848

SUPPLEMENTARY INFORMATION:

I. Background

In accordance with section 3011 of the Affordable Care Act, the Department of Health and Human Services (HHS) developed the National Quality Strategy to create national aims and priorities to guide local, state, and national efforts to improve the quality of health care. The National Quality Strategy established three aims supported by six priorities.

The three aims are as follows:

- *Better Care:* Improve the overall quality, by making health care more patient-centered, reliable, accessible, and safe.
- *Healthy People/Healthy Communities:* Improve the health of the U.S. population by supporting proven interventions to address behavioral, social, and environmental determinants of health in addition to delivering higher-quality care.
- *Affordable Care:* Reduce the cost of quality health care for individuals, families, employers, and government.

The six priorities are: ''(1) Making care safer by reducing harm caused by the delivery of care; (2) ensuring that each person and family are engaged as partners in their care; (3) promoting effective communication and coordination of care; (4) promoting the most effective prevention and treatment practices for the leading causes of mortality, starting with cardiovascular disease; (5) working with communities to promote wide use of best practices to enable healthy living; and (6) making quality care more affordable for individuals, families, employers, and governments by developing and spreading new health care delivery models.''

The survey, now under development, hereinafter referred to as the ''Hospice Survey'' supports the National Quality Strategy goal of Better Care and the priorities of—

- Ensuring that each person and family are engaged as partners in their care (priority #2); and
- Promoting effective communication and coordination of care (priority #3).

The Centers for Medicare & Medicaid Services (CMS) has previously implemented national surveys called Consumer Assessment of Healthcare Providers and Systems (CAHPS®) surveys in both in-patient and out-patient settings and for different services. Specifically, CMS has implemented CAHPS® surveys for Medicare health and drug plans, inpatient hospitals, and home health agencies. CMS and the Agency for Healthcare Research and Quality (AHRQ) have also developed CAHPS® surveys for in-center hemodialysis facilities, nursing homes, and clinician and group practices. None of these CAHPS® surveys address experiences with hospice services.

Hospice focuses on caring for patients at the end of their lives and on helping their families. In the **Federal Register** we have defined hospice and hospice care as follows:

Hospice means a public agency or private organization or subdivision of either of these that is primarily engaged in providing hospice care as defined in this section.

> Hospice care means a comprehensive set of services described in section 1861(dd)(1) of the Act, identified and coordinated by an interdisciplinary group to provide for the physical, psychosocial, spiritual, and emotional needs of a terminally ill patient and/or family members, as delineated in a specific patient plan of care.[1]

The Hospice Foundation of America is one of many private organizations that agree with the following statement:

> Hospice is a special concept of care designed to provide comfort and support to patients and their families when a life-limiting illness no longer responds to cure-oriented treatments.[2]

The National Hospice and Palliative Care Organization (NHPCO), a leading organization for hospice providers, describes hospice care as follows:

> The focus of hospice relies on the belief that each of us has the right to die pain-free and with dignity, and that our loved ones will receive the necessary support to allow us to do so.[3]

The planned CMS Hospice Survey differs from other CMS patient experience surveys because the target population for the Hospice Survey is bereaved family members or close friends of patients who died in hospice care. The reasons for focusing on family members/friends are that the patient is not the best source of information for the entire trajectory of hospice care, and that many hospice patients are very ill and unable to answer survey questions.

Given the unique environment and patient population of hospice care, existing patient experience instruments designed for other settings are only partially relevant for capturing hospice care experiences. A rigorous, well-designed Hospice Survey will allow us to understand: (1) Patient experiences throughout their hospice care, as reported by their family members/friends; and (2) the perspectives of family members/friends with regard to their own experiences with hospice. This information will ultimately be used to help improve the quality of care patients and their families and friends receive in hospice.

We are in the process of reviewing potential topic areas, as well as publicly available instruments and measures, for the purpose of developing a Hospice Survey that will enable objective comparisons of hospice experiences across the country. This survey will be used to help consumers make more informed decisions about providers, as well as provide information to drive improvements in the quality of hospice care. The principal focus of this effort is to develop a survey of family members or friends who are 18 years of age and older and who are knowledgeable about the care provided to the person enrolled in hospice.

II. Solicitation of Information

We are soliciting the submission of suggested topic areas (such as ''communication with providers,'' ''pain

[1] 42 CFR 418.3 Accessed November 19, 2012 *http://www.gpo.gov/fdsys/pkg/CFR-2011-title42-vol3/xml/CFR-2011-title42-vol3-part418.xml#seqnum418.3.*

[2] Hospice Foundation of America, accessed November 2, 2012 *http://www.hospicefoundation.org/whatishospice.*

[3] Caring Connections, accessed November 1, 2012 *http://www.caringinfo.org/i4a/pages/index.cfm?pageid=3356.*

control'' or ''non-pain symptom management,'' as well as publicly available instruments for capturing family members' or friends' experiences with hospice care. We are interested in instruments and items that can measure quality of care from the family member/friend's perspective, including all potential hospice settings (for example, home, nursing home, hospital, and free-standing hospice) and instruments that track changes over time.

We are looking for suggested topic areas and publicly available instruments in which the information was identified by family members/friends as important to them in evaluating hospice care. Existing instruments are preferred if they have been tested, have a high degree of reliability and validity, and report evidence of wide use.

The following information would be especially helpful in any comments responding to this request for information:

• A brief cover letter summarizing the information requested for submitted instruments and topic areas, respectively, and how the submission will help fulfill the intent of the survey.

• (Optional) Information about the person submitting the material for the purposes of follow up questions about the submission which includes the following:

++ Name.
++ Title.
++ Organization.
++ Mailing address.
++ Telephone number.
++ Email address.
++ Indication that the instrument is publicly available.

• When submitting topic areas, we encourage including to the extent available the following information:

++ Detailed descriptions of the suggested topic area(s) and specific purpose(s).
++ Relevant peer-reviewed journal articles or full citations.

• When submitting publicly available instruments or survey questions, we encourage including to the extent available the following information:

++ Name of the instrument.
++ Copies of the full instrument in all available languages.
++ Topic areas included in the instrument.
++ Measures derived from the instrument.
++ Instrument reliability (internal consistency, test-retest, etc) and validity (content, construct, criterion-related).
++ Results of cognitive testing (one-on-one testing with a small number of respondents to ensure that they understand the questionnaire.)
++ Results of field testing.
++ Current use of the instrument (who is using it, what it is being used for, what population it is being used with, how instrument findings are reported, and by whom the findings are used).
++ Relevant peer-reviewed journal articles or full citations.
++ CAHPS® trademark status.
++ National Quality Forum (NQF) endorsement status.
++ Survey administration instructions.
++ Data analysis instructions.
++ Guidelines for reporting survey data.

CMS is developing this survey and plans to submit it to AHRQ for recognition as a Consumer Assessment of Healthcare Providers and Systems (CAHPS®) survey. The survey will be developed in accordance with CAHPS® Survey Design Principles and implementation instructions will be based on those for CAHPS® instruments (*https://www.cahps.AHRQ.gov/About-CAHPS/Principles.aspx*).

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

Dated: December 5, 2012.

Marilyn Tavenner,

Acting Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 2013–01299 Filed 1–24–13; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–4171–NC]

Medicare Program; Request for Information To Aid in the Design and Development of a Survey Regarding Patient Experiences With Hospital Outpatient Surgery Departments/Ambulatory Surgery Centers and Patient-Reported Outcomes From Surgeries and Procedures Performed in These Settings

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

ACTION: Request for information.

SUMMARY: This document is a request for information regarding hospital outpatient surgery departments (HOSDs) and ambulatory surgery centers (ASCs), as well as patient-reported outcomes from surgeries or other procedures performed in these settings.

DATES: The information solicited in this notice must be received at the address provided below by March 26, 2013.

ADDRESSES: In responding to this solicitation, please reply via email to *AmbSurgSurvey@cms.hhs.gov* or by postal mail at Centers for Medicare and Medicaid Services, Attention: Memuna Ifederah, Mailstop C1–25–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

FOR FURTHER INFORMATION CONTACT: Memuna Ifederah, (410) 768–6849 or Caren Ginsberg (410) 786–0713.

SUPPLEMENTARY INFORMATION:

I. Background

In accordance with section 3011 of the Affordable Care Act, the Department of Health and Human Services (HHS) developed the National Quality Strategy to create national aims and priorities to guide local, state, and national efforts to improve the quality of health care. The National Quality Strategy established three aims supported by six priorities.

The 3 aims are as follows:

• Better Care: Improve the overall quality, by making health care more patient-centered, reliable, accessible, and safe.

• Healthy People/Healthy Communities: Improve the health of the U.S. population by supporting proven interventions to address behavioral, social, and environmental determinants of health in addition to delivering higher quality care.

• Affordable Care: Reduce the cost of quality health care for individuals, families, employers, and government.[1]

The six priorities are: ''(1) Making care safer by reducing harm caused by the delivery of care; (2) ensuring that each person and family are engaged as partners in their care; (3) promoting effective communication and coordination of care; (4) promoting the most effective prevention and treatment practices for the leading causes of mortality, starting with cardiovascular disease; (5) working with communities to promote wide use of best practices to enable health living; and (6) making quality care more affordable for individuals, families, employers and governments by developing and spreading new health care delivery models''.

Surveys focusing on the patient experience as well as the Hospital Outpatient Surgery Department/

[1] Please see U.S. Department of Health and Human Services, *Report to Congress, National Strategy for Quality Improvement in Health Care,* (March 2011), available at *http://www.healthcare.gov/law/resources/reports/nationalqualitystrategy032011.pdf.*

Ambulatory Surgery Patient Experience of Care Survey now under development support the National Quality Strategy of better care and the priorities of—

- Ensuring that each person and family are engaged as partners in their care (priority #2); and
- Promoting effective communication and coordination of care (priority #3).

Since 1995, the Agency for Healthcare Research and Quality (AHRQ) and its Consumer Assessment of Healthcare Providers and Systems (CAHPS®) Consortium, in partnership with the Centers for Medicare & Medicaid Services (CMS), has developed standardized CAHPS® Surveys and tools for a variety of populations to collect data on patient's experiences with and ratings of care. CMS and AHRQ have developed CAHPS® surveys for in-center hemodialysis facilities, nursing homes, and clinician and group practices. CMS has already implemented CAHPS® surveys for health and drug plans, hospitals, and home health agencies.

We are developing a standardized Hospital Outpatient Surgical Department/Ambulatory Surgical Center (HOSD/ASC) Experience of Care Survey to evaluate the care received in these facilities from the patient's perspective. Two related CAHPS® surveys exist; however, they do not collect information specific to the patient experience of care in HOSD/ASC facilities. In 2006, CMS began implementing the Hospital CAHPS® (HCAHPS) Survey, which collects data on hospital inpatients experiences with and ratings of hospital inpatient care. The HCAHPS Survey includes neither patients who receive outpatient surgical care from hospital-based outpatient surgical departments, nor patients who received such care from freestanding ASCs. The Surgical Care CAHPS® Survey, developed by the American College of Surgeons (ACS) and the Surgical Quality Alliance (SQA) focuses on both inpatient and outpatient surgeries and includes questions related to the patient's experience before, during, and after surgery. However, this survey focuses on the care provided by the physician rather than the facility. Hospital outpatient surgery departments and ASCs will be the unit of analysis for this HOSD/ASC survey instrument. The Hospital Outpatient Surgery Department/Ambulatory Surgery Center Patient Experience of Care Survey will be used to help consumers make informed choices about providers as well as improving the quality of care.

II. Solicitation of Information

This document solicits input for developing this new patient experience survey, including the following:

- Relevant topic areas such as communication between patients and health care providers; access to care; customer service; provision of pre- and post-surgical care information; access to follow-up care; care coordination; patient preferences; environment; and safety.
- Publicly available surveys, survey questions, and measures indicating— (1) patient experience and/or level of patient satisfaction with experience in HOSDs/ASCs; and (2) patient-reported outcomes from surgeries or other procedures (for example, colonoscopies, endoscopies) performed in HOSDs and ASCs. These surveys, survey questions, and measures should measure and assess quality of care and patient-reported outcomes from the patient's perspective, and track changes over time.

We are interested in suggestions for topic areas, and publicly available surveys, questions or measures that address the following specifically for outpatient surgery:

- Issues that are that are highly relevant to DHHS and CMS, because they support DHHS's and CMS's efforts for improved quality and efficiency of care and are included in or facilitate alignment with other CMS programs.
- Identification of gaps in the quality of care delivered in outpatient surgical departments.
- Measures of surgical care coordination and related care coordination activities.
- Identification and assessment of patient-reported outcomes, such as pain, nausea and vomiting, deep vein thrombosis, infection, pneumonia, and urinary retention.

We are looking for suggested topic areas, as well as any publicly available surveys, questions and measures in which—(1) the source of information is from patients who directly received care at HOSDs or ASCs; and (2) patients identified the topic areas such as those listed above as important to them in evaluating HOSD or ASC care (for example, wait time and medical staff and physician communication). We are seeking topic areas, surveys, questions and measures that are applicable across outpatient surgical settings (for example, freestanding settings, hospital based settings, for-profit settings; not-for-profit settings; rural settings; urban settings; multi-specialty and single-specialty surgery departments/centers). We prefer existing surveys, questions, and measures that have been tested and have a high degree of reliability and validity, and for which there is evidence of wide use.

This request for information solicits input from consumers, researchers, vendors, health plans, HOSDs, ASCs, surgeons, advocacy organizations, community-based providers, and other stakeholders and interested parties. This call for topic areas, publicly available surveys, questions, and measures is occurring now because of the multi-phased survey development and testing process necessary to produce a standardized instrument. The target population for the survey is adults (defined in CAHPS surveys as 18 years old and older) who recently have had surgery or other procedures, such as a colonoscopy or endoscopy, in a surgical outpatient setting.

CMS is developing this survey and plans to submit it to AHRQ for recognition as a CAHPS® survey. The survey will be developed in accordance with CAHPS® Survey Design Principles and implementation instructions will be based on those for CAHPS® instruments (*https://www.cahps.AHRQ.gov/About-CAHPS/Principles.aspx*).

We are asking respondents to include the following in their submissions:

- A brief cover letter summarizing the information requested above for submitted topic areas, surveys, questions, and measures, and how the submission will help fulfill the intent of the patient experiences survey.
- (Optional) Information about the person submitting the material for purposes of follow-up questions about the submission, including the following:

++ Name.
++ Title.
++ Organization.
++ Mailing address.
++ Telephone number.
++ Email address.
++ Indication that the topic area or instrument is publicly available.

- When submitting topic areas, respondents should include to the extent available the following information:

++ Detailed descriptions of the suggested topic area(s) and specific purpose(s).
++ Sample questions, in all available languages.
++ Relevant peer-reviewed journal articles or full citations.
++ Name of the instrument.
++ Copies of the full instrument in all available languages.
++ Topic areas included in the survey.
++ Measures derived from the survey.
++ Survey reliability (internal consistency, test-retest, etc.) and

validity (content, construct, criterion-related).

++ Results of cognitive testing (one-on-one testing with a small number of respondents to ensure that they understand the questionnaire).

++ Results of field testing.

++ Current use of the instrument (who is using it, what it is being used for, what population it is being used with, how instrument findings are reported, and by whom the findings are used).

++ Relevant peer-review journal articles or full citations.

++ CAHPS® trademark status.

++ Survey administration instructions.

++ Data analysis instructions.

++ Guidelines for reporting survey data.

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

Dated: December 13, 2012.

Marilyn Tavenner,

Acting Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 2013–01300 Filed 1–24–13; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Proposed Projects

Title: Guidance for Tribal TANF.

OMB No.: 0970–0157.

Description

42 U.S.C. 612 (Section 412 of the Social Security Act) requires each Indian Tribe that elects to administer and operate a TANF program to submit a TANF Tribal Plan. The TANF Tribal Plan is a mandatory statement submitted to the Secretary by the Indian Tribe, which consists of an outline of how the Indian Tribes TANF program will be administered and operated. It is used by the Secretary to determine whether the plan is approvable and to determine that the Indian Tribe is eligible to receive a TANF assistance grant. It is also made available to the public.

Respondents

Indian Tribes applying to operate a TANF program.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total Burden hours
Request for State Data Needed to Determine the Amount of a Tribal Family Assistance Grant	23	1	68	1564

Estimated Total Annual Burden Hours: 1564.

In compliance with the requirements of Section 506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. Email address: *infocollection@acf.hhs.gov.* All requests should be identified by the title of the information collection.

The Department specifically requests comments on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2013–01450 Filed 1–24–13; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Proposed Projects

Title: ANA Project Impact Assessment Survey.

OMB No.: 0970–0379

Description: The information collected by the Project Impact Assessment Survey is needed for two main reasons: (1) To collect crucial information required to report on the Administration for Native Americans' (ANA) established Government Performance and Results Act (GPRA) measures, and (2) to properly abide by ANA's congressionally-mandated statute (42 United States Code 2991 *et seq.*) found within the Native American Programs Act of 1974, as amended, which states that ANA will evaluate projects assisted through ANA grant dollars ''including evaluations that describe and measure the impact of such projects, their effectiveness in achieving stated goals, their impact on related programs, and their structure and mechanisms for delivery of services.'' The information collected with this survey will fulfill ANA's statutory requirement and will also serve as an important planning and performance tool for ANA.

Respondents: Tribal Governments, Native American nonprofit organizations, and Tribal Colleges and Universities.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
ANA Project Impact Assessment Survey	85	1	6	510

Estimated Total Annual Burden Hours: 510.

In compliance with the requirements of Section 506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 370 L'Enfant Promenade SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. Email address: *infocollection@acf.hhs.gov.* All requests should be identified by the title of the information collection.

The Department specifically requests comments on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2013–01577 Filed 1–24–13; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0876]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Pretesting of Tobacco Communications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995 (the PRA).

DATES: Fax written comments on the collection of information by February 25, 2013.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0674. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Daniel Gittleson, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–5156, *daniel.gittleson@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Pretesting of Tobacco Communications—(OMB Control Number 0910–0674)—Extension

In order to conduct educational and public information programs relating to tobacco use, as authorized by section 1003(d)(2)(D) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 393(d)(2)(D)), and to develop stronger health warnings on tobacco packaging as authorized by the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act), it is beneficial for FDA to conduct research and studies relating to the control and prevention of disease as authorized by section 301 of the Public Health Service Act (42 U.S.C. 241(a)). In conducting such research, FDA will employ formative pretests to assess the likely effectiveness of tobacco communications with specific target audiences.

The information collected will serve two major purposes. First, as formative research it will provide the critical knowledge needed about target audiences. FDA must first understand critical influences on people's decisionmaking process when choosing to use, not use, or quit using tobacco products. In addition to understanding the decisionmaking processes of adults, it is also critical to understand the decisionmaking processes among adolescents (ages 13 to 17), where communications will aim to discourage tobacco use before it starts. Knowledge of these decisionmaking processes will be applied by FDA to help design effective communication strategies, messages, and warning labels. Second, as initial testing, it will allow FDA to assess the potential effectiveness of messages and materials in reaching and successfully communicating with their intended audiences. Pretesting messages with a sample of the target audience will allow FDA to refine messages while they are still in the developmental stage. By utilizing appropriate qualitative and quantitative methodologies, FDA will be able to: (1) Better understand characteristics of the target audience—its attitudes, beliefs, and behaviors—and use risk communications; (2) more efficiently and effectively design messages and select formats that have the greatest potential to influence the target audience's attitudes and behavior in a favorable way; (3) determine the best promotion and distribution channels to reach the target audience with appropriate messages; and (4) expend limited program resource dollars wisely and effectively.

In the **Federal Register** of August 17, 2012 (77 FR 49819), FDA published a 60-day notice requesting public comment on the proposed collection of information. Three comments were received, which included one comment that was not PRA-related and beyond the scope of this document, and one comment that was in full support of pretesting tobacco communications. The third commenter indicated that the authorizing statute was incorrectly identified. The correct authorizing statute is section 1003(d)(2)(D) of the FD&C Act. The commenter also

indicated that there was not enough information provided about the design and methodology of the pretests and the studies to effectively comment on the collection of information. In response, the information collection is for a broad spectrum of pretests and studies using a variety of methodologies and is dependent on the material being tested and the target audience. Each separate collection and pretest will be submitted for OMB review and approval prior to the collection or pretest being released to the public.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Individual In-Depth Interviews	360	1	360	0.75 (45 minutes)	270
General Public Focus Group Interviews.	144	1	144	1.5 hours	216
Intercept Interviews: Central Location.	600	1	600	0.25 (15 minutes)	150
Intercept Interviews: Telephone [2]	10,000	1	10,000	0.08 (5 minutes)	800
Self-Administered Surveys	2,400	1	2,400	0.25 (15 minutes)	600
Gatekeeper Reviews	400	1	400	0.50 (30 minutes)	200
Omnibus Surveys	2,400	1	2,400	0.17 (10 minutes)	408
Total (General Public)	16,304				2,644
Physician Focus Group Interviews	144	1	144	1.5 hours	216
Total (Physician)	144				216
Total (Overall)	16,448				2,860

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Brief interviews with callers to test message concepts and strategies following their call-in request to the FDA Center for Tobacco Products 1–800 number.

The number of respondents to be included in each new pretest will vary, depending on the nature of the material or message being tested and the target audience. However, for illustrative purposes, table 1 provides examples of the types of studies that may be administered and estimated burden levels that may be incurred during each year of the 3-year period. Time to read, view, or listen to the message being tested is built into the ''Hours per Response'' figures.

Dated: January 17, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–01445 Filed 1–24–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0032]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Antimicrobial Animal Drug Distribution Reports Under Section 105 of the Animal Drug User Fee Amendments of 2008

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by February 25, 2013.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0659 and title, ''Antimicrobial Animal Drug Distribution Reports Under Section 105 of the Animal Drug User Fee Amendments of 2008.'' Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Jonna Capezzuto, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–3794, *Jonnalynn.capezzuto@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance. Antimicrobial Animal Drug Distribution Reports Under Section 105 of the Animal Drug User

Fee Amendments of 2008—(OMB Control Number 0910–0659)—Extension

Section 105 of the Animal Drug User Fee Amendments of 2008 (ADUFA II) (Pub. L. 316) amended section 512 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360b) by, among other things, creating section 512(l)(3) to require that the sponsor of each new animal drug that contains an antimicrobial agent submit an annual report to FDA on the amount of each antimicrobial active ingredient in the drug that is sold or distributed for use in food-producing animals, including information on any distributor-labeled product. The legislation was enacted to address the problem of antimicrobial resistance and to help ensure that FDA has the necessary information to examine safety concerns related to the use of antibiotics in food-producing animals (154 Congressional Record H7534).

Each report must specify: (1) The amount of each antimicrobial active ingredient by container size, strength,

and dosage form; (2) quantities distributed domestically and quantities exported; and (3) a listing of the target animals, indications, and production classes that are specified on the approved label of the product. The first report under the statute was to be submitted not later than March 31, 2010.

The report covered the period of the preceding calendar year and included separate information for each month of the calendar year.

We are now seeking to further implement the statutory requirements of ADUFA II and enhance its public health and safety mission as envisioned by Congress by introducing an electronic form for the submission of the required annual reports under ADUFA II. The e-form FDA 3744a will enable sponsors to submit electronically and capture all information as mandated by Section 105 of ADUFA II. Form FDA 3744 will continue to be designated for paper submissions.

List of information required on form FDA 3744 and e-form FDA 3744a:

- Application Type
- Application Number
- Firm Name
- Dosage Form(s)
- Production Class(es)
- Animal Species—Food Animal or Food and Non-Food Animal
- Indications
- Active Ingredient(s)
- Domestic Quantities
  - Unit of Measure for All Active Ingredients
  - Calendar Year
  - Quantity Sold by Month for All Active Ingredients
  - Annual Total Sold for All Active Ingredients
- Export Quantities
  - Unit of Measure for All Active Ingredients
  - Calendar Year
  - Quantity Sold by Month for All Active Ingredients
  - Annual Total Sold for All Active Ingredients
- Individual Product Information for All Active Ingredients
  - Dosage Form
  - Container Size
  - Container Units
  - Active Ingredient Strength
- Quantities of Individual Products Sold or Distributed (Domestic and Export)
  - Unit of Measure for All Active Ingredients
  - Quantity Sold by Month for All Active Ingredients
  - Annual Total Sold for All Active Ingredients

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

FD&C Act section 512(1)(3)	Form FDA No.	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours	Capital costs
Annual Reports for Sponsors With Active Applications—Paper Submission.	3744	14	5.9	83	60	4,980	$6,975
Annual Reports for Sponsors With Active Applications—Electronic Submission.	e-Form 3744a	12	6.7	80	50	4,000	0
Annual Reports for Sponsors With Inactive Applications—Paper Submission.	3744	13	6.2	81	2	162	0
Annual Reports for Sponsors With Inactive Applications—Electronic Submission.	e-Form 3744a	11	7.3	80	2	160	0
Total						9,302	$6,975

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

The total annual responses were calculated by multiplying the number of respondents times the number of responses per respondent. Total burden hours were calculated by multiplying total annual responses times the average burden per response. As explained in the supporting statement for the subject collection of information (OMB control number 0910–0659), the initial one-time capital costs are for the design of the report. Here, e-form FDA 3744a and reporting via the Electronic Submission Gateway are provided by FDA. Thus, the remaining cost, as described in approved OMB control number 0910–0659 is $6,975 per year (3 hours × $46.50 wage rate × 50 sponsors) = $6,975. FDA believes that the sponsors already possess the computer equipment needed to prepare the report so that additional capital expenditures will not be necessary.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

21 CFR 514.80(b)(5)	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Records and reports concerning experience with approved new animal drugs—special drug experience report	34	1	34	2	68

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

Total annual records were calculated by multiplying the number of recordkeepers times the number of records per recordkeeper. Total hours were calculated by multiplying total annual records times the average burden per recordkeeping.

In the **Federal Register** of January 17, 2012 (77 FR 2302), FDA published a 60-day notice requesting public comment on the proposed collection of information to which three comments were received: two from organizations and one from a member of Congress. The commenters generally supported the collection of sales data, and stated that this information would be useful in assessing antimicrobial drugs used in food-producing animals to better address the problem of antimicrobial resistance. One commenter stated that the information supplied by drug companies should be submitted in a format that would allow it to be easily merged with data from other FDA databases.

Beyond the scope of this **Federal Register** notice, all commenters recommended collection of antimicrobial use information in addition to the current requirements of ADUFA II sales reporting. All commenters also recommended revisions to the public reporting of the data being collected. The commenters requested FDA report sales of antimicrobial drug classes by month, by route of administration, by indication, by over-the-counter or prescription status, or grouped by their importance in human medicine. It was recommended that FDA collect and publicly report distribution information down to the state or regional level. ADUFA II requires that no class with fewer than three distinct sponsors of approved applications shall be independently reported; it was recommended that FDA seek additional authority from Congress to report sales figures for all antimicrobial classes regardless of the number of distinct drug sponsors. There was also a recommendation that all of the information collected be made publicly available in a searchable database.

FDA has considered the comments, but at this time we can only require the submission of information on the new e-form FDA 3744a that is expressly required to be submitted by section 512(l)(3) of the FD&C Act. We are pursuing notice and comment rulemaking to codify these requirements, and are currently assessing any additional data requirements. In this regard, FDA published an Advance Notice of Proposed Rulemaking on July 27, 2012, in which FDA solicited comment on the following: (1) Whether FDA should require submission of an estimate of the amount of antimicrobial ingredient sold or distributed for use in each approved food animal species, (2) how FDA can best compile and present required summary information, and (3) alternative methods there may be for obtaining additional data and information about the extent of antimicrobial drug use in food-producing animals and are there alternative methods the Agency can employ within its existing authority.

Dated: January 17, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–01446 Filed 1–24–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0001]

Vaccines and Related Biological Products 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 Committee: Vaccines and Related Biological Products Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the Agency on FDA's regulatory issues.

Date and Time: The meeting will be held on February 27, 2013 between approximately 8:30 a.m. and 2:45 p.m.

Location: National Institutes of Health (NIH) Fishers Lane Conference Center, Terrace Level, Rooms 508–510, 5635 Fishers Lane, Rockville, MD, 20852. Please enter the building through the main front entrance on Fishers Lane and take the elevators down to the T-Terrace Level. For those unable to attend in person, the meeting will also be webcast. The link for the webcast is available at *http://videocast.nih.gov.*

Contact Person: Donald W. Jehn or Denise Royster, Center for Biologics Evaluation and Research (HFM–71), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–0314, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area). 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 at *http://www.fda.gov/AdvisoryCommittees/default.htm* and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

Agenda: On February 27, 2013, the committee will meet in open session to discuss and make recommendations on the selection of strains to be included in the influenza virus vaccine for the 2013–2014 influenza season.

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 meeting link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before February 20, 2013. Oral presentations from the public will be scheduled between approximately 12:35 p.m. and 1:35 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 February 12, 2013. 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 February 13, 2013.

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 Donald W. Jehn or Denise Royster 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: *January 22, 2013.*

Jill Hartzler Warner,

Acting Associate Commissioner for Special Medical Programs.

[FR Doc. 2013–01561 Filed 1–24–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Population Sciences and Epidemiology Integrated Review Group, Behavioral Genetics and Epidemiology Study Section.

Date: February 20, 2013.

Time: 8:00 a.m. to 7:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Sir Francis Drake Hotel, 450 Powell Street at Sutter, San Francisco, CA 94102.

Contact Person: George Vogler, Ph.D., Scientific Review Officer, PSE IRG, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3140, Bethesda, MD 20892, 301–435–0694.

Name of Committee: Immunology Integrated Review Group, Immunity and Host Defense Study Section.

Date: February 21–22, 2013.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Dallas Marriott Suites Medical/Market Center, 2493 North Stemmons Freeway, Dallas, TX 75207.

Contact Person: Patrick K Lai, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2215, MSC 7812, Bethesda, MD 20892, 301–435–1052, *laip@csr.nih.gov.*

Name of Committee: Emerging Technologies and Training Neurosciences Integrated Review Group, Molecular Neurogenetics Study Section.

Date: February 21–22, 2013.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Sheraton Delfina Santa Monica Hotel, 530 West Pico Boulevard, Santa Monica, CA 90405.

Contact Person: Eugene Carstea, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5194, MSC 7846, Bethesda, MD 20892, (301) 408–9756, *carsteae@csr.nih.gov.*

Name of Committee: Genes, Genomes, and Genetics Integrated Review Group, Prokaryotic Cell and Molecular Biology Study Section.

Date: February 21, 2013.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Renaissance M Street Hotel, 1143 New Hampshire Avenue, NW., Washington, DC 20037.

Contact Person: Dominique Lorang-Leins, Ph.D., Scientific Review Officer, National Institutes of Health, Center for Scientific Review, 6701 Rockledge Drive, Room 5108, MSC 7766, Bethesda, MD 20892, 301.326.9721, *Lorangd@mail.nih.gov.*

Name of Committee: Cardiovascular and Respiratory Sciences Integrated Review Group, Myocardial Ischemia and Metabolism Study Section.

Date: February 21–22, 2013.

Time: 8:00 a.m. to 12:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Embassy Suites Alexandria, 1900 Diagonal Road, Alexandria, VA 22314.

Contact Person: Kimm Hamann, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4118A, MSC 7814, Bethesda, MD 20892, 301–435–5575, *hamannkj@csr.nih.gov.*

Name of Committee: Genes, Genomes, and Genetics Integrated Review Group, Molecular Genetics A Study Section.

Date: February 21–22, 2013.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Renaissance M Street Hotel, 1143 New Hampshire Avenue NW., Washington, DC 20037.

Contact Person: Michael M Sveda, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 1114, MSC 7890, Bethesda, MD 20892, 301–435–3565, *svedam@csr.nih.gov.*

Name of Committee: Molecular, Cellular and Developmental Neuroscience Integrated Review Group, Neural Oxidative Metabolism and Death Study Section.

Date: February 21–22, 2013.

Time: 8:00 a.m. to 12:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Fairmont Hotel San Francisco, 950 Mason Street, San Francisco, CA 94108.

Contact Person: Carol Hamelink, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4192, MSC 7850, Bethesda, MD 20892, (301) 213–9887, *hamelinc@csr.nih.gov.*

Name of Committee: Bioengineering Sciences & Technologies Integrated Review Group, Gene and Drug Delivery Systems Study Section.

Date: February 21–22, 2013.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Courtyard by Marriott, 5520 Wisconsin Avenue, Chevy Chase, MD 20815.

Contact Person: Amy L Rubinstein, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5152, MSC 7844, Bethesda, MD 20892, 301–408–9754, *rubinsteinal@csr.nih.gov.*

Name of Committee: Infectious Diseases and Microbiology Integrated Review Group, Virology–B Study Section.

Date: February 21–22, 2013.

Time: 8:30 a.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Marina del Rey Hotel, 13534 Bali Way, Marina del Rey, CA 90292.

Contact Person: John C Pugh, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 1206, MSC 7808, Bethesda, MD 20892, (301) 435–2398, *pughjohn@csr.nih.gov.*

Name of Committee: Brain Disorders and Clinical Neuroscience Integrated Review Group, Clinical Neuroimmunology and Brain Tumors Study Section.

Date: February 21–22, 2013.

Time: 8:30 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Hotel Nikko San Francisco, 222 Mason Street, San Francisco, CA 94102.

Contact Person: Jay Joshi, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5196, MSC 7846, Bethesda, MD 20892, (301) 408–9135, *joshij@csr.nih.gov.*

Name of Committee: Infectious Diseases and Microbiology Integrated Review Group, Pathogenic Eukaryotes Study Section.

Date: February 21–22, 2013.

Time: 8:30 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Marina del Rey Hotel, 13534 Bali Way, Marina del Rey, CA 90292.

Contact Person: Tera Bounds, DVM, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3198, MSC 7808, Bethesda, MD 20892, 301 435–2306, *boundst@csr.nih.gov.*

Name of Committee: Population Sciences and Epidemiology Integrated Review Group, Infectious Diseases, Reproductive Health, Asthma and Pulmonary Conditions Study Section.

Date: February 21–22, 2013.

Time: 8:30 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Sir Francis Drake Hotel, 450 Powell Street at Sutter, San Francisco, CA 94102.

Contact Person: Lisa Steele, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3139, MSC 7770, Bethesda, MD 20892, 301–594–6594, *steeleln@csr.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: January 18, 2013.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2013–01472 Filed 1–24–13; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the National Cancer Advisory Board, February 7, 2013, 6:30 p.m. to February 8, 2013, 5:00 p.m., National Institutes of Health, Building 31, 31 Center Drive, Conference 10, Bethesda, MD 20892 which was published in the **Federal Register** on January 14, 2013, 78 FR 2682.

This notice is being amended to cancel the Ad hoc Global Cancer Research Subcommittee on February 7, 2013 from 6:30 p.m. to 8:30 p.m. at the Hyatt Regency Bethesda Hotel, One Bethesda Metro Center, Bethesda, MD 20814, and to add the Ad hoc Subcommittee on Communications meeting on February 7, 2013 from 6:30 p.m. to 8:30 p.m. which will convene at the same location.

Dated: January 18, 2013.

Carolyn A. Baum,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2013–01470 Filed 1–24–13; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; LURN Telephone Review Panel.

Date: February 26, 2013.

Time: 12:00 p.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892.

Contact Person: Xiaodu Guo, MD, Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 761, 6707 Democracy Boulevard, Bethesda, MD 20892–5452, (301) 594–4719, *guox@extra.niddk.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.847, Diabetes, Endocrinology and Metabolic Research; 93.848, Digestive Diseases and Nutrition Research; 93.849, Kidney Diseases, Urology and Hematology Research, National Institutes of Health, HHS)

Dated: January 18, 2013.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2013–01467 Filed 1–24–13; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel; ''OMICS'' Technologies for Predictive Modeling of Infectious.

Date: February 25–27, 2013.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Sheraton Silver Spring Hotel, 8777 Georgia Avenue, Silver Spring, MD 20910.

Contact Person: Eleazar Cohen, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, National Institutes of Health, NIAID, 6700 B Rockledge Drive, Room 3129, Bethesda, MD 20892, 301–435–3564, *ec17w@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: January 18, 2013.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2013–01469 Filed 1–24–13; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Adult Psychopathology.
Date: February 19, 2013.
Time: 2:30 p.m. to 4:00 p.m.
Agenda: To review and evaluate grant applications.
Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).
Contact Person: Jane A Doussard-Roosevelt, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3184, MSC 7848, Bethesda, MD 20892, (301) 435–4445, *doussarj@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Behavioral Genetics and Epidemiology: Collaborative Applications.
Date: February 20, 2013.
Time: 8:30 a.m. to 6:00 p.m.
Agenda: To review and evaluate grant applications.
Place: Sir Francis Drake Hotel, 450 Powell Street at Sutter, San Francisco, CA 94102.
Contact Person: George Vogler, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3140, MSC 7770, Bethesda, MD 20892, 301–435–0694, *voglergp@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; PAR10–169: Academic Industrial Partnership (2013/05).
Date: February 20–21, 2013.
Time: 9:00 a.m. to 5:00 p.m.
Agenda: To review and evaluate grant applications.
Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892.
Contact Person: Mehrdad Mohseni, MD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5211, MSC 7854, Bethesda, MD 20892, 301–435–0484, *mohsenim@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Small Business: Sensory Technologies.
Date: February 21–22, 2013.
Time: 8:00 a.m. to 5:00 p.m.
Agenda: To review and evaluate grant applications.
Place: Renaissance Mayflower Hotel, 1127 Connecticut Avenue NW., Washington, DC 20036.
Contact Person: Paek-Gyu Lee, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4201, MSC 7812, Bethesda, MD 20892, (301) 613–2064, *leepg@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Small Business: Medical Imaging.
Date: February 21–22, 2013.
Time: 8:00 a.m. to 5:00 p.m.
Agenda: To review and evaluate grant applications.
Place: Doubletree Guest Suites Santa Monica, 1707 Fourth Street, Santa Monica, CA 90401.
Contact Person: Leonid V Tsap, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5128, MSC 7854, Bethesda, MD 20892, (301) 435–2507, *tsapl@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; RFA Panel: Tobacco Control Regulatory Research.
Date: February 21, 2013.
Time: 8:00 a.m. to 6:00 p.m.
Agenda: To review and evaluate grant applications.
Place: Holiday Inn Inner Harbor, 301 W. Lombard Street, Baltimore, MD 21201.
Contact Person: Tomas Drgon, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3152, MSC 7770, Bethesda, MD 20892, 301–435–1017, *tdrgon@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Small Business: Risk, Prevention and Health Behavior.
Date: February 21–22, 2013.
Time: 8:00 a.m. to 5:00 p.m.
Agenda: To review and evaluate grant applications.
Place: Fairmont Hotel San Francisco, 950 Mason Street, San Francisco, CA 94108.
Contact Person: Claire E Gutkin, Ph.D., MPH, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3106, MSC 7808, Bethesda, MD 20892, 301–594–3139, *gutkincl@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Pathophysiology and Clinical Studies of Osteonecrosis of the Jaw.
Date: February 21, 2013.
Time: 10:00 a.m. to 2:00 p.m.
Agenda: To review and evaluate grant applications.
Place: Sir Francis Drake Hotel, 450 Powell Street at Sutter, San Francisco, CA 94102.
Contact Person: Yi-Hsin Liu, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4214, MSC 7814, Bethesda, MD 20892, 301–435–1781, *liuyh@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Neurobiology of Neurodegeneration.
Date: February 21, 2013.
Time: 1:30 p.m. to 2:30 p.m.
Agenda: To review and evaluate grant applications.
Place: Fairmont Hotel San Francisco, 950 Mason Street, San Francisco, CA 94108.
Contact Person: Laurent Taupenot, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4811, MSC 7850, Bethesda, MD 20892, 301–435–1203, *taupenol@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Small Business: Biomedical Sensing, Measurement and Instrumentation.
Date: February 22, 2013.
Time: 8:00 a.m. to 5:00 p.m.
Agenda: To review and evaluate grant applications.
Place: Doubletree Guest Suites Santa Monica, 1707 Fourth Street, Santa Monica, CA 90401.
Contact Person: Guo Feng Xu, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5122, MSC 7854, Bethesda, MD 20892, 301–237–9870, *xuguofen@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; RFA Panel: Patient Safety Research during Neonatal Care.
Date: February 22, 2013.
Time: 8:00 a.m. to 5:00 p.m.
Agenda: To review and evaluate grant applications.
Place: Embassy Suites Alexandria, 1900 Diagonal Road, Alexandria, VA 22314.
Contact Person: Priscah Mujuru, RN, MPH, DRPH, COHNS, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3139, MSC 7770, Bethesda, MD 20892, 301–594–6594, *mujurup@mail.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Health Services Organization and Delivery Overflow.
Date: February 22, 2013.
Time: 8:00 a.m. to 5:00 p.m.
Agenda: To review and evaluate grant applications.
Place: Embassy Suites at the Chevy Chase Pavilion, 4300 Military Road NW., Washington, DC 20015.
Contact Person: Jacinta Bronte-Tinkew, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3164, MSC 7770, Bethesda, MD 20892, (301) 806–0009, *brontetinkewjm@csr.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: January 18, 2013.

Anna Snouffer,

Deputy Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2013–01471 Filed 1–24–13; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Announcement of Requirements and Registration for the 2013 NIBIB DEsign by Biomedical Undergraduate Teams (DEBUT) Challenge

Authority: 15 U.S.C. 3719.

SUMMARY: The National Institute of Biomedical Imaging and Bioengineering (NIBIB) DEBUT Challenge is open to teams of undergraduate students working on projects that develop innovative solutions to unmet health and clinical problems. NIBIB's mission is to improve health by leading the development and accelerating the application of biomedical technologies. The goals of the challenge are (1) to provide undergraduate students valuable experiences such as working in teams, identifying unmet clinical needs, and designing, building, and debugging solutions for such open-ended problems; (2) to generate novel, innovative tools to improve health care, consistent with NIBIB's purpose to support research, training, the dissemination of health information, and other programs with respect to biomedical imaging and engineering and associated technologies and modalities with biomedical applications; and (3) to highlight and acknowledge the contributions and accomplishments of undergraduate students.

DATES: The competition begins January 25, 2013.

Submission Period: January 28, 2013, to June 6, 2013, 11:59 p.m. EST.

Judging Period: June 10, 2013, to July 25, 2013.

Winners announced: August 12, 2013.

Award ceremony: September 2013, Biomedical Engineering Society Conference (exact date to be announced at *http://debut2013.challenge.gov/*).

FOR FURTHER INFORMATION CONTACT: *info@nibib.nih.gov* or (301) 451–4792.

SUPPLEMENTARY INFORMATION:

Subject of Challenge Competition: The NIBIB DEBUT Challenge solicits entries that develop innovative solutions to unmet health and clinical problems under one of the following categories:

- Diagnostic Devices/Methods
- Therapeutic Devices/Methods
- Technology to Aid Underserved Populations and Individuals with Disabilities.

Eligibility Rules for Participating in the Competition:

1. To be eligible to win a prize under this challenge, each individual on the Student Team must

(a) Be a citizen or permanent resident of the United States;

(b) Be an undergraduate student enrolled full-time in an undergraduate curriculum during the academic year 2012–2013;

(c) Have his/her own active Challenge.gov account that he/she has created at *www.challenge.gov*;

(d) Form or join a ''Student Team'' with at least two other individuals who satisfy the criteria in (a), (b), and (c) above for the purpose of developing an entry for submission to this challenge. While it is expected that most of the individuals participating in the competition may be students from biomedical engineering departments, interdisciplinary teams including students from other fields are welcome and encouraged;

(e) Acknowledge understanding and acceptance of the *DEBUT challenge rules* by signing the NIBIB DEBUT Challenge Certification Form found at *http://www.nibib.nih.gov/Training/Undergrad_Grad/DEBUT/NIBIB_DEBUT_Certification_Form.pdf.* Each entry must include one NIBIB DEBUT Challenge Certification Form, completed with dates and the printed names and signatures of each individual member of the Student Team. Entries that do not provide a complete Certification Form will be disqualified from the challenge;

(f) Comply with all the requirements under this section; and

(g) Not be a federal employee acting within the scope of his/her employment. Federal employees seeking to participate in this challenge outside the scope of their employment should consult their ethics official prior to developing a submission.

2. By participating in this challenge, each individual agrees to abide by all rules of this challenge and the *Challenge.gov Terms of Participation* (*http://challenge.gov/terms*).

3. Each entry into this challenge must have been conceived, designed, and implemented by the Student Team. Student Teams participating in capstone design projects are especially encouraged to enter the challenge.

4. Each Student Team may submit only one entry into this challenge through one member of the Student Team appointed as ''Corresponding Student'' by that Student Team. The Corresponding Student will carry out all correspondence regarding the Student Team's entry.

5. The Corresponding Student will submit a Student Team's entry on behalf of the Student Team by following the links and instructions at *http://debut2013.challenge.gov/* and certify that the entry meets all the challenge rules.

6. Each entry into this challenge must describe an original biomedical engineering project that falls into one of the following *3 categories:*

(a) Diagnostic Devices/Methods e.g., sensors, imaging devices, imaging agents, telehealth, clinical laboratory diagnostics

(b) Therapeutic Devices/Methods e.g., implants, biomaterials, surgical tools, tissue engineering, drug and gene delivery

(c) Technology to Aid Underserved Populations and Individuals with Disabilities e.g., point-of-care technologies, devices/methods to address health disparities, m-health, aids for individuals with disabilities (see *http://www.ada.gov/pubs/adastatute08.htm#12102* for a definition of ''disability'').

The examples under the different categories above are provided for illustration but not limitation. It is possible for an entry to fit into more than one category. In such instances, Student Teams should choose the category to which the entry is most closely related.

7. Each entry must comply with Section 508 standards that require federal agencies' electronic and information technology be accessible to people with disabilities, *http://www.section508.gov/.*

8. Each individual on the Student Team must be 13 years of age or older. Individuals who are younger than 18 must have their parent or legal guardian complete the Parental Consent Form found at *http://cphome.s3.amazonaws.com/forms/parental_consent_form.pdf.*

9. Each entry must be submitted as *a single pdf file* and must include the following:

- Cover letter, on department letterhead, from a faculty member from the Biomedical Engineering, Bioengineering or similar department of the institution in which the Student Team members are enrolled, verifying that the entry was achieved by the named Student Team that is enrolled full-time in an undergraduate curriculum during the academic year 2012–2013, and describing clearly any contribution from the advisor or any

other individual outside the Student Team;

• The NIBIB DEBUT Challenge Certification Form (downloadable from *http://www.nibib.nih.gov/Training/Undergrad_Grad/DEBUT/NIBIB_DEBUT_Certification_Form.pdf*) completed with dates and the printed names and signatures of each individual member of the Student Team;

• Completed Cover Page (downloadable from *http://www.nibib.nih.gov/Training/Undergrad_Grad/DEBUT/NIBIB_DEBUT_Cover_Page.doc* listing project title, team member information, and challenge category the entry is submitted under;

• Project Description (not to exceed 6 pages using Arial font and a font size of at least 11 points) that includes the following 4 sections:

(1) Abstract

(2) Description of clinical need or problem, including background and current methods available

(3) Design, including a discussion of the innovative aspects

(4) Evidence of a working prototype (results/graphics obtained with the designed solution)

The 6-page limit includes any graphics, but excludes the cover page and any references. Submissions exceeding 6 pages for the project description will not be accepted. An optional 2-minute video displaying the operation of the device/method may be included. However the 6-page Project Description must be a stand-alone explanation of the project; and

• A completed Parental Consent Form, accessible at *http://cphome.s3.amazonaws.com/forms/parental_consent_form.pdf,* for each individual on the Student Team who is under the age of 18.

10. NIBIB will claim no rights to intellectual property. Individuals on the Student Team will retain intellectual property ownership as applicable arising from their entry. By participating in this challenge, such individuals grant to NIBIB an irrevocable, paid-up, royalty-free, nonexclusive worldwide license to post, link to, share, and display publicly the entry on the Web, in newsletters or pamphlets, and in other information products. It is the responsibility of the individuals on the Student Team to obtain any rights necessary to use, disclose, or reproduce any intellectual property owned by third parties and incorporated in the entry for all anticipated uses of the entry.

11. All entries must be submitted by the challenge deadline, June 6, 2013, 11:59 p.m. EST.

12. Entries must not infringe upon any copyright or any other rights of any third party.

13. By participating in this challenge, each individual agrees to assume any and all risks and waive claims against the federal government and its related entities, except in the case of willful misconduct, for any injury, death, damage, or loss of property, revenue, or profits, whether direct, indirect, or consequential, arising from participation in this prize challenge, whether the injury, death, damage, or loss arises through negligence or otherwise.

14. Based on the subject matter of the challenge, the type of work that it will possibly require, as well as an analysis of the likelihood of any claims for death, bodily injury, property damage, or loss potentially resulting from challenge participation, individuals are not required to obtain liability insurance or demonstrate financial responsibility in order to participate in this challenge.

15. By participating in this challenge, each individual agrees to indemnify the federal government against third party claims for damages arising from or related to challenge activities.

16. An individual shall not be deemed ineligible because the individual used federal facilities or consulted with federal employees during this challenge if the facilities and employees are made available to all individuals participating in the challenge on an equitable basis.

Prize: One winning Student Team will be selected for each of the three challenge categories. The winning Student Team in each category will be awarded a $10,000 prize, to be distributed among the members of the Student Team. The prize will be distributed equally among the Student Team. Each member of the winning Student Teams must provide his/her bank information to enable electronic transfer of funds. Two honorable mentions will also be awarded in each challenge category, without any accompanying monetary prize or travel reimbursement.

Winning Student Teams will be honored at the NIBIB DEBUT Award Ceremony during the 2013 Annual Meeting of the Biomedical Engineering Society (BMES) in Seattle, Washington, in September 2013. Updated information on the BMES annual meeting can be found at *http://bmes.org/annualmeeting.* Each winning Student Team will receive, in addition to the prize, up to $2,000 toward the travel and registration costs for the members of the Student Team to attend the award ceremony. Travel must comply with National Institutes of Health policy and applicable laws and regulations (*http://oma.od.nih.gov/manualchapters/management/1500/*), for example:

—Air travel must be by coach class, unless an alternative is medically necessary and documented.

—If you choose to drive to the meeting instead of taking a common carrier (airplane, train or bus), you may be reimbursed at 51 cents per mile, not to exceed the cost of common carrier.

—Limousine/taxi reimbursements are provided to and from airports as well as to and from meetings. Receipts are required whenever a fare exceeds $75 per trip.

—Per diem rates include lodging, meals, and incidental expenses (M&IE). Reimbursement for these varies by city. The current allowable room rate and the M&IE for the award ceremony location can be found at *http://www.gsa.gov/portal/category/21287.*

Honorable mention awardees are welcome to attend the award ceremony with funds from other sources; NIBIB will not provide travel reimbursement for Student Teams awarded with Honorable Mention.

Basis Upon Which Winner Will Be Selected: The winning entry in each category of the challenge will be selected based on the following criteria:

• Significance of the problem addressed—Does the entry address an important problem or a critical barrier to progress in clinical care or research?

• Impact on potential users and clinical care—How likely is it that the entry will exert a sustained, powerful influence on the problem and medical field addressed?

• Innovative design (creativity and originality of concept)—Does the entry utilize novel theoretical concepts, approaches or methodologies, or instrumentation?

• Working prototype that implements the design concept and produces targeted results—Has evidence been provided (in the form of results, graphs, photographs, films, etc.) that a working prototype has been achieved?

The above four criteria will be weighed equally and will apply to all challenge categories. *Additional Information:* For more information and to submit entries, visit *http://debut2013.challenge.gov/.*

The NIBIB prize-approving official will be the Director of NIBIB. Prizes will be paid using electronic funds transfer and may be subject to federal income taxes. NIH will comply with the Internal Revenue Service (IRS) withholding and reporting requirements, where applicable.

Dated: January 17, 2013.

Lawrence A. Tabak,

Deputy Director, National Institutes of Health.

[FR Doc. 2013–01433 Filed 1–24–13; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Center for Substance Abuse Prevention; Notice of Meeting

Pursuant to Public Law 92–463, notice is hereby given that the Substance Abuse and Mental Health Services Administration's (SAMHSA) Center for Substance Abuse Prevention (CSAP) Drug Testing Advisory Board (DTAB) will meet on February 11, 2013, from 10:30 a.m. to 4:30 p.m. and February 12, 2013, from 9:00 a.m. to 2:00 p.m. E.S.T. The DTAB will convene in both open and closed sessions over these two days.

On February 11, 2013, from 10:30 a.m. to 4:30 p.m., the meeting will be open to the public and will include updates on the proposed revisions to the Mandatory Guidelines for Federal Workplace Drug Testing Programs, the custody and control form, and the medical review officer certification. The meeting also will include federal drug testing updates from the Department of Transportation, the Department of Defense, the Nuclear Regulatory Commission, and the Federal Drug-Free Workplace Programs.

The public is invited to attend the open session in person or to listen via teleconference. Due to the limited seating space and call-in capacity, registration is requested. Public comments are welcome. To register, make arrangements to attend, obtain the teleconference call-in numbers and access codes, submit written or brief oral comments, or request special accommodations for persons with disabilities, please register at the SAMHSA Advisory Committee's Web site at *http://nac.samhsa.gov/Registration/meetingsRegistration.aspx* or contact the CSAP DTAB Designated Federal Official, Dr. Janine Denis Cook (see contact information below).

On February 12, 2013, between 9:00 a.m. and 2:00 p.m., the Board will meet in closed session to discuss proposed revisions to the Mandatory Guidelines for Federal Workplace Drug Testing Programs. Therefore, this portion of the meeting is closed to the public as determined by the Administrator, SAMHSA, in accordance with 5 U.S.C. 552b(c)(9)(B) and 5 U.S.C. App. 2, Section 10(d).

Meeting information and a roster of DTAB members may be obtained by accessing the SAMHSA Advisory Committee's Web site, *http://www.nac.samhsa.gov/DTAB/meetings.aspx,* or by contacting Dr. Cook.

Committee Name: Substance Abuse and Mental Health Services Administration's Center for Substance Abuse Prevention, Drug Testing Advisory Board.

Dates/Time/Type: February 11, 2013, from 10:30 a.m. to 4:30 p.m. E.S.T.: Open; February 12, 2013, from 9:00 a.m. to 2:00 p.m. E.S.T.: Closed.

Place: Sugarloaf Conference Room, SAMHSA Office Building, 1 Choke Cherry Road, Rockville, Maryland 20857.

Contact: Janine Denis Cook, Ph.D., Designated Federal Official, CSAP Drug Testing Advisory Board, 1 Choke Cherry Road, Room 7–1043, Rockville, Maryland 20857, *Telephone:* 240–276–2600, *Fax:* 240–276–2610, *Email: janine.cook@samhsa.hhs.gov.*

Janine Denis Cook,

Designated Federal Official, DTAB, Division of Workplace Programs, Center for Substance Abuse Prevention, Substance Abuse and Mental Health Services Administration.

[FR Doc. 2013–01477 Filed 1–24–13; 8:45 am]

BILLING CODE 4162–20–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[Docket No. USCG–2012–1091]

Availability of Draft Environmental Assessment for the Proposed Modification of the Bayonne Bridge Across the Kill Van Kull Between Bayonne, Hudson County, NJ and Staten Island, Richmond County, NY

AGENCY: Coast Guard, DHS.

ACTION: Notice of availability extending comment period and notice of third public meeting.

SUMMARY: This notice extends the public comment period on a Draft Environmental Assessment (Draft EA) which examines the reasonably foreseeable environmental impacts and socio-economic impacts of the proposed modification of the historic Bayonne Bridge across the Kill Van Kull between Bayonne, New Jersey and Staten Island, New York. This notice also announces a third public meeting, in Newark, NJ, on this Draft EA. Because the Bayonne Bridge is a structure over navigable waters of the United States, the proposed bridge modification would require a Coast Guard Bridge Permit Amendment. This notice provides information on how to participate in the public comment process for the Draft EA, which includes an opportunity to submit oral or written comments at three public meetings to consider an application by the Port Authority of New York & New Jersey (PANYNJ) for Coast Guard approval of the modification to the Bayonne Bridge across the Kill Van Kull.

DATES: Written comments and related material may be submitted to our online docket via *http://www.regulations.gov* on or before March 5, 2013, or must reach the Docket Management Facility by that date.

The public meetings will be held on February 5, 2013, in Bayonne, NJ, February 7, 2013, in Staten Island, NY, and February 13, 2013, in Newark, NJ (see the Background and Purpose section below for more details). As previously noted for the first two meetings, any requests for an oral or sign language interpreter must be received by January 25, 2013. Such requests for the February 13, 2013 meeting in Newark, NJ, must be received by February 1, 2013.

ADDRESSES: You may submit comments identified by docket number USCG–2012–1091 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.

We have provided a copy of the Draft EA (document USCG–2012–1091–0002) in our online docket at *http://www.regulations.gov.* Also, the Coast Guard First District Bridge Office at 1 South Street Bldg 1, New York, NY 10004–1466 will maintain a printed copy of the Draft EA for public review. The document will be available for inspection at this location between 8 a.m. and 4 p.m., Monday through Friday, except Federal holidays. The document will also be available for

inspection in the locations shown in the section below titled ''Viewing the comments and the Draft EA.''

FOR FURTHER INFORMATION CONTACT: If you have questions on this notice or the public meetings, call or email Christopher Bisignano, Bridge Management Specialist, First Coast Guard District, U.S. Coast Guard; telephone 212–668–7165, email *Christopher.J.Bisignano@uscg.mil.* If you have questions on viewing or submitting material to the docket, call Docket Operations at 202–366–9826.

Authority: The Draft Environmental Assessment has been prepared in accordance with the National Environmental Policy Act (NEPA) (42 United States Code (U.S.C.) 4321 et. seq.); Council on Environmental Quality (CEQ) Regulations for Implementing NEPA (40 Code of Federal Regulations (CFR) 1500–1508) and associated CEQ guidelines; Department of Homeland Security Management Directive 5100.1, Environmental Planning Program; and United States Coast Guard (USCG) Commandant Instruction (COMDTINST) M16475.1D, National Environmental Policy Act Implementing Procedures and Policy for Considering Environmental Impacts.

SUPPLEMENTARY INFORMATION: On January 4, 2013, the Coast Guard published a notice in the **Federal Register** announcing the availability of the Draft EA, inviting comments on it, and announcing the dates and locations of two public meetings on the Draft EA (78 FR 740). This notice supplements that earlier notice by extending the comment period to March 5, 2013, and it announces a third public meeting to be held February 13, 2013, in Newark, NJ. Please note that it is the U.S. Coast Guard Office of Bridge Programs' policy to provide 30 days of notice prior to holding a public meeting; however, due to extenuating circumstances, that policy is being waived for the third public meeting in Newark, NJ.

Public Participation and Request for Comments

We encourage you to submit comments and related material on the Draft EA. All comments received, including comments received at the public meeting, 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 notice (USCG–2012–1091) and provide a reason for each suggestion or recommendation. You may submit your comments and material online, or by fax, mail or hand delivery, but please use only one of these means. We recommend that you include your name and a mailing address, an email address, or a 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,* insert ''USCG–2012–1091'' in the Search box, press Enter, and then look for this notice in the docket and click the Comment button next to it. If you submit your comments by mail or hand delivery, submit them in an unbound format, no larger than 8½ by 11 inches, suitable for copying and electronic filing. If you submit them by mail and would like to know that they reached the Facility, please enclose a stamped, self-addressed postcard or envelope. We will consider all comments and material received during the comment period.

Viewing the comments and the Draft EA: To view the comments and Draft EA go to *http://www.regulations.gov,* insert ''USCG–2012–1091'' in the Search box, press Enter, then click on the ''Open Docket Folder'' option. If you do not have access to the Internet, you may view the docket online by visiting the Docket Management Facility in Room W12–140 on the ground floor of the Department of Transportation West Building, 1200 New Jersey Avenue SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. We have an agreement with the Department of Transportation to use the Docket Management Facility. The Draft EA is also available online at *http://www.uscg.mil/d1/prevention/Bridges.asp, www.dhs.gov/nepa,* and *http://www.panynj.gov/bayonnebridge/,* and is available 10 a.m.–3 p.m., Monday through Friday (except Federal holidays and as noted below), for inspection at the following locations:

1. U.S. Coast Guard Battery Bldg, 1 South Street, Building 1, New York, NY 10004
2. U.S. Coast Guard Sector New York, 212 Coast Guard Drive, Staten Island, NY 10305
3. Bayonne City Hall, 630 Avenue C, Bayonne, NJ 07002
4. Staten Island Borough Hall, 10 Richmond Terrace, Room 100, Staten Island, NY 10301
5. Bayonne Public Library, 630 Avenue C, Bayonne, NJ 07002 (Also available from 12 p.m.–5 p.m. on Saturdays)
6. Port Richmond—NY Public Library, 75 Bennett Street, Staten Island, NY 10302 (Also available 12 p.m.–5 p.m. on Thursdays and Saturdays)
7. Ironbound Community Corp, 317 Elm Street, Newark, NJ 07105
8. New York Assembly District 61, 853 Forest Avenue, Staten Island, NY 10301
9. New Jersey Legislative District 31, 447 Broadway, Bayonne, NJ 07002
10. New York City Council District 49, 130 Stuyvesant Place, Staten Island, NY 10301
11. Staten Island Community Board 1, 1 Edgewater Plaza, Room 217, Staten Island, NY 10305

Copies of all written communications from the public meetings will be available for review by interested persons on the online docket, USCG–2012–1091 via *http://www.regulations.gov.*

Transcripts of the meetings will be available for public review approximately 30 days after the meetings. All comments will be made part of the official case record.

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, system of records notice regarding our public dockets in the January 17, 2008, issue of the **Federal Register** (73 FR 3316).

Background and Purpose

Port Authority of New York and New Jersey (PANYNJ) has proposed to modify the Bayonne Bridge across navigable waters of the United States by raising the roadway thereby increasing the vertical navigational clearance from approximately 151 feet to 215 feet at Mean High Water. A thorough description of the project and how it would be completed can be found at the project's Web site: *http://www.panynj.gov/bayonnebridge/.*

The proposed bridge modification project has been identified as a significant project under ''Implementing Executive Order 13604 on Improving Performance of Federal Permitting and Review of Infrastructure Projects: A Federal Plan for Modernizing the Federal Permitting and Review Process for Better Projects, Improved Environmental and Community Outcomes, and Quicker Decisions,'' dated June 2012, which requires agencies to identify and expedite the permitting and environmental review process for regionally or nationally significant infrastructure projects. The existing Bayonne Bridge has a vertical navigational clearance of approximately 151 feet above the Kill Van Kull at Mean High Water. The applicant proposes to

increase the vertical navigational clearance to approximately 215 feet above the waterway at Mean High Water to provide greater clearances to accommodate larger, Post-Panamax vessels and thereby ensure the long-term viability of the Port of New York and New Jersey. Post-Panamax vessels are wider and taller ships with deeper drafts that will be able to traverse through the Panama Canal once improvements on the canal are completed in 2014. The expanded purpose of the project is to improve the substandard features and seismic stability of the existing bridge and ensure it conforms to modern highway and structural design standards. In addition, the existing bridge is eligible for listing on the National Register of Historic Places. Therefore, the Coast Guard has initiated consultation under Section 106 of the National Historic Preservation Act. The Advisory Council on Historic Preservation has accepted the Coast Guard invitation to participate in the Section 106 process.

The Coast Guard issued the NEPA Workplan, dated September 2011, which provided a discussion of the project's Purpose and Need, project alternatives and the framework of the environmental analysis. On October 31, 2011, the Coast Guard held a coordination meeting with city, state and federal agencies to discuss the project's scope and the NEPA Workplan. On November 14, 2011, the Coast Guard issued a solicitation requesting comments from the general public for the scope of the project and the NEPA Workplan. Comments received following the meeting and during the solicitation comment period included concerns from the U.S. Federal Highway Administration, U.S. Environmental Protection Agency, various private organizations and individuals, and others regarding additional cargo volumes due to larger ships entering the Port of New York and New Jersey, the expansion of the port and port facilities, and the related impacts to air quality and traffic. In response to these comments, an Induced Demand Analysis was conducted by an independent source to study the impact of the proposed action to those communities surrounding the Port of New York and New Jersey. Further information regarding this analysis can be found in Chapter 18 of the Draft EA and in Appendix I. In addition, the Coast Guard met with representatives from minority and low income communities in Staten Island, NY and Newark, NJ to explain the Coast Guard bridge permit process and to ensure those communities have a voice in the public comment process. Based on the information received to date, the Coast Guard has determined that a Draft Environmental Assessment is the most appropriate level of environmental documentation for this project. Should the Coast Guard determine that there are no significant impacts following the comment period; a Finding of No Significant Impact would be issued. Under NEPA procedures, should significant impacts be discovered during the review process, the level of environmental documentation may be elevated to an Environmental Impact Statement. The Draft EA and appendices, Coast Guard NEPA Workplan dated September 2011, ''Bayonne Bridge Navigational Clearance Program Responses to Scoping Comments NEPA Workplan,'' dated February 2012, are available online in the *www.regulations.gov* docket as well as at *http://www.uscg.mil/d1/prevention/Bridges.asp.*

Alternatives for the proposed project considered include: (1) Taking no action; (2) various build alternatives that satisfy the purpose and need; (3) a tunnel; (4) new cargo terminals constructed downstream of the Bayonne Bridge; and (5) a ferry service in lieu of the bridge. Build alternatives included raising the roadway within the existing superstructure (preferred), jacking the arch superstructure, converting to a lift bridge, or constructing a new bridge.

As a structure over navigable waters of the United States, it requires a Coast Guard Bridge Permit Amendment pursuant to the Bridge Act of March 23, 1906, as amended, Title 33 U.S.C. 491. Additionally, the bridge permit amendment would be the major federal action in this undertaking since federal funds will not be used, and therefore the Department of Homeland Security, through the Coast Guard is the federal lead agency for review of potential effects on the human environment, including historic properties, pursuant to the National Environmental Policy Act of 1969 (NEPA), as amended (42 U.S.C. 4321 et seq.) and the National Historic Preservation Act (NHPA), as amended (16 U.S.C. 470 et seq.).

The Coast Guard, with assistance from PANYNJ, has prepared a Draft EA in accordance with NEPA. See ''Viewing the comments and Draft EA'' above. The Draft EA identifies and examines the reasonable alternatives (including ''No Build'') and assesses the potential for impact to the human environment, including historic properties, of the alternative proposals.

We are seeking public input on the Draft EA, including comments on completeness and adequacy of the document, and on other environmental and historic preservation concerns that may be related to the proposed bridge modification project. This includes suggesting analyses and methodologies for use in the Draft EA or possible sources of data or information not included in the Draft EA. Your comments will be considered while making the decision to prepare a final Environmental Assessment, or elevate the document to an Environmental Impact Statement.

Public Meetings

The Coast Guard will hold three public meetings on the Draft EA, one in Bayonne, NJ, one in Staten Island, NY, and one in Newark, NJ to provide an opportunity for oral comments. The specific times and locations are as follows:

1. The first public meeting will be held on Tuesday, February 5, 2013, from 4 p.m.–9 p.m. at Bayonne High School Auditorium, 669 Avenue A (30th Street and Avenue A Entrance), Bayonne, NJ 07002.

2. The second public meeting will be held on Thursday, February 7, 2013, from 4 p.m.–9 p.m. at Snug Harbor Cultural Center Great Hall, 1000 Richmond Terrace, Building P, 2nd Floor, Staten Island, NY 10301.

3. The third public meeting will be held on Wednesday, February 13, 2013, from 4 p.m. to 9 p.m. at LeRoy Smith Public Safety Building, 60 Nelson Place, 14th Floor Conference Room, Newark, NJ 07102.

The Coast Guard and PANYNJ will make brief presentations at 4 p.m. and 7 p.m. at each meeting to accommodate the differing schedules of those wishing to attend. The purpose of these meetings is to consider an application by the PANYNJ for Coast Guard approval of the modification to the historic Bayonne Bridge across the Kill Van Kull, mile 1.5, between Bayonne, NJ and Staten Island, NY. All interested persons may present data, views, and comments, orally or in writing, concerning the impact of the proposed bridge project on navigation and the human environment.

The public meetings will be informal. A representative of the Coast Guard will preside, make a brief opening statement and announce the procedure to be followed at the meetings. Attendees who request an opportunity to present oral comments at a public meeting must sign up to speak at the meeting site at the designated time of the meeting. Speakers will be called in the order of receipt of the request. Attendees at the meetings, who wish to present testimony, and have not previously

made a request to do so, will follow those having submitted a request, as time permits. All oral presentations will be limited to three minutes. The public meetings may end early if all present wishing to speak have done so. Any oral comments provided at the meetings will be transcribed and placed into the docket by the Coast Guard. Written comments and related material may also be submitted to Coast Guard personnel specified at that meeting for placement into the docket by the Coast Guard.

Information on Service for Individuals With Disabilities

For information on facilities or services for individuals with disabilities or to request special assistance at the public meeting, contact Christopher Bisignano, Bridge Management Specialist, First Coast Guard District, U.S. Coast Guard; at the telephone number or email address indicated under the **FOR FURTHER INFORMATION CONTACT** section of this notice. As previously noted for the first two meetings, any requests for an oral or sign language interpreter must be received by January 25, 2013. Such requests for the February 13, 2013 meeting in Newark, NJ, must be received by February 1, 2013.

This notice is issued under the authority of 5 U.S.C. 552(a). Additionally, the draft EA has been prepared in accordance with the Bridge Act of March 23, 1906, as amended, Title 33 U.S.C. 491 and the National Environmental Policy Act (NEPA) (42 U.S.C. 4321 et. seq.); Council on Environmental Quality (CEQ) Regulations for Implementing NEPA (40 Code of Federal Regulations (CFR) 1500–1508) and associated CEQ guidelines; Department of Homeland Security Management Directive 5100.1, Environmental Planning Program; and United States Coast Guard (USCG) Commandant Instruction (COMDTINST) M16475.1D, National Environmental Policy Act Implementing Procedures and Policy for Considering Environmental Impacts.

Dated: January 18, 2013.

Brian L. Dunn,

Administrator, Office of Bridge Programs, U.S. Coast Guard.

[FR Doc. 2013–01502 Filed 1–24–13; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[USCG–2013–0029]

Great Lakes Pilotage Advisory Committee

AGENCY: Coast Guard, DHS.

ACTION: Committee Management; Notice of Federal Advisory Committee Meeting.

SUMMARY: The Great Lakes Pilotage Advisory Committee (GLPAC) will meet on February 11, 2013, in Cleveland, Ohio. The meeting will be open to the public.

DATES: GLPAC will meet on Monday, February 11, 2013, from 12:30 p.m. to 3:30 p.m. Please note the meeting may close early if the committee completes its business. Written material and requests to make oral presentations should reach us on or before February 8, 2012.

ADDRESSES: The meeting will be held at Coast Guard District 9 Headquarters, 1240 East 9th Street, Cleveland, Ohio 44199, in conference room 1629. All visitors to Coast Guard District 9 Headquarters will have to pre-register to be admitted to the building. Please provide your name, telephone number and organization by close of business on February 8, 2013, to the contact person listed in **FOR FURTHER INFORMATION CONTACT** below. Additionally, all visitors to Coast Guard District 9 Headquarters must produce valid photo identification for access to the facility.

For information on facilities or services for individuals with disabilities or to request special assistance at the meeting, contact the person listed in **FOR FURTHER INFORMATION CONTACT** below as soon as possible.

To facilitate public participation, we are inviting public comment on the issues to be considered by the committee as listed in the ''Agenda'' section below. Comments must be submitted in writing no later than February 8, 2013, and must be identified by [USCG–2013–0029] and may be submitted by *one* of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Fax:* 202–493–2251.
- *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.
- *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.

Instructions: All submissions received must include the words ''Department of Homeland Security'' and the docket number for this action. Comments received will be posted without alteration at *http://www.regulations.gov,* including any personal information provided. You may review a Privacy Act notice regarding our public dockets in the January 17, 2008, issue of the **Federal Register** (73 FR 3316).

Docket: For access to the docket to read documents or comments related to this notice, go to *http://www.regulations.gov,* and use ''USCG–2013–0029'' as your search term.

A public comment period of up to one hour will be held during the meeting on February 11, 2013, after the committee completes its work on the agenda given under **SUPPLEMENTARY INFORMATION**. Speakers are requested to limit their comments to 5 minutes. Please note that the public comment period may end before the hour allotted, following the last call for comments. Contact the individual listed below to register as a speaker.

FOR FURTHER INFORMATION CONTACT: Mr. David Dean, GLPAC Alternate Designated Federal Officer (ADFO), Commandant (CG–5522), U.S. Coast Guard Headquarters, 2100 Second Street SW., Stop 7580, Washington, DC 20593–7580; telephone 202–372–1533, fax 202–372–1914, or email at *David.J.Dean@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: Notice of this meeting is given under the *Federal Advisory Committee Act,* 5 U.S.C. App. (Pub. L. 92–463). GLPAC was established under the authority of 46 U.S.C. 9307, and makes recommendations to the Secretary of Homeland Security and the Coast Guard on matters relating to Great Lakes pilotage, including review of proposed Great Lakes pilotage regulations and policies.

GLPAC expects to meet at least once more this year at the conclusion of the comprehensive pilotage study mentioned in the agenda below. Further information about GLPAC is available by searching on ''Great Lakes Pilotage Advisory Committee'' at *http://www.faca.gov.* Agenda

The GLPAC will meet to review, discuss and formulate recommendations on the following issues:

2013/2014 Appendix A rulemakings which establishes the rates that pilots can charge industry for their services.

Memorandum of Arrangements between the U.S. and Canada concerning definitions and procedures for pilotage in the shared waters of the Great Lakes.

Establishing a permanent split of St. Lawrence River pilotage assignments through a change point at Iroquois Lock.

Status of vacant ratemaking position in Great Lakes Pilotage Division.

Status of Great Lakes Pilotage Division office location.

Presentation and discussion of the latest draft of the comprehensive pilotage study; a copy of the draft study is posted to the electronic docket. Please see instructions below for access.

This will be followed by a public comment period of up to one hour. Speakers are requested to limit their comments to 5 minutes.

More detailed information and materials relating to these issues appear in the docket, including a copy of the draft pilotage study, at *http://www.regulations.gov.* Use ''USCG–2013–0029'' as your search term.

Dated: January 18, 2013.

D.A. Goward,

Director Marine Transportation Systems, U.S. Coast Guard.

[FR Doc. 2013–01563 Filed 1–24–13; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–4099–DR; Docket ID FEMA–2013–0001]

Pennsylvania; Amendment No. 1 to Notice of a Major Disaster Declaration

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This notice amends the notice of a major disaster declaration for the Commonwealth of Pennsylvania (FEMA–4099–DR), dated January 10, 2013, and related determinations.

DATES: *Effective Date:* January 17, 2013.

FOR FURTHER INFORMATION CONTACT: Dean Webster, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW., Washington, DC 20472, (202) 646–2833.

SUPPLEMENTARY INFORMATION: The notice of a major disaster declaration for the Commonwealth of Pennsylvania is hereby amended to include the following area among those areas determined to have been adversely affected by the event declared a major disaster by the President in his declaration of January 10, 2013.

Montgomery County for Public Assistance, including direct federal assistance.

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households in Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050 Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

W. Craig Fugate,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2013–01548 Filed 1–24–13; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–4099–DR; Docket ID FEMA–2013–0001]

Pennsylvania; Major Disaster and Related Determinations

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This is a notice of the Presidential declaration of a major disaster for the Commonwealth of Pennsylvania (FEMA–4099–DR), dated January 10, 2013, and related determinations.

DATES: *Effective Date:* January 10, 2013.

FOR FURTHER INFORMATION CONTACT: Dean Webster, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW., Washington, DC 20472, (202) 646–2833.

SUPPLEMENTARY INFORMATION: Notice is hereby given that, in a letter dated January 10, 2013, the President issued a major disaster declaration under the authority of the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121 *et seq.* (the ''Stafford Act''), as follows:

I have determined that the damage in certain areas of the Commonwealth of Pennsylvania resulting from Hurricane Sandy during the period of October 26 to November 8, 2012, is of sufficient severity and magnitude to warrant a major disaster declaration under the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121 et seq. (the ''Stafford Act''). Therefore, I declare that such a major disaster exists in the Commonwealth of Pennsylvania.

In order to provide Federal assistance, you are hereby authorized to allocate from funds available for these purposes such amounts as you find necessary for Federal disaster assistance and administrative expenses.

You are authorized to provide Public Assistance in the designated areas and Hazard Mitigation throughout the Commonwealth. Direct Federal assistance is authorized. Consistent with the requirement that Federal assistance is supplemental, any Federal funds provided under the Stafford Act for Public Assistance and Hazard Mitigation will be limited to 75 percent of the total eligible costs.

Further, you are authorized to make changes to this declaration for the approved assistance to the extent allowable under the Stafford Act.

The Federal Emergency Management Agency (FEMA) hereby gives notice that pursuant to the authority vested in the Administrator, under Executive Order 12148, as amended, Thomas J. McCool, of FEMA is appointed to act as the Federal Coordinating Officer for this major disaster.

The following areas of the Commonwealth of Pennsylvania have been designated as adversely affected by this major disaster:

Bedford, Bucks, Cameron, Dauphin, Forest, Franklin, Fulton, Huntingdon, Juniata, Monroe, Northampton, Pike, Potter, Somerset, Sullivan, and Wyoming Counties for Public Assistance. Direct federal assistance is authorized.

All counties within the Commonwealth of Pennsylvania are eligible to apply for assistance under the Hazard Mitigation Grant Program.

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households in Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050, Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance

(Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

W. Craig Fugate,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2013–01545 Filed 1–24–13; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–4097–DR; Docket ID FEMA–2012–0002]

Massachusetts; Major Disaster and Related Determinations

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This is a notice of the Presidential declaration of a major disaster for the Commonwealth of Massachusetts (FEMA–4097–DR), dated December 19, 2012, and related determinations.

DATES: *Effective Date:* December 19, 2012.

FOR FURTHER INFORMATION CONTACT: Peggy Miller, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW., Washington, DC 20472, (202) 646–3886.

SUPPLEMENTARY INFORMATION: Notice is hereby given that, in a letter dated December 19, 2012, the President issued a major disaster declaration under the authority of the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121 *et seq.* (the ''Stafford Act''), as follows:

I have determined that the damage in certain areas of the Commonwealth of Massachusetts resulting from Hurricane Sandy during the period of October 27 to November 8, 2012, is of sufficient severity and magnitude to warrant a major disaster declaration under the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121 et seq. (the ''Stafford Act''). Therefore, I declare that such a major disaster exists in the Commonwealth of Massachusetts.

In order to provide Federal assistance, you are hereby authorized to allocate from funds available for these purposes such amounts as you find necessary for Federal disaster assistance and administrative expenses.

You are authorized to provide Public Assistance in the designated areas and Hazard Mitigation throughout the Commonwealth. Direct Federal assistance is authorized. Consistent with the requirement that Federal assistance is supplemental, any Federal funds provided under the Stafford Act for Public Assistance and Hazard Mitigation will be limited to 75 percent of the total eligible costs.

Further, you are authorized to make changes to this declaration for the approved assistance to the extent allowable under the Stafford Act.

The Federal Emergency Management Agency (FEMA) hereby gives notice that pursuant to the authority vested in the Administrator, under Executive Order 12148, as amended, James N. Russo, of FEMA is appointed to act as the Federal Coordinating Officer for this major disaster.

The following areas of the Commonwealth of Massachusetts have been designated as adversely affected by this major disaster:

Barnstable, Bristol, Duke, Nantucket, Plymouth, and Suffolk Counties for Public Assistance. Direct federal assistance is authorized.

All counties within the Commonwealth of Massachusetts are eligible to apply for assistance under the Hazard Mitigation Grant Program.

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households in Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050, Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

W. Craig Fugate,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2013–01541 Filed 1–24–13; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–4098–DR; Docket ID FEMA–2013–0001]

Ohio; Major Disaster and Related Determinations

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This is a notice of the Presidential declaration of a major disaster for the State of Ohio (FEMA–4098–DR), dated January 3, 2013, and related determinations.

DATES: *Effective Date:* January 3, 2013.

FOR FURTHER INFORMATION CONTACT: Dean Webster, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW., Washington, DC 20472, (202) 646–2833.

SUPPLEMENTARY INFORMATION: Notice is hereby given that, in a letter dated January 3, 2013, the President issued a major disaster declaration under the authority of the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121 *et seq.* (the ''Stafford Act''), as follows:

I have determined that the damage in certain areas of the State of Ohio resulting from severe storms and flooding due to the remnants of Hurricane Sandy during the period October 29–30, 2012, is of sufficient severity and magnitude to warrant a major disaster declaration under the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121 *et seq.* (the ''Stafford Act''). Therefore, I declare that such a major disaster exists in the State of Ohio.

In order to provide Federal assistance, you are hereby authorized to allocate from funds available for these purposes such amounts as you find necessary for Federal disaster assistance and administrative expenses.

You are authorized to provide Public Assistance in the designated areas and Hazard Mitigation throughout the State. Consistent with the requirement that Federal assistance is supplemental, any Federal funds provided under the Stafford Act for Public Assistance and Hazard Mitigation will be limited to 75 percent of the total eligible costs.

Further, you are authorized to make changes to this declaration for the approved assistance to the extent allowable under the Stafford Act.

The Federal Emergency Management Agency (FEMA) hereby gives notice that pursuant to the authority vested in the Administrator, under Executive Order 12148, as amended, Warren J. Riley, of FEMA is appointed to act as the Federal Coordinating Officer for this major disaster.

The following areas of the State of Ohio have been designated as adversely affected by this major disaster:

Cuyahoga County for Public Assistance.

All counties within the State of Ohio are eligible to apply for assistance under the Hazard Mitigation Grant Program.

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households in Presidentially Declared Disaster Areas; 97.049,

Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050, Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

W. Craig Fugate,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2013–01547 Filed 1–24–13; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Citizenship and Immigration Services

[OMB Control Number 1615–0046]

Agency Information Collection Activities: Inter-Agency Alien Witness and Informant Record, Form I–854, Extension Without Change, of a Currently Approved Collection

ACTION: 60-Day notice.

The Department of Homeland Security, U.S. Citizenship and Immigration Services (USCIS) will be submitting the following information collection request for review and clearance in accordance with the Paperwork Reduction Act of 1995. The information collection is published in the **Federal Register** to obtain comments from the public and affected agencies. Comments are encouraged and will be accepted for 60 days until March 26, 2013.

During this 60 day period, USCIS will be evaluating whether to revise the Form I–854. Should USCIS decide to revise Form I–854 we will advise the public when we publish the 30-day notice in the **Federal Register** in accordance with the Paperwork Reduction Act. The public will then have 30 days to comment on any revisions to the Form I–854.

Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the Department of Homeland Security (DHS), USCIS, Office of Policy and Strategy, Laura Dawkins, Chief, Regulatory Coordination Division, 20 Massachusetts Avenue NW., Washington, DC 20529–2140. Comments may be submitted to DHS via email at *uscisfrcomment@uscis.dhs.gov* and must include OMB Control Number 1615–0046 in the subject box. Comments may also be submitted via the Federal eRulemaking Portal at *www.Regulations.gov* under e-Docket ID number USCIS–2006–0062.

All submissions received must include the agency name and Docket ID. Regardless of the method used for submitting comments or material, all submissions will be posted, without change, to the Federal eRulemaking Portal at *http://www.regulations.gov,* and will include any personal information you provide. Therefore, submitting this information makes it public. You may wish to consider limiting the amount of personal information that you provide in any voluntary submission you make to DHS. DHS may withhold information provided in comments from public viewing that it determines may impact the privacy of an individual or is offensive. For additional information, please read the Privacy Act notice that is available via the link in the footer of *http://www.regulations.gov.*

(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 agencies 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 submission of responses.

Overview of This Information Collection

(1) *Type of Information Collection:* Extension without Change, of a currently approved information collection.

(2) *Title of the Form/Collection:* Inter-Agency Alien Witness and Informant Record.

(3) *Agency form number, if any, and the applicable component of the Department of Homeland Security sponsoring the collection:* Form I–854. U.S. Citizenship and Immigration Services (USCIS).

(4) *Affected public who will be asked or required to respond, as well as a brief abstract: Primary:* Individuals or Households. Form I–854 is used by law enforcement agencies to bring alien witnesses and informants to the United States in ''S'' nonimmigrant classification.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* 136 responses at 4 hours and 15 minutes per response.

(6) *An estimate of the total public burden (in hours) associated with the collection:* 578 annual burden hours.

If you have additional comments, suggestions, or need a copy of the proposed information collection instrument with instructions, or additional information, please visit the Federal eRulemaking Portal site at: *http://www.regulations.gov.*

We may also be contacted at: USCIS, Office of Policy and Strategy, Regulatory Coordination Division, 20 Massachusetts Avenue NW., Washington, DC 20529–2140, Telephone number 202–272–8377.

Dated: January 18, 2013.

Laura Dawkins,

Chief, Regulatory Coordination Division, Office of Policy and Strategy, U.S. Citizenship and Immigration Services, Department of Homeland Security.

[FR Doc. 2013–01514 Filed 1–24–13; 8:45 am]

BILLING CODE 9111–97–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Citizenship and Immigration Services

[OMB Control Number 1615–0113]

Agency Information Collection Activities: InfoPass System, No Form Number; Extension, Without Change, of a Currently Approved Collection

ACTION: 30-Day notice.

SUMMARY: The Department of Homeland Security (DHS), U.S. Citizenship and Immigration Services (USCIS) will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995. The information collection notice was previously published in the **Federal Register** on October 31, 2012, at 77 FR 65898, allowing for a 60-day public comment period. USCIS did receive 1 comment in connection with the 60-day notice.

DATES: The purpose of this notice is to allow an additional 30 days for public comments. Comments are encouraged and will be accepted until February 25, 2013. This process is conducted in accordance with 5 CFR 1320.10.

ADDRESSES: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, must be directed to the OMB USCIS Desk Officer via email at *oira_submission@omb.eop.gov.* The comments submitted to the OMB USCIS Desk Officer may also be submitted to DHS via the Federal eRulemaking Portal Web site at *http://www.regulations.gov* under e-Docket ID number USCIS–2009–0024 or via email at *uscisfrcomment@uscis.dhs.gov.* All submissions received must include the agency name and the OMB Control Number 1615–0113.

SUPPLEMENTARY INFORMATION:

Comments

Regardless of the method used for submitting comments or material, all submissions will be posted, without change, to the Federal eRulemaking Portal at *www.regulations.gov,* and will include any personal information you provide. Therefore, submitting this information makes it public. You may wish to consider limiting the amount of personal information that you provide in any voluntary submission you make to DHS. For additional information please read the Privacy Act notice that is available via the link in the footer of *www.regulations.gov.*

Note: The address listed in this notice should only be used to submit comments concerning this information collection. Please do not submit requests for individual case status inquiries to this address. If you are seeking information about the status of your individual case, please check ''My Case Status'' online at: *https://egov.uscis.gov/cris/Dashboard.do,* or call the USCIS National Customer Service Center at 1–800–375–5283.

Written comments and suggestions from the public and affected agencies should address one or more of the following four points:

(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 submission of responses.

Overview of This Information Collection

(1) *Type of Information Collection Request:* Extension, Without Change, of a Currently Approved Collection.

(2) *Title of the Form/Collection:* InfoPass System.

(3) *Agency form number, if any, and the applicable component of the DHS sponsoring the collection:* No Form Number; USCIS.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract: Primary:* Individuals or households. The InfoPass system allows an applicant or petitioner to schedule an interview appointment with USCIS through USCIS' Internet Web site.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* 1,043,319 respondents with an estimated burden of .1 hour per response.

(6) *An estimate of the total public burden (in hours) associated with the collection:* 104,332 hours.

If you need a copy of the information collection instrument with supplementary documents, or need additional information, please visit *http://www.regulations.gov.* We may also be contacted at: USCIS, Office of Policy and Strategy, Regulatory Coordination Division, 20 Massachusetts Avenue NW., Washington, DC 20529–2134; Telephone 202–272–8377.

Dated: January 18, 2013.

Laura Dawkins,

Chief, Regulatory Coordination Division, Office of Policy and Strategy, U.S. Citizenship and Immigration Services, Department of Homeland Security.

[FR Doc. 2013–01515 Filed 1–24–13; 8:45 am]

BILLING CODE 9111–97–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–5690–N–02]

Notice of Revised Information Collection for Public Comment; Public Housing Authority Executive Compensation Information

AGENCY: Office of the Assistant Secretary for Public and Indian Housing, HUD.

ACTION: Notice of Revised Information Collection.

SUMMARY: The revised information collection described below will be submitted to the Office of Management and Budget (OMB) for review, as required by the Paperwork Reduction Act. The Department is soliciting public comments on the subject proposal.

DATES: *Comments Due Date:* March 26, 2013.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name/or OMB Control number and should be sent to: Colette Pollard, Departmental Reports Management Officer, QDAM, Department of Housing and Urban Development, 451 7th Street SW., Room 4160, Washington, DC 20410–5000; telephone 202–402–3400 (this is not a toll-free number) or email Ms. Pollard at *Colette_Pollard@hud.gov.* 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. (Other than the HUD USER information line and TTY numbers, telephone numbers are not toll-free.)

FOR FURTHER INFORMATION CONTACT: Arlette Mussington, Office of Policy, Programs and Legislative Initiatives, PIH, Department of Housing and Urban Development, 451 7th Street SW. (L'Enfant Plaza, Room 2206), Washington, DC 20410; telephone 202–402–4109, (this is not a toll-free number).

SUPPLEMENTARY INFORMATION: The Department is submitting a revision to the proposed information collection to OMB for review, as required by the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 35, as amended). This Notice is soliciting comments from members of the public and affected agencies concerning the revised collection of information to: (1) Evaluate whether the revisions are 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; (3) Enhance the quality, utility, and clarity of the information to be collected; and (4) Minimize the burden of the collection of information on those who are to respond; including the use of appropriate automated collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

This Notice also lists the following information:

Title of Proposal: Public Housing Authority Executive Compensation Information.

OMB Control Number, if applicable: 2577–0272.

Description of the need for the information and proposed use: Pursuant to PIH Notice 2011–48, HUD has been collecting information on the compensation provided by public housing authorities (PHAs) to their five most highly compensated employees, similar to the information that non-profit organizations receiving federal tax exemptions are required to report to the IRS annually. Since PHAs receive significant direct federal funds, such compensation information has been collected by HUD to enhance oversight by HUD and by state and local authorities. After HUD began this information collection, Congress included a provision in its fiscal year 2012 appropriations legislation that placed a specific cap on the use of Section 8 and Section 9 funds to pay the salaries of PHA officials. To obtain information that will help HUD determine PHA compliance with this and future legislation, and to achieve the same overall objectives of the original information collection, HUD is revising the data collection instrument to collect information on base salary, and bonus and incentive compensation, and the extent to which such payments are made with federal funds.

Changes include obtaining data on total cash compensation paid for with Section 8 and Section 9 funds. The new elements replace several segments such as ''Reportable Compensation from PHA and Related Organizations'' and ''Contributions to Employee Benefit Plans and Deferred Compensation from the PHA and Related Organizations''.

Agency form numbers, if applicable: HUD–52725.

Estimation of the total numbers of hours needed to prepare the information collection including number of respondents, frequency of response, and hours of response: The number of burden hours is 1372. The number of respondents is 4116, the number of responses is 4116, the frequency of response is annually, and the burden hour per response is 20 minutes.

Status of the proposed information collection: This is a revised collection.

Authority: The Paperwork Reduction Act of 1995, 44 U.S.C., Chapter 35, as amended.

Dated: January 18, 2013.

Merrie Nichols-Dixon,

Deputy Director, Office of Policy, Program and Legislative Initiatives.

[FR Doc. 2013–01558 Filed 1–24–13; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–5687–N–02]

Notice of Proposed Information Collection: Comment Request; Housing Counseling Training Program

AGENCY: Office of the Assistant Secretary for Housing, HUD.

ACTION: Notice.

SUMMARY: The proposed information collection requirement described below will be submitted to the Office of Management and Budget (OMB) for review, as required by the Paperwork Reduction Act. The Department is soliciting public comments on the subject proposal.

DATES: *Comments Due Date:* March 26, 2013.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB Control Number and should be sent to: Reports Liaison Officer, Department of Housing and Urban Development, 451 7th Street SW., Washington, DC 20410, Room 9120 or the number for the Federal Information Relay Service (1–800–877–8339).

FOR FURTHER INFORMATION CONTACT: Jerrold Mayer, Deputy Director, Office of Outreach and Capacity Building, Office of Housing Counseling, U.S. Department of Housing and Urban Development, Santa Ana Federal Building, 34 Civic Center Plaza, Room 7015, Santa Ana, CA 92701–4003, telephone number (714) 796–1200, extension 3211 (this is not a toll free number).

SUPPLEMENTARY INFORMATION: The Department is submitting the proposed information collection to OMB for review, as required by the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35, as amended).

This Notice is soliciting comments from members of the public and affected agencies concerning the proposed collection of information to: (1) Evaluate whether the proposed collection 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; (3) Enhance the quality, utility, and clarity of the information to be collected; and (4) Minimize the burden of the collection of information on those who are to respond; including the use of appropriate automated collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

This Notice also lists the following information:

Title of Proposal: Housing Counseling Training Program.

OMB Control Number, if applicable: 2502–0567.

Description of the need for the information and proposed use: The Housing Counseling Training NOFA, which requests narrative responses, forms, and supporting documentation, is used by the Department's Office of Housing Counseling to rank applications submitted through Grants.gov. The collection allows HUD to evaluate and select the most qualified applicant(s). Post-award collection, such as quarterly reports, will allow HUD to evaluate grantee performance.

Agency form numbers, if applicable: SF 424, SF 424 Supp, HUD 424CB, SF–LLL, HUD 2880, HUD 96010, HUD 2994a.

Estimation of the total numbers of hours needed to prepare the information collection including number of respondents, frequency of response, and hours of response: The number of burden hours is 963. The number of respondents is 15, the number of responses is 51, the frequency of response is on occasion, and the burden hour per response is 79.14.

Status of the proposed information collection: This is an extension of a currently approved collection.

Authority: The Paperwork Reduction Act of 1995, 44 U.S.C., Chapter 35, as amended.

Dated: January 18, 2013.

Laura M. Marin,

Acting General Deputy Assistant Secretary for Housing—Acting General Deputy Federal Housing Commissioner.

[FR Doc. 2013–01560 Filed 1–24–13; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–5681–N–04]

Federal Property Suitable as Facilities To Assist the Homeless

AGENCY: Office of the Assistant Secretary for Community Planning and Development, HUD.

ACTION: Notice.

SUMMARY: This Notice identifies unutilized, underutilized, excess, and surplus Federal property reviewed by HUD for suitability for possible use to assist the homeless.

FOR FURTHER INFORMATION CONTACT: Juanita Perry, Department of Housing

and Urban Development, 451 Seventh Street SW., Room 7262, Washington, DC 20410; telephone (202) 402–3970; TTY number for the hearing- and speech-impaired (202) 708–2565, (these telephone numbers are not toll-free), or call the toll-free Title V information line at 800–927–7588.

SUPPLEMENTARY INFORMATION: In accordance with the December 12, 1988 court order in *National Coalition for the Homeless* v. *Veterans Administration,* No. 88–2503–OG (D.D.C.), HUD publishes a Notice, on a weekly basis, identifying unutilized, underutilized, excess and surplus Federal buildings and real property that HUD has reviewed for suitability for use to assist the homeless. Today's Notice is for the purpose of announcing that no additional properties have been determined suitable or unsuitable this week.

Dated: January 17, 2013.

Mark Johnston,

Deputy Assistant Secretary for Special Needs.

[FR Doc. 2013–01308 Filed 1–24–13; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[FWS–R2–ES–2012–N240; FXES11150200000–134–FF02ENEH00]

Draft Candidate Conservation Agreement With Assurances and Draft Environmental Assessment; Rio Grande Cutthroat Trout, New Mexico and Colorado

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of availability; request for comment.

SUMMARY: Vermejo Park, LLC, d/b/a Vermejo Park Ranch (Applicant), has applied for an enhancement of survival permit pursuant to Section 10(a)(1)(A) of the Endangered Species Act of 1973, as amended. The permit application includes a draft Candidate Conservation Agreement with Assurances (CCAA) between the U.S. Fish and Wildlife Service (Service) and Vermejo Park Ranch for the Rio Grande cutthroat trout in Taos County, New Mexico, and Costilla County, Colorado. If the Rio Grande cutthroat trout becomes listed in the future, the enhancement of survival permit will become effective, authorizing incidental take of Rio Grande cutthroat trout resulting from ongoing, otherwise lawful activities on enrolled lands. The draft CCAA and the draft environmental assessment are available for public review, and we seek public comment on the potential issuance of the above permit.

DATES: To ensure consideration, please send your written comments by March 26, 2013.

ADDRESSES: Persons wishing to review the application, the draft CCAA, the draft EA, or other related documents may obtain copies by written or telephone request to Field Supervisor, New Mexico Ecological Services Field Office, 505–346–2525 (U.S. mail address below). Electronic copies of these documents are available for review on the New Mexico Ecological Services Field Office Web site: *http://www.fws.gov/southwest/es/NewMexico/.* The application and related documents will be available for public inspection, by appointment only, during normal business hours (8 a.m. to 4:30 p.m.) at the New Mexico Ecological Services Field Office at the address below.

Comments concerning the application, the draft CCAA, the draft EA, or other related documents should be submitted in writing to the Field Supervisor, by U.S. mail at the New Mexico Ecological Services Field Office, U.S. Fish and Wildlife Service, 2105 Osuna NE., Albuquerque, NM 87113; by telephone at 505–346–2525; or by facsimile at 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.

Please refer to Permit number TE72923A–0 when submitting comments. Please specify if comments are in reference to the draft CCAA, draft EA, or both.

FOR FURTHER INFORMATION CONTACT: Wally ''J'' Murphy, Field Supervisor, U.S. Fish and Wildlife Service, New Mexico Ecological Services Field Office, at the address above.

SUPPLEMENTARY INFORMATION: With the assistance of the Service, the Applicant proposes to implement conservation measures for the Rio Grande cutthroat trout by removing threats to its survival and reintroducing it to historically occupied streams. The proposed CCAA would be in effect for 25 years on Vermejo Park Ranch in Taos County, New Mexico, and Costilla County, Colorado. This area constitutes the CCAA's Covered Area. The CCAA has been developed in support of a section 10(a)(1)(A) of the Endangered Species Act (16 U.S.C. 1531 *et seq.*) (Act) enhancement of survival permit.

If approved, Vermejo Park Ranch will be provided assurances that, should the Rio Grande cutthroat trout be listed, the Service will not require them to provide additional land, water, or financial resources, nor will there be any further restrictions to their land, water, or financial resources than they committed to under the CCAA provisions (50 CFR 17.22(d) and 17.32(d)). Furthermore, if the Rio Grande cutthroat trout is listed, participants would be provided incidental take authorization under the enhancement of survival permit for the level of incidental take on the enrolled lands consistent with the activities under the CCAA provisions.

Background

The Rio Grande cutthroat trout (*Oncorhynchus clarkii virginalis*) is native to the Rio Grande, Pecos River, and Canadian River basins in New Mexico and Colorado. It is the southernmost subspecies of cutthroat trout. Because of nonnative species introductions, Rio Grande cutthroat trout are now restricted to streams that are narrow and small compared to the larger streams they once occupied; these populations occupy approximately 10 percent of historical habitat. Rio Grande cutthroat trout face a variety of imminent threats, including fragmentation and isolation, small population size, presence of nonnative trout, whirling disease, poor habitat conditions, fire, drought, and the effects of climate change. Because of the range contraction and the imminent threats, we made the Rio Grande cutthroat trout a candidate species on May 14, 2008 (73 FR 27900), indicating that listing of the Rio Grande cutthroat trout was warranted but precluded by higher priority actions. The species was given a listing priority number of 9, indicating a subspecies facing imminent threats of moderate to low magnitude.

Currently, cooperative efforts are in place to restore this subspecies to the Rio Costilla watershed, where much of the habitat for Rio Grande cutthroat trout exists on private land. The CCAA was initiated in order to facilitate conservation and restoration of the Rio Grande cutthroat trout on private lands in New Mexico. Expected conservation benefits for the Rio Grande cutthroat trout from implementation of the conservation measures in this CCAA will be recognized through additional connected populations being maintained over time.

Furthermore, Rio Grande cutthroat trout conservation will be enhanced by providing regulatory assurances under the Act for the participating property owner. There will be a measure of security for the participating landowner in the knowledge that they will not incur additional land use restrictions if the species is listed under the Act. The

Applicant has committed to implementation of the CCAA and requests issuance of the enhancement of survival permit in order to address the take prohibitions of section 9 of the Act should the species become listed in the future.

The draft CCAA and application for the enhancement of survival permit are not eligible for categorical exclusion under the National Environmental Policy Act (NEPA) of 1969. A draft environmental assessment has been prepared to further analyze the direct, indirect, and cumulative impacts of the CCAA on the quality of the human environment and other natural resources.

Public Availability of Comments

All comments we receive become part of the public record. Requests for copies of comments will be handled in accordance with the Freedom of Information Act, NEPA, and Service and Department of the Interior policies and procedures. 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 to withhold your personal identifying information from public review, we cannot guarantee we will be able to do so.

Authority

We provide this notice under section 10(c) of the Act (16 U.S.C. 1531 *et seq.*) and its implementing regulations (50 CFR 17.22 and 17.32), and the National Environmental Policy Act (42 U.S.C. 4371 *et seq.*) and its implementing regulations (40 CFR part 1506.6).

Joy E. Nicholopoulos,

Acting Regional Director, Region 2, Albuquerque, New Mexico.

[FR Doc. 2013–01573 Filed 1–24–13; 8:45 am]

BILLING CODE 4310–55–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[FWS–HQ–FHC–2013–N008; 94140–1341–0000–N5]

Quagga Mussel Strategic Planning Meeting

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of meeting.

SUMMARY: This notice announces a meeting to gather information for planning an FY13 strategy to minimize the spread of quagga mussels from the Colorado River and a framework for working beyond FY13. Priorities for minimizing the spread of these mussels will be discussed. The meeting is open to the public.

DATES: The meeting is scheduled from 9 a.m. to 4:30 p.m., Wednesday, February 20, 2013.

ADDRESSES: The meeting will take place at the Utah Division of Wildlife, 1594 W North Temple, Salt Lake City, UT 84114.

FOR FURTHER INFORMATION CONTACT: David Britton, Aquatic Invasive Species Coordinator, by telephone at 817–272–3714, or by email to *David_Britton@fws.gov.*

SUPPLEMENTARY INFORMATION:

Background

In FY12, Congress directed the U.S. Fish and Wildlife Service to spend approximately $1,000,000 for implementation of mandatory operational inspection and decontamination stations at Federally managed or interjurisdictional water bodies considered to be of highest risk, as called for in the February 2010 Quagga—Zebra Mussel Action Plan for Western U.S. Waters. The U.S. Fish and Wildlife Service, as is the rest of the Federal government, is currently operating under the Continuing Appropriations Resolution, 2013 (Pub. L 112–175), which provides funding through March 27, 2013. We would like input from partners in order to maximize benefit from actions funded in FY13.

Agenda (Tentative)

9 a.m. Introductions
9:15 a.m. Overview and Background Presentation
9:45 a.m. Group Discussion
Noon Lunch
1 p.m. Group Discussion
4 p.m. Public Comment Period
4:30 p.m. Closeout and Adjourn

Accessibility Information

The meeting location is accessible to wheelchair users. If you require additional accommodations, please notify us at least 1 week in advance of the meeting.

Authority: We publish this notice under the Nonindigenous Aquatic Nuisance Prevention and Control Act of 1990.

Dated: January 17, 2013.

Mike Oetker,

Assistant Regional Director, Fisheries, U.S. Fish and Wildlife Service.

[FR Doc. 2013–01468 Filed 1–24–13; 8:45 am]

BILLING CODE 4310–55–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[FWS–HQ–IA–2013–N013; FXIA16710900000P5–123–FF09A30000]

Endangered Species; Marine Mammals; Receipt of Applications for Permit

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of receipt of applications for permit.

SUMMARY: We, the U.S. Fish and Wildlife Service, invite the public to comment on the following applications to conduct certain activities with endangered species, marine mammals, or both. With some exceptions, the Endangered Species Act (ESA) and Marine Mammal Protection Act (MMPA) prohibit activities with listed species unless Federal authorization is acquired that allows such activities.

DATES: We must receive comments or requests for documents on or before February 25, 2013. We must receive requests for marine mammal permit public hearings, in writing, at the address shown in the **ADDRESSES** section by February 25, 2013.

ADDRESSES: Brenda Tapia, Division of Management Authority, U.S. Fish and Wildlife Service, 4401 North Fairfax Drive, Room 212, Arlington, VA 22203; fax (703) 358–2280; or email *DMAFR@fws.gov.*

FOR FURTHER INFORMATION CONTACT: Brenda Tapia, (703) 358–2104 (telephone); (703) 358–2280 (fax); *DMAFR@fws.gov* (email).

SUPPLEMENTARY INFORMATION:

I. Public Comment Procedures

A. How do I request copies of applications or comment on submitted applications?

Send your request for copies of applications or comments and materials concerning any of the applications to the contact listed under **ADDRESSES**. Please include the **Federal Register** notice publication date, the PRT-number, and the name of the applicant in your request or submission. We will not consider requests or comments sent to an email or address not listed under **ADDRESSES.** If you provide an email address in your request for copies of applications, we will attempt to respond to your request electronically.

Please make your requests or comments as specific as possible. Please confine your comments to issues for which we seek comments in this notice, and explain the basis for your

comments. Include sufficient information with your comments to allow us to authenticate any scientific or commercial data you include.

The comments and recommendations that will be most useful and likely to influence agency decisions are: (1) Those supported by quantitative information or studies; and (2) Those that include citations to, and analyses of, the applicable laws and regulations. We will not consider or include in our administrative record comments we receive after the close of the comment period (see **DATES**) or comments delivered to an address other than those listed above (see **ADDRESSES**).

B. May I review comments submitted by others?

Comments, including names and street addresses of respondents, will be available for public review at the street address listed under **ADDRESSES**. The public may review documents and other information applicants have sent in support of the application unless our allowing viewing would violate the Privacy Act or Freedom of Information Act. 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.

II. Background

To help us carry out our conservation responsibilities for affected species, and in consideration of section 10(a)(1)(A) of the Endangered Species Act of 1973, as amended (16 U.S.C. 1531 *et seq.*), and the Marine Mammal Protection Act of 1972, as amended (16 U.S.C. 1361 *et seq.*), along with Executive Order 13576, ''Delivering an Efficient, Effective, and Accountable Government,'' and the President's Memorandum for the Heads of Executive Departments and Agencies of January 21, 2009—Transparency and Open Government (74 FR 4685; January 26, 2009), which call on all Federal agencies to promote openness and transparency in Government by disclosing information to the public, we invite public comment on these permit applications before final action is taken. Under the MMPA, you may request a hearing on any MMPA application received. If you request a hearing, give specific reasons why a hearing would be appropriate. The holding of such a hearing is at the discretion of the Service Director.

III. Permit Applications

A. Endangered Species

Applicant: Archie Carr Center for Sea Turtle Research, University of Florida, Gainesville, FL; PRT–724540

The applicant requests re-issuance of a permit to import biological samples collected from wild, captive held, and/or captive hatched leatherback sea turtle (*Dermochelys coriacea*), hawksbill sea turtle (*Eretmochelys imbricata*), green sea turtle (*Chelonia mydas*), Kemp's ridley sea turtle (*Lepidochelys kempii*), and olive ridley sea turtle (*Lepidochelys olivacea*) for the purpose of scientific research. Samples are to be collected from live or salvaged specimens. This notification covers activities conducted by the applicant over a 5-year period.

Applicant: University of Oregon, Eugene, OR; PRT–91312A

The applicant requests a permit to import biological samples collected from live captive held mandrills (*Mandrillus sphinx*), drills (*Mandrillus leucophaeus*), and red-eared guenons (*Cercopithecus erythrotis*) from Cameroon for the purpose of scientific research. This notification covers activities to be conducted by the applicant over a 5-year period.

Applicant: Cherane Pefley, Loxahatchee Groves, FL; PRT–94164A

The applicant requests a captive-bred wildlife registration under 50 CFR 17.21(g) for the golden parakeet (*Guarouba guarouba*) to enhance the species' propagation or survival. This notification covers activities to be conducted by the applicant over a 5-year period.

Applicant: Tanganyika Wildlife Park, Goddard, KS; PRT–93905A

The applicant requests a permit to import two captive-born Siamang (*Symphalangus syndactylus*) from the Dortmond Zoo, Germany for the purpose of enhancement of the survival of the species.

Multiple Applicants

The following applicants each request a permit to import the sport-hunted trophy of one male bontebok (*Damaliscus pygargus pygargus*) culled from a captive herd maintained under the management program of the Republic of South Africa, for the purpose of enhancement of the survival of the species.

Applicant: Veronica Kosich, Cutskill, NY; PRT–94126A

Applicant: Randy Shepherd, Sublimity, OR; PRT–93904A

B. Endangered Marine Mammals and Marine Mammals

Applicant: U.S. Fish and Wildlife Service National Forensics Laboratory, Ashland, OR; PRT–053639

The applicant requests renewal of the permit to export/re-export and import/re-import of biological specimens from any endangered or threatened species for the purpose of forensics activities which will directly or indirectly enhance the survival of the species in the wild. In addition, the applicant requests amendment to include FWS-jurisdiction marine mammal species, including marine otters (*Lontra felina*), sea otters (*Enhydra lutris*), all species of Sirenia (*Trichechus manatus, T. senegalensis, T. inunguis,* and *Dugong dugon*), polar bears (*Ursus maritimus*), and walrus (*Odobenus rosmarus*) for the purpose of scientific research. This notification covers activities to be conducted by the applicant over a 5-year period.

Applicant: U.S. Geological Survey, Alaska Science Center, Anchorage, AK; PRT–801652

The applicant requests a renewal and amendment of the permit to take walrus (*Odobenus rosmarus*) for capture/release, biological sampling, radio tagging and incidental harassment for the purpose of scientific research. In addition, the permit would authorize import and export of biological specimens. This notification covers activities to be conducted by the applicant over a 5-year period.

Concurrent with publishing this notice in the **Federal Register**, we are forwarding copies of the above applications to the Marine Mammal Commission and the Committee of Scientific Advisors for their review.

Brenda Tapia,

Program Analyst/Data Administrator, Branch of Permits, Division of Management Authority.

[FR Doc. 2013–01559 Filed 1–24–13; 8:45 am]

BILLING CODE 4310–55–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[FWS–R3–ES–2012–N306: FXES11130300000F3–234–FF03E00000]

Endangered and Threatened Wildlife and Plants; Permit Applications

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of availability of permit applications; request for comments.

SUMMARY: We, the U.S. Fish and Wildlife Service (USFWS), invite the public to comment on the following applications to conduct certain activities with endangered species. With some exceptions, the Endangered Species Act (Act) prohibits activities with endangered and threatened species unless a Federal permit allows such activity. The Act requires that we invite public comment before issuing these permits.

DATES: We must receive any written comments on or before February 25, 2013.

ADDRESSES: Send written comments by U.S. mail to the Regional Director, Attn: Lisa Mandell, U.S. Fish and Wildlife Service, Ecological Services, 5600 American Blvd. West, Suite 990, Bloomington, MN 55437–1458; or by electronic mail to *permitsR3ES@fws.gov.*

FOR FURTHER INFORMATION CONTACT: Lisa Mandell, (612) 713–5343.

SUPPLEMENTARY INFORMATION:

Background

We invite public comment on the following permit applications for certain activities with endangered species authorized by section 10(a)(1)(A) of the Act (16 U.S.C. 1531 *et seq.*) and our regulations governing the taking of endangered species in the Code of Federal Regulations (CFR) at 50 CFR 17. Submit your written data, comments, or request for a copy of the complete application to the address shown in **ADDRESSES.**

Permit Applications

Permit Application Number: TE049738

Applicant: Third Rock Consultants, LLC, Lexington, KY

The applicant requests a permit renewal to take (capture and release) the Indiana bat (*Myotis sodalis*), gray bat (*Myotis grisescens*), Virginia big-eared bat (*Corynorhinus townsendii virginianus*), Ozark big-eared bat (*Corynorhinus townsendii ingens*), and American burying beetle (*Nicrophorus americanus*), and the following Federally listed fish and mussel species:

Erimystax cahni	Slender chub.
Etheostoma chienense	Relict darter.
Etheostoma percnurum	Duskytail darter.
Hybopsis monacha	Spotfin chub.
Notropis albizonatus	Palezone shiner.
Phoxinus cumberlandensis	Blackside dace.
Noturus flavipinnis	Yellowfin madtom.
Noturus stanauli	Pygmy madtom.
Scaphirhynchus albus	Pallid sturgeon.
Alasmidonta atropurpurea	Cumberland elktoe.
Cyprogenia stegaria	Fanshell.
Dromus dromas	Dromedary pearlymussel.
Epioblasma brevidens	Cumberland combshell.
Epioblasma capsaeformis	Oyster mussel.
Epioblasma obliquata obliquata	Purple cat's paw.
Epioblasma torulosa rangiana	Northern riffleshell.
Lampsilis orbiculata (=l. abrupta)	Pink mucket.
Obovaria retusa	Ring pink.
Pegias fibula	Littlewing pearlymussel.
Plethobasus cooperianus	Orangefoot pimpleback.
Pleurobema clava	Clubshell.
Pleurobema gibberum	Cumberland pigtoe.
Pleurobema plenum	Rough pigtoe.
Potamilus capax	Fat pocketbook.
Quadrula intermedia	Cumberland monkeyface.
Villosa perpurpurea	Purple bean.
Villosa trabilis	Cumberland bean.

Activities are proposed throughout the range of the species in Alabama, Florida, Georgia, Illinois, Indiana, Iowa, Kentucky, Michigan, Mississippi, Missouri, North Carolina, Ohio, South Carolina, and Tennessee. Proposed activities are for the enhancement of survival of the species in the wild through surveys to document presence/absence of the species, population monitoring, and evaluation of potential impacts to the species.

Permit Application Number: TE839763

Applicant: John O. Whitaker, Indiana State University, Terre Haute, IN

The applicant requests a permit renewal to take (capture and release) Indiana bats and gray bats throughout the range of the species. Proposed activities are for scientific research aimed at recovery of the species and enhancement of survival in the wild.

Permit Application Number: TE106220

Applicant: Brianne L. Walters, Indiana State University, Terre Haute, IN

The applicant requests a permit renewal to take (capture and release) Indiana bats within the States of Illinois, Indiana, and Ohio. Proposed activities are for scientific research aimed at recovery of the species and enhancement of survival in the wild.

Permit Application Number: TE151109

Applicant: Ohio Department of Natural Resources, Division of Wildlife, Columbus, OH

The applicant requests a permit renewal, with amendments, to take American burying beetles in the State of Ohio. Proposed activities are for the conservation and recovery of the species, including population monitoring, habitat management,

captive breeding, and release to the wild.

Permit Application Number: TE042946

Applicant: Southern Illinois University Carbondale, James M. Garvey, P.I., Carbondale, IL

The applicant requests a permit renewal to take (capture and release) pallid sturgeon within the Mississippi River from St. Louis, Missouri, to the mouth of the Ohio River. Proposed activities are for the recovery and survival of the species in the wild.

Permit Application Number: TE10891A

Applicant: Illinois State Museum Research and Collection Center, Dr. Everett Cashatt, P.I., Springfield, IL

The applicant requests a permit amendment to add certain activities to an existing permit for the Hine's emerald dragonfly (*Somatochlora hineana*) to estimate population size in the interest of recovery of the species.

Permit Application Number: TE182436

Applicant: Illinois Natural History Survey, Champaign, IL

The applicant requests a permit renewal to take (capture and release) the Indiana bat throughout Illinois. Proposed activities are for the documentation of species presence and habitat use, population monitoring, and evaluation of impacts to enhance recovery and survival of the species in the wild.

Permit Application Number: TE38835A

Applicant: Land Conservancy of West Michigan, Grand Rapids, MI

The applicant requests a permit renewal to take (harass/harm) the Karner blue butterfly (*Lycaeides melissa samuelis*) in the context of habitat management to benefit the species in Kent County, Michigan. Proposed activities include management and monitoring of the species in the interest of conservation and recovery.

Permit Application Number: TE174388

Applicant: Metroparks of the Toledo Area, Toledo, OH

The applicant requests a permit renewal to take (harass/harm) the Karner blue butterfly in the context of habitat management to benefit the species within the properties owned and managed by Metroparks of the Toledo Area in Ohio. Proposed activities include management and monitoring of the species in the interest of conservation and recovery.

Permit Application Number: TE088720

Applicant: George T. Watters, Ohio State University, Columbus, OH

The applicant requests a permit renewal to take (capture, sample and release; propagate and release) Federally endangered mussels within the States of Illinois, Indiana, Kentucky, Michigan, Ohio, Pennsylvania, and West Virginia. Proposed activities are for scientific research in the interest of species recovery and for enhancement of populations through captive propagation and release.

Permit Application Number: TE38821A

Applicant: Stantec Consulting Services, Louisville, KY

The applicant requests a permit renewal to take (capture and release) the Indiana bat, gray bat, Virginia big-eared bat, Ozark big-eared bat, Federally listed mussels, and Copperbelly watersnake (*Nerodia erythrogaster neglecta*) throughout Alabama, Arkansas, Connecticut, Delaware, Illinois, Indiana, Iowa, Maryland, Massachusetts, Michigan, Mississippi, Missouri, New Hampshire, New Jersey, New York, North Carolina, Ohio, Pennsylvania, Rhode Island, South Carolina, Tennessee, Vermont, Virginia, and West Virginia. Proposed activities are for the documentation of presence/probable absence of the species and documentation of habitat use to enhance the recovery and survival of the species in the wild.

Permit Application Number: TE38862A

Applicant: George R. Cunningham, Omaha, NE

The applicant requests a permit renewal to take (capture and release) the Topeka shiner (*Notropis topeka*) within the States of Iowa, Kansas, Minnesota, Missouri, Nebraska, and South Dakota. Proposed activities are for the purpose of presence/absence determination and population monitoring to enhance the recovery and survival of the species in the wild.

Permit Application Number: TE839777

Applicant: Don R. Helms, Helms & Associates, Bellevue, IA

The applicant requests a permit renewal to take (capture and release; capture and relocate) endangered mussels throughout the States of Illinois, Indiana, Iowa, Michigan, Minnesota, Missouri, Ohio, and Wisconsin. The following mussel species are included in the requested permit renewal: Clubshell, fanshell, fat pocketbook, Higgins' eye pearlymussel (*Lampsilis higginsii*), northern riffleshell, orangefoot pimpleback, pink mucket pearlymussel, purple cat's paw pearlymussel, rayed bean (*Villosa fabalis*), ring pink (*Obovaria retusa*), rough pigtoe, scaleshell (*Leptodea leptodon*), snuffbox (*Epioblasma triquetra*), sheepnose (*Plethobasus cyphyus*), spectaclecase (*Cumberlandia monodonta*), white cat's paw pearlymussel (*Epioblasma obliquata perobliqua*), and winged mapleleaf (*Quadrula fragosa*). Proposed activities are for the recovery and enhancement of survival of the species in the wild.

Permit Application Number: TE38837A

Applicant: Cardno JFNew, Walkerton, IN

The applicant requests a permit renewal to take (capture and release) Indiana bats, gray bats, and Virginia big-eared bats throughout the range of the species. Proposed activities are for the enhancement of recovery and survival of the species in the wild.

Permit Application Number: TE38793A

Applicant: Kenneth S. Mierzwa, Eureka, CA

The applicant requests a permit renewal, with amendments, to take the Hine's emerald dragonfly throughout the range of the species, including Alabama, Illinois, Indiana, Michigan, Missouri, Ohio, and Wisconsin. Proposed activities are for the enhancement of recovery and survival of the species in the wild.

Permit Application Number: TE02365A

Applicant: Lynn W. Robbins, Southwest Missouri State University, Springfield, MO

The applicant requests a permit renewal to take (capture, sample, and release) Indiana bats, gray bats, and Ozark big-eared bats throughout the range of the species in the States of Arkansas, Iowa, Kansas, Missouri, Nebraska, and Ohio. Proposed activities are for scientific research, documentation of presence/probable absence of the species, and documentation of habitat use to enhance the recovery and survival of the species in the wild.

Permit Application Number: TE06822A

Applicant: Upper Peninsula Land Conservancy, Marquette, MI

The applicant requests a permit renewal to take Piping Plover (*Charadrius melodus*) within Michigan's Upper Peninsula. Proposed activities involve protection of nests and adults, collection, and participating in captive rearing/release in accordance with

USFWS protocols. Activities proposed are for the recovery of the species in the wild.

Permit Application Number: TE106217

Applicant: Toledo Zoological Society, Toledo, OH

The applicant requests a permit renewal to take (capture and hold) Mitchell's satyr butterflies (*Neonympha mitchelli mitchelli*) for captive propagation and release into the wild. Activities are proposed in the interest of conservation and recovery of the species and enhancement of the survival of the species in the wild.

Permit Application Number: TE43541A

Applicant: Dr. Francesca Cuthbert, University of Minnesota, St. Paul, MN

The applicant requests a permit renewal to take (capture and release; capture and rear) piping plover in Michigan and Wisconsin. The research entails capture and marking of piping plovers, erecting nesting exclosures to improve nesting success, salvaging orphaned eggs and nestlings, and captive rearing and release. Proposed activities are for the enhancement and recovery of the species in the wild.

Permit Application Number: TE94321A

Applicant: Brian J. O'Neill, Deerfield, IL

The applicant requests a permit to take (capture and release) the following listed species throughout their range, within the States of Kentucky, Illinois, Indiana, Iowa, Minnesota, Missouri, Ohio, Pennsylvania, Tennessee, West Virginia, and Wisconsin: Palezone shiner, blackside dace, relict darter, tuxedo darter (*Etheostoma lemniscatum*), cumberland darter (*Etheostoma susanae*), scioto madtom (*Noturus trautmani*), pallid sturgeon, cumberland elktoe, fanshell, dromedary pearlymussel, cumberland combshell, oyster mussel, tan riffleshell (*Epioblasma florentina walkeri*), Purple cat's paw, White cat's paw, northern riffleshell, tubercled blossom (*Epioblasma torulosa torulosa*), cracking pearlymussel (*Hemistena lata*), pink mucket, Higgins' eye pearlymussel, scaleshell, ring pink, littlewing pearlymussel, white wartyback (*Plethobasus cicatricosus*), orangefoot pimpleback, clubshell, rough pigtoe, fat pocketbook, winged mapleleaf, cumberland bean, sheepnose, snuffbox, spectaclecase, and rayed bean. Proposed activities are for the recovery and enhancement of survival of the species in the wild.

Permit Application Number: TE207523

Applicant: The Nature Conservancy—Michigan Chapter, Lansing, MI

The applicant requests a permit renewal to take (harass/harm through habitat management; census and monitoring) Mitchell's satyr butterflies (*Neonympha mitchellii mitchellii*), Karner blue butterflies, and Pitcher's thistle (*Cirsium pitcheri*) within the State of Michigan. Proposed activities are for the conservation and recovery of the species through habitat management.

Permit Application Number: TE94330A

Applicant: Robert A. Krebs, Cleveland Heights, OH

The applicant requests a permit to take (capture and release) snuffbox, rayed bean, purple cat's paw, clubshell, northern riffleshell, fanshell, pink mucket, sheepnose, and rabbitsfoot (*Quadrula cylindrica cylindrica*) throughout the State of Ohio. Proposed activities are for the recovery and enhancement of survival of the species in the wild.

Public Comments

We seek public review and comments on these permit applications. Please refer to the permit number when you submit comments. Comments and materials we receive are available for public inspection, by appointment, during normal business hours at the address shown in the **ADDRESSES** section. 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.

Dated: January 18, 2013.

Lynn M. Lewis,

Assistant Regional Director, Ecological Services, Midwest Region.

[FR Doc. 2013–01575 Filed 1–24–13; 8:45 am]

BILLING CODE 4310–55–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLWO320000 L19900000 PO0000]

Renewal of Approved Information Collection

AGENCY: Bureau of Land Management, Interior.

ACTION: 30-day Notice and request for comments.

SUMMARY: The Bureau of Land Management (BLM) has submitted an information collection request to the Office of Management and Budget (OMB) to continue the collection of information under the General Mining Law. The Office of Management and Budget (OMB) has assigned control number 1004–0025 to this information collection.

DATES: The OMB is required to respond to this information collection request within 60 days but may respond after 30 days. For maximum consideration, written comments should be received on or before February 25, 2013.

ADDRESSES: Please submit comments directly to the Desk Officer for the Department of the Interior (OMB #1004–0025), Office of Management and Budget, Office of Information and Regulatory Affairs, fax 202–395–5806, or by electronic mail at *oira_submission@omb.eop.gov.* Please provide a copy of your comments to the BLM. You may do so via mail, fax, or electronic mail.

Mail: U.S. Department of the Interior, Bureau of Land Management, 1849 C Street NW., Room 2134LM, Attention: Jean Sonneman, Washington, DC 20240.

Fax: to Jean Sonneman at 202–245–0050.

Electronic mail: Jean_Sonneman@blm.gov.

Please indicate ''Attn: 1004–0025'' regardless of the form of your comments.

FOR FURTHER INFORMATION CONTACT: Sonia Santillan, at 202–912–7123. Persons who use a telecommunication device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339, to leave a message for Ms. Santillan. You may also review the information collection request online at *http://www.reginfo.gov/public/do/PRAMain.*

SUPPLEMENTARY INFORMATION: The Paperwork Reduction Act (44 U.S.C. 3501–3521) and OMB regulations at 5 CFR part 1320 provide that an agency may not conduct or sponsor a collection of information unless it displays a currently valid OMB control number.

Until OMB approves a collection of information, you are not obligated to respond. In order to obtain and renew an OMB control number, Federal agencies are required to seek public comment on information collection and recordkeeping activities (see 5 CFR 1320.8(d) and 1320.12(a)).

As required at 5 CFR 1320.8(d), the BLM published a 60-day notice in the **Federal Register** on September 4, 2012 (77 FR 53905), and the comment period ended November 4, 2012. The BLM received no comments. The BLM now requests comments on the following subjects:

1. Whether the collection of information is necessary for the proper functioning of the BLM, including whether the information will have practical utility;
2. The accuracy of the BLM's estimate of the burden of collecting the information, including the validity of the methodology and assumptions used;
3. The quality, utility and clarity of the information to be collected; and
4. How to minimize the information collection burden on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other forms of information technology.

Please send comments as directed under **ADDRESSES** and **DATES**. Please refer to OMB control number 1004–0025 in your correspondence. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

The following information is provided for the information collection:

Title: Mineral Surveys, Mineral Patent Applications, Adverse Claims, Protests, and Contests (43 CFR parts 3860 and 3870).

OMB Control Number: 1004–0025.

Abstract: On its face, the General Mining Law (30 U.S.C. 29, 30, and 39) authorizes a holder of an unpatented claim for hardrock minerals to apply for fee title (patent) to the Federal land (as well as minerals) embraced in the claim. Since 1994, a rider on the annual appropriation bill for the Department of the Interior has prevented the BLM from processing mineral patent applications unless the applications were grandfathered under the initial legislation. While grandfathered applications are rare at present, the approval to collect the information continues to be necessary because of the possibility that the moratorium will be lifted.

Frequency of Collection: On occasion.

Description of Respondents: Owners of unpatented mining claims and mill sites upon the public lands, and of reserved mineral lands of the United States, National Forests, and National Parks.

Estimated Annual Burdens: 10 responses.

Estimated Hour Burden: 556 hours.

Estimated ''Non-Hour Cost'' Burden: $173,600.

The ''Non-Hour Cost'' burden estimate includes $13,400 for fixed document processing fees, $1,200 for publication costs, and $159,000 for case-by-case fees for validity examinations.

Jean Sonneman,

Information Collection Clearance Officer, Bureau of Land Management.

[FR Doc. 2013–01518 Filed 1–24–13; 8:45 am]

BILLING CODE 4310–84–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLCON03000 L16100000.DP0000]

Notice of Availability of the Draft Resource Management Plan and Draft Environmental Impact Statement for the Grand Junction Field Office in Colorado

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of Availability.

SUMMARY: In accordance with the National Environmental Policy Act of 1969, as amended, and the Federal Land Policy and Management Act of 1976, as amended, the Bureau of Land Management (BLM) has prepared a Draft Resource Management Plan (RMP) and Draft Environmental Impact Statement (EIS) for the Grand Junction Field Office (GJFO) and by this notice is announcing the opening of the public comment period.

DATES: To ensure that comments will be considered, the BLM must receive written comments on the Draft RMP/Draft EIS within 90 days following the date the Environmental Protection Agency publishes this notice of the Draft RMP/Draft EIS in the **Federal Register.** The BLM will announce future meetings or hearings and any other public participation activities at least 15 days in advance through public notices, media releases, and/or mailings.

ADDRESSES: You may submit comments related to the GJFO Draft RMP/Draft EIS by any of the following methods:

- *email: gjfo_rmp@blm.gov.*
- *fax:* 970–244–3083.
- *mail:* BLM—GJFO RMP, 2815 H Road, Grand Junction, CO 81506. Copies of the GJFO Draft RMP/Draft EIS are available in the GJFO at the above address or on the Web site at: *http://www.blm.gov/co/st/en/fo/gjfo/rmp.html.*

FOR FURTHER INFORMATION CONTACT: Collin Ewing, Planning and Environmental Coordinator, telephone 970–244–3027; see address above; email *cewing@blm.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 individual during normal business hours. The FIRS is available 24 hours a day, 7 days a week, to leave a message or question with the above individual. You will receive a reply during normal business hours.

SUPPLEMENTARY INFORMATION: The BLM prepared the GJFO Draft RMP/Draft EIS to analyze and revise the current management decisions for public lands and resources within the GJFO planning area. The current management decisions for resources are described in the Grand Junction Record of Decision and Approved Resource Management Plan (RMP) (approved January, 1987), as amended (1987 GJFO RMP).

The GJFO planning area includes approximately 2.2 million acres of BLM, National Park Service, U.S. Forest Service, U.S. Bureau of Reclamation, state, local, and private lands located in northwestern Colorado, primarily in Mesa and Garfield counties, with additional small tracts located in Montrose and Rio Blanco counties. Within the GJFO planning area, the BLM administers approximately 1.1 million surface acres and 1.2 million acres of Federal oil and gas mineral (subsurface) estate. Surface management decisions made as a result of this Draft RMP/Draft EIS will apply only to the BLM-administered lands in the GJFO planning area.

The formal public scoping process for the GJFO RMP/EIS began on October 15, 2008, with the publication of a Notice of Intent in the **Federal Register,** and ended on January 9, 2009. The BLM held three scoping open houses in December 2008. The BLM held an additional six public workshops in February 2009 for travel management data collection to give the public the opportunity to review its route inventory for completeness and accuracy, as well as offer suggestions for possible reroutes or new routes that

would complement the existing system. Following the travel management workshops, the BLM held an additional public comment period was held from July 17 through August 21, 2009, to help the BLM evaluate the quantity and quality of the experiences and desired recreation setting available in the planning area. The BLM used public scoping comments to identify planning issues that led to the formulation of alternatives and framed the scope of analysis in the Draft RMP/Draft EIS. The scoping process was also used to introduce the public to preliminary planning criteria, which set limits on the scope of the Draft RMP/Draft EIS.

Major issues considered in the Draft RMP/Draft EIS include travel management; energy development; recreation management; lands and realty/community growth and expansion; wildlife and fish; special designation areas; lands with wilderness characteristics; water, soil, and riparian areas; special status species management; and vegetation management, among others.

The Draft RMP/Draft EIS evaluates in detail four alternatives, including the No Action Alternative (Alternative A) and three action alternatives (Alternatives B, C, and D). The BLM has identified Alternative B as the preferred alternative. Identification of this alternative, however, does not represent the final agency direction, and the Proposed RMP may reflect changes or adjustments based on information received during public comment, from new information, or from changes in BLM policies or priorities. The Proposed RMP may include objectives and actions described in the other analyzed alternatives.

Alternative A would retain the current management goals, objectives and direction specified in the 1987 GJFO RMP. Alternative B seeks to balance resources among competing human interests and land uses with the conservation of natural and cultural resource values, while sustaining the ecological integrity of certain key habitats for plant, wildlife and fish species. It incorporates a balanced level of protection, restoration, enhancement, and use of resources and services to meet ongoing programs and land uses. Goals and objectives focus on environmental, economic and social outcomes achieved by strategically addressing demands across the landscape. Alternative C emphasizes non-consumptive use and management of resources through protection, restoration and enhancement, while also providing for multiple uses, including livestock grazing and mineral development. This alternative would establish the greatest number of special designation areas with specific measures to protect or enhance resource values within these areas. Goals and objectives focus on environmental and social outcomes achieved by sustaining relatively unmodified physical landscapes and natural and cultural resource values for current and future generations. Alternative D emphasizes active management for natural resources, commodity production, and public use opportunities. Resource uses, such as recreation, livestock grazing, mineral leasing and development, would be emphasized. Existing uses would continue and new uses would be accommodated to the greatest extent possible while maintaining resource conditions.

Pursuant to 43 CFR 1610.7–2(b), this notice announces a concurrent public comment period on proposed Areas of Critical Environmental Concern (ACECs). Proposed ACECs and the resource use limitations which would occur if formally designated are as follows:

- Atwell Gulch, up to 6,100 acres, Alternatives B, and C: No surface occupancy; close to fluid mineral leasing; Visual Resource Management (VRM) Class II; right-of-way (ROW) exclusion area; close to motorized travel including over-snow motorized travel; close to mechanized travel; issue no special recreation permits for competitive events; close 2,900 acres to livestock grazing; close to fossil collection; only allow vegetation treatments for the benefit of the identified relevance and importance values.
- Badger Wash, up to 2,200 acres, Alternatives A, B, C and D: No surface occupancy; close to fluid mineral leasing; limit travel to designated routes; VRM Class II; ROW exclusion area; issue no special recreation permits for competitive events.
- Colorado River Riparian, 880 acres, Alternative C: No surface occupancy; classify as unsuitable for coal leasing; limit travel to designated routes; VRM Class II; ROW avoidance area; and only allow vegetation treatments for the benefit of the identified relevance and importance values.
- Coon Creek, 110 acres, Alternative C: No surface occupancy; limit travel to designated routes; VRM Class III; ROW avoidance area; and close to livestock grazing.
- Dolores River Riparian, 7,400 acres, Alternatives B and C: No surface occupancy; close to fluid mineral leasing; limit travel to designated routes; VRM Class II; ROW avoidance area; issue no special recreation permits for competitive events; only allow vegetation treatments for the benefit of the identified relevance and importance values; only allow camping in designated sites; and close to recreational placer mining.
- Glade Park-Pinyon Mesa, 27,200 acres, Alternative C: No surface occupancy; close to fluid mineral leasing; limit travel to designated routes; VRM Class II; ROW avoidance area; only allow vegetation treatments for the benefit of the identified relevance and importance values; and open to livestock grazing outside of occupied sage-grouse habitat.
- Gunnison River Riparian, 460 acres, Alternative C: No surface occupancy; limit travel to designated routes; VRM Class II; ROW avoidance area; and only allow camping in designated sites.
- Hawxhurst Creek, 860 acres, Alternative C: No surface occupancy; limit travel to designated routes; VRM Class II; and ROW avoidance area.
- Indian Creek, 1,700 acres, Alternatives B and C: No surface occupancy; limit travel to designated routes; VRM Class II; and ROW exclusion area.
- John Brown Canyon, 1,400 acres, Alternative C: No surface occupancy; close to fluid mineral leasing; limit travel to designated routes; and VRM Class II.
- Juanita Arch, 1,600 acres, Alternatives B and C: No surface occupancy; close to fluid mineral leasing; close to motorized and mechanized travel; VRM Class II; ROW exclusion area.
- Mt. Garfield, up to 5,700 acres, Alternatives B and C: No surface occupancy; close to fluid mineral leasing; close to motorized travel including over-snow travel; VRM Class I; ROW exclusion area; close to fossil collection; classify as unsuitable for coal leasing; close to recreational target shooting; close to livestock grazing.
- Nine-mile Hill Boulders, 90 acres, Alternative C: Close to motorized travel including over-snow travel; close to mechanized travel; VRM Class II; ROW exclusion area; issue no special recreation permits for competitive events.
- The Palisade, up to 32,200 acres, Alternatives A, B, C and D: No surface occupancy; close to fluid mineral leasing; close to motorized travel; VRM Class I; ROW exclusion area; issue no special recreation permits for competitive events; limit forestry cutting units to 20 acres or less in the pinyon-juniper woodlands; close to mineral material disposal.

• Plateau Creek, 220 acres, Alternative C: No surface occupancy; VRM Class II; limit travel to designated routes; close to recreational target shooting; only allow camping in designated sites; ROW avoidance area; close to all types of collection (e.g., fossil, vegetation, rocks, etc.); only allow vegetation treatments and wildlife habitat improvements for the benefit of the identified relevance and importance values; classify as unsuitable for coal leasing; issue only Class I and II special recreation permits; and close to livestock grazing.

• Prairie Canyon, 6,900 acres, Alternative C: No surface occupancy; close to fluid mineral leasing; VRM Class II; limit travel to designated routes; close to recreational target shooting; ROW exclusion area; close to vegetative materials sales; and only allow vegetation treatments and wildlife habitat improvements for the benefit of the identified relevance and importance values.

• Pyramid Rock, up to 1,300 acres, Alternatives A, B, C and D: No surface occupancy; close to fluid mineral leasing; VRM Class II; close to all modes of travel; close to recreational target shooting; close to camping; ROW exclusion area; close to all types of collection (e.g., fossil, vegetation, rocks, etc.); classify as unsuitable for coal leasing; issue no special recreation permits for competitive events; close to livestock grazing.

• Reeder Mesa, 470 acres, Alternative C: No surface occupancy; VRM Class III; limit travel to designated routes; ROW exclusion area.

• Roan and Carr Creeks, up to 33,600 acres, Alternatives B and C: No surface occupancy; close to fluid mineral leasing; VRM Class II; close to motorized travel including over-snow travel; close to mechanized travel; ROW avoidance area; and classify as unsuitable for coal leasing.

• Rough Canyon, up to 2,800 acres, Alternatives A, B, C and D: No surface occupancy; close to fluid mineral leasing; VRM Class II; limit travel to designated routes; ROW exclusion area; close to mineral material disposal.

• Sinbad Valley, 6,400 acres, Alternatives B and C: No surface occupancy; close to fluid mineral leasing; VRM Class II; close to motorized travel, except for Tabeguache Trail; ROW avoidance area.

• South Shale Ridge, 28,200 acres, Alternatives B and C: No surface occupancy; close to fluid mineral leasing; VRM Class II; limit travel to designated routes; and ROW exclusion area.

• Unaweep Seep, up to 85 acres, Alternatives A, B, C and D: No surface occupancy; close to fluid mineral leasing; close to motorized travel including over-snow travel; close to mechanized travel; VRM Class II; ROW exclusion area; close to camping; issue no special recreation permits for competitive events; close to fossil collection; and close to mineral material disposal.

Please note that public comments and information submitted including names, street addresses, and email addresses of persons who submit comments will be available for public review and disclosure at the above address during regular business hours (8:00 a.m. to 4:00 p.m.), Monday through Friday, except holidays.

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.

Authority: 40 CFR 1506.6, 40 CFR 1506.10, 43 CFR 1610.2.

Helen M. Hankins,

BLM Colorado State Director.

[FR Doc. 2013–01400 Filed 1–24–13; 8:45 am]

BILLING CODE 4310–JB–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLOR957000–L63100000–HD0000–13XL1165AF: HAG13–0093]

Filing of Plats of Survey: Oregon/Washington

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice.

SUMMARY: The plats of survey of the following described lands are scheduled to be officially filed in the Bureau of Land Management, Oregon State Office, Portland, Oregon, 30 days from the date of this publication.

Willamette Meridian

Oregon

T. 17 S., R. 17 E., accepted January 7, 2013
T. 20 S., R. 8 W., accepted January 7, 2013
T. 38 S., R. 2 E., accepted January 10, 2013
T. 21 S., R. 6 W., accepted January 10, 2013
T. 22 S., R. 7 W., accepted January 10, 2013
T. 25 S., R. 3 W., accepted January 10, 2013
T. 20 S., R. 7 W., accepted January 10, 2013
T. 29 S., R. 9 W., accepted January 10, 2013

ADDRESSES: A copy of the plats may be obtained from the Public Room at the Bureau of Land Management, Oregon State Office, 333 SW. 1st Avenue, Portland, Oregon 97204, upon required payment.

FOR FURTHER INFORMATION CONTACT: Kyle Hensley, (503) 808–6132, Branch of Geographic Sciences, Bureau of Land Management, 333 SW. 1st Avenue, Portland, Oregon 97204. Persons who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 to contact the above individual during normal business hours. The FIRS is available 24 hours a day, 7 days a week, to leave a message or question with the above individual. You will receive a reply during normal business hours.

SUPPLEMENTARY INFORMATION: A person or party who wishes to protest against this survey must file a written notice with the Oregon State Director, Bureau of Land Management, stating that they wish to protest. A statement of reasons for a protest may be filed with the notice of protest and must be filed with the Oregon State Director within thirty days after the protest is filed. If a protest against the survey is received prior to the date of official filing, the filing will be stayed pending consideration of the protest. A plat will not be officially filed until the day after all protests have been dismissed or otherwise resolved. 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.

Timothy J. Moore,

Acting, Chief Cadastral Surveyor of Oregon/Washington.

[FR Doc. 2013–01460 Filed 1–24–13; 8:45 am]

BILLING CODE 4310–33–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLWY–957400–13–L14200000–BJ0000]

Filing of Plats of Survey, Wyoming and Nebraska

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice.

SUMMARY: The Bureau of Land Management (BLM) has filed the plats of survey of the lands described below in the BLM Wyoming State Office, Cheyenne, Wyoming, on the dates indicated.

FOR FURTHER INFORMATION CONTACT: Bureau of Land Management, 5353 Yellowstone Road, P.O. Box 1828, Cheyenne, Wyoming 82003.

SUPPLEMENTARY INFORMATION: These surveys were executed at the request of the Bureau of Land Management and the U.S. Forest Service, and are necessary for the management of resources. The lands surveyed are:

The plat and field notes representing the dependent resurvey of a portion of the Fourteenth Standard Parallel North, through Range 83 West, the east, west and north boundaries, and a portion of the subdivisional lines, Township 57 North, Range 83 West, Sixth Principal Meridian, Wyoming, Group No. 804, was accepted June 22, 2012.

The supplemental plat showing amended lottings, Township 52 North, Range 72 West, Sixth Principal Meridian, Wyoming, Group No. 868, was accepted July 31, 2012 and is based upon the dependent resurvey plat of Township 52 North, Range 72 West, accepted February 7, 1980, and supplemental plat of Township 52 North, Range 72 West, accepted September 13, 1985.

The supplemental plat showing amended lottings, Township 52 North, Range 72 West, Sixth Principal Meridian, Wyoming, Group No. 868, was accepted August 14, 2012, and is based upon the dependent resurvey plat of Township 52 North, Range 72 West, accepted February 7, 1980, and the supplemental plat of Township 52 North, Range 72 West, accepted September 13, 1985.

The plat and field notes representing the dependent resurvey of a portion of the subdivisional lines, the survey of the subdivision of section 8, and the metes and bounds survey of Lot 17, section 8, Township 56 North, Range 73 West, Sixth Principal Meridian, Wyoming, Group No. 836, was accepted August 14, 2012.

The supplemental plat showing amended lottings, Township 33 North, Range 109 West, Sixth Principal Meridian, Wyoming, Group No. 873 was accepted September 26, 2012, and is based upon the dependent resurvey plat of Township 33 North, Range 109 West, accepted October 31, 2007.

The plat and field notes representing the dependent resurvey of a portion of the north boundary, a portion of the subdivisional lines, and the survey of the subdivision of certain sections, Township 50 North, Range 83 West, Sixth Principal Meridian, Wyoming, Group No. 843, was accepted November 14, 2012.

The plat and field notes representing the dependent resurvey of Lot No. 39 and Lot No. 42, a portion of Lot No. 38 and Lot No. 40, a portion of the Twelfth Guide Meridian West, through Township 55 North, between Ranges 96 and 97 West, a portion of the subdivisional lines and the survey of the subdivision of section 7, Township 55 North, Range 96 West, Sixth Principal Meridian, Wyoming, Group No. 844, was accepted November 14, 2012.

The plat and field notes representing the corrective dependent resurvey of portions of the subdivisional lines, Township 29 North, Range 100 West, Sixth Principal Meridian, Wyoming, Group No. 849, was accepted December 7, 2012.

The plat and field notes representing the dependent resurvey of a portion of the subdivisional lines, Township 20 North, Range 82 West, Sixth Principal Meridian, Wyoming, Group No. 853, was accepted December 7, 2012.

The plat and field notes representing the dependent resurvey of portions of the west and north boundaries and the subdivisional lines; the corrective dependent resurvey of a portion of the north boundary, and the survey of the subdivision of sections 5, 6, 7 and 8, Township 30 North, Range 52 West, Sixth Principal Meridian, Nebraska, Group No. 176, was accepted December 7, 2012.

Copies of the preceding described plats and field notes are available to the public at a cost of $1.10 per page.

Dated: January 16, 2013.

John P. Lee,

Chief Cadastral Surveyor, Division of Support Services.

[FR Doc. 2013–01458 Filed 1–24–13; 8:45 am]

BILLING CODE 4310–22–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLUT980300–L11200000–PH0000–24–1A]

Notice of Utah's Recreation Resource Advisory Council/Resource Advisory Council Meeting

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of meeting.

SUMMARY: In accordance with the Federal Land Policy and Management Act (FLPMA) and the Federal Advisory Committee Act of 1972 (FACA), the U.S. Department of the Interior, Bureau of Land Management's (BLM) Utah Recreation Resource Advisory Council (RecRAC)/Resource Advisory Council (RAC) will meet as indicated below.

DATES: The RAC will meet on February 21, 2013, from 1:00–5:00 p.m., and the RecRAC/RAC will meet on February 22, 2013, from 8:30 a.m. to 4:00 p.m.

ADDRESSES: The meeting will be held at the BLM-Utah State Office, 440 West 200 South, Salt Lake City, Utah, in the Monument Conference Room on the fifth floor.

FOR FURTHER INFORMATION CONTACT: Sherry Foot, Special Programs Coordinator, Utah State Office, Bureau of Land Management, 440 West 200 South, Salt Lake City, Utah 84101; phone (801) 539–4195; *sfoot@blm.gov.*

SUPPLEMENTARY INFORMATION: On February 21, agenda topics will include current events within BLM Utah; an update on alternatives for regional planning through 2015 and interim guidance for Utah on Sage-grouse; an update on the draft strategic plan for Utah public lands within the BLM's National Landscape Conservation System; and the RAC's involvement with the Utah Film Commission.

On February 22, the RecRAC will listen to fee presentations from the BLM Monticello Field Office, which is proposing to increase fees for recreational boating on the San Juan River in San Juan County, Utah; the BLM Red Cliffs National Conservation Area, which is proposing to increase fees at the Red Cliffs Recreation Area in Washington County, Utah; and the Manti-La Sal National Forest, which is proposing to increase fees at the Seely Guard Station in Emery County, Utah. An additional topic will cover updates on the St. George/Cedar City Resource Management Plans.

The public may address the RecRAC/RAC during a public comment period from 10:45–11:15 a.m. Written comments may also be sent to the BLM at the address listed in the **FOR FURTHER INFORMATION CONTACT** section of this notice. The meeting is open to the public; however, transportation, lodging, and meals are the responsibility of the participating individuals.

Following the business meeting, a BLM-Utah State Director's awards function for invited guests will

recognize public land partners and outgoing RAC members.

Jenna Whitlock,

Associate State Director.

[FR Doc. 2013–01572 Filed 1–24–13; 8:45 am]

BILLING CODE 4310–DQ–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLNMP0000 L13110000.XH0000]

Notice of Public Meeting, Pecos District Resource Advisory Council Meeting, New Mexico

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of public meeting.

SUMMARY: In accordance with the Federal Land Policy and Management Act and the Federal Advisory Committee Act of 1972, the U.S. Department of the Interior, Bureau of Land Management (BLM), Pecos District Resource Advisory Council (RAC), will meet as indicated below.

DATES: The meeting is on February 26–27, 2013, from 9 a.m.–4 p.m.

ADDRESSES: The meeting will be at the Bureau of Land Management Roswell Field Office, 2909 West 2nd Street, Roswell, NM, on February 26, with an optional tour for RAC members of off-highway vehicle management areas on February 27. The public may send written comments to the RAC, 2909 W. 2nd Street, Roswell, NM 88201.

FOR FURTHER INFORMATION CONTACT: Betty Hicks, Pecos District, Bureau of Land Management, 2909 W. 2nd Street, Roswell, NM 88201, 575–627–0242. Persons who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8229 to contact the above individual during normal business hours. The FIRS is available 24 hours a day, 7 days a week, to leave a message or question with the above individual. You will receive a reply during normal business hours.

SUPPLEMENTARY INFORMATION: The 10-member RAC advises the Secretary of Interior, through the Bureau of Land Management, on a variety of planning and management issues associated with public land management in New Mexico. Planned agenda items include an Update on Hunting Unitization, Buried Utilities, Information on the Lesser prairie chicken, Discussion of Recreation Fee—Fort Stanton National Conservation Area, SLO/BLM Land Exchange, and a Feral Pig Presentation. A half-hour public comment period during which the public may address the Council is scheduled to begin at 3 p.m. on February 26. All RAC meetings are open to the public. Depending on the number of individuals wishing to comment and time available, the time for individual oral comments may be limited.

Douglas J. Burger,

District Manager.

[FR Doc. 2013–01571 Filed 1–24–13; 8:45 am]

BILLING CODE 4310–VA–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–PWR–PWRO–10629; PX.P0131800B.00.1]

Draft Environmental Impact Statement for Tuolumne Wild and Scenic River Comprehensive Management Plan, Yosemite National Park, Madera, Mariposa, Mono and Tuolumne Counties, California

AGENCY: National Park Service, Interior.

ACTION: Notice of availability.

SUMMARY: Pursuant to § 102(2) (C) of the National Environmental Policy Act of 1969 (Pub. L. 91–190, as amended), and the Council on Environmental Quality Regulations (40 CFR part 1500–1508), the National Park Service has prepared a Draft Environmental Impact Statement (DEIS) for the proposed Tuolumne Wild and Scenic River Comprehensive Management Plan (TRPCMP). The TRPCMP/DEIS addresses requirements of the Wild and Scenic Rivers Act (Pub. L. 90–542, as amended) (WSRA), and will provide long-term guidance for management of the 54 miles of the Tuolumne River that flows through Yosemite National Park. The DEIS evaluates potential environmental consequences of implementing a range of alternatives, including a no-action (continue with current management) alternative and five action alternatives. Both the agency-preferred and environmentally preferred alternatives are identified.

The purpose of the TRPCMP is to guide the park in protecting the river's free-flowing character and the values that make it worthy of designation by (1) reviewing and updating river corridor boundaries and segment classifications, (2) prescribing a process for the protection of the river's free-flowing condition, (3) identifying and documenting the condition of the river's outstandingly remarkable values, (4) establishing management objectives for river values and a monitoring program for ensuring the objectives are met, (5) identifying management actions needed to protect and enhance river values, and (6) defining visitor use and user capacity for the river corridor. Portions of the 1980 Yosemite General Management Plan (GMP) addressing management inside the Tuolumne Wild and Scenic River corridor also will be updated; specific GMP amendments are outlined in the DEIS.

Proposal and Alternatives: Based on a thorough examination of the river's baseline conditions, the TRPCMP/DEIS presents a multi-faceted approach to river management and stewardship. Because of the WSRA mandate to ''protect and enhance'' river values, most of the plan's contents are common to all the action alternatives, including (1) all WSRA management elements (boundaries, classifications, § 7 determination process), (2) an ecological restoration program and other management actions, (3) a monitoring program, and (3) a user capacity management program. As discussed in detail in the DEIS, Alternative 5 is deemed to be the environmentally preferred course of action.

Since the conservation planning and environmental impact analysis process began in 2005, the TRPCMP/DEIS has been methodically developed by park subject-matter experts, with attention to information provided by culturally-associated American Indian tribes, gateway communities, nonprofit organizations, and interested members of the public. Throughout the early conservation planning and environmental impact analysis effort, information was sought at over 127 public meetings, workshops, and presentations. At these events, the public was invited to share ideas that could be used in the development of a range of alternatives that would achieve NPS goals, while ensuring accessibility, public safety, resource protection, and protection and enhancement of river values.

As noted above, a no-action alternative and five action alternatives for managing the Tuolumne Wild and Scenic River are identified and analyzed. The five action alternatives represent the primary themes expressed during public scoping. Potential impacts are analyzed and appropriate mitigation measures are assessed for each alternative. Per WSRA direction, all of the action alternatives would protect and enhance the values for which the Tuolumne was designated, including its free-flowing condition, excellent water quality, and outstandingly remarkable values. In addition, all action alternatives would preserve and sustain

wilderness character, including natural ecosystem function and opportunities for primitive recreation in the more than 90 percent of the river corridor that is classified wild per the WSRA (some portions are also located in designated wilderness). Differences among the alternatives revolve primarily around a range of desired visitor experiences, levels of facilities needed to protect and enhance river values in Tuolumne Meadows and Glen Aulin, and use levels throughout the river corridor. The scenic segment below O'Shaughnessy Dam and the Tioga Road corridor east of Tuolumne Meadows would be managed the same under all the action alternatives in a manner that is protective of river values.

The guidance for those segments of the river classified as wild (which are also part of congressionally designated wilderness) are similar under all the alternatives, although differences in visitor use management are identified and assessed. All alternatives accommodate traditional cultural practices by American Indian tribes. Numeric user capacities differ among the alternatives, based on the types of visitor experiences, levels of facilities needed to protect river values, and actions taken to achieve the various objectives. Day and overnight capacities for the entire river corridor—and the actions required to manage to proposed capacities—are considered for all alternatives.

No Action Alternative. Continuing current management and trends would result in additional localized impacts associated with roadside parking in Tuolumne Meadows and facilities located in sensitive riverine locations.

Common to Action Alternatives. In response to public comments and in keeping with findings related to baseline conditions, all action alternatives call for an ecological restoration program, elimination of roadside parking in Tuolumne Meadows with slight expansion of existing parking areas, elimination of social trails in meadows and riparian areas, removal of concessioner housing from sensitive areas, relocation of the Cathedral Lakes trailhead to the current visitor center location, retention of the Tuolumne Meadows campground, and either no expansion or a reduction of overnight lodging.

Alternative 1. Alternative 1 responds to those members of the public who advocated emphasis on primitive and self-reliant experiences in the river corridor while providing a wilderness staging area and a focal point for High Sierra interpretation and education at Tuolumne Meadows. Subalpine meadow and riparian areas would be protected from visitor-related impacts by restoring informal trails, mitigating the hydrologic impacts caused by historic trail segments, and eliminating all facilities except trails and roads from meadow and riparian areas. Most amenities and commercial services would be discontinued at Tuolumne Meadows, including the store and grill, gas station, Tuolumne Meadows Lodge, and trail rides. The Glen Aulin High Sierra Camp would be removed and the area restored to natural conditions. Overall, use levels in the river corridor would be the lowest in the range of alternatives considered.

Alternative 2. Alternative 2 responds to those members of the public who voiced a desire for a greater diversity of day use opportunities (including limited kayaking, by permit) and a modest increase in campground capacity, while retaining the rustic lodges at Tuolumne Meadows and Glen Aulin. This alternative would facilitate resource enjoyment and stewardship by a broad spectrum of visitors, including people discovering the area for the first time, by encouraging short interpretive walks and picnicking. To facilitate these connections, a picnic and parking area would be located across from the Parsons Lodge trailhead on Tioga Road. The visitor center and other core visitor services would be co-located at the site of the existing Tuolumne Meadows store. Overall, use levels in the river corridor would be the highest in the range of alternatives considered, and river values would be protected by directing visitors to those areas most able to withstand use.

Alternative 3. Alternative 3 responds to those members of the public who desired a Tuolumne experience largely the same as today, while facilitating the changes needed to protect and enhance river values. Alternative 3 would emphasize the historic character of Tuolumne, while providing opportunities for visitors to connect with the river through its historic landscape character and traditional, unconfined experiences. Wilderness-oriented recreational opportunities would be encouraged and river-related systems would be sustained by natural ecological processes. Most facilities at Tuolumne Meadows would remain in their dispersed locations, however some may be relocated to protect sensitive areas. Glen Aulin High Sierra Camp would remain at a slightly reduced capacity. Overall, use levels would fall within the middle of the range of alternatives considered.

Alternative 4. Alternative 4 responds to those members of the public who wanted visitor activities and amenities to be secondary to protecting and enhancing the integrity and connectivity of river-related ecological communities, particularly at Tuolumne Meadows. The rustic lodge at Tuolumne Meadows would be reduced to half its current capacity and other commercial services would be eliminated, including the gas station and commercial day rides. Facilities and like functions at Tuolumne Meadows would be consolidated and visitor experiences would be facilitated in a manner that connects people with the river and emphasizes the importance of protecting meadow and riparian ecosystems. Capacity at the Glen Aulin High Sierra Camp would be reduced. Overall, use levels would fall within the middle of the range of alternatives considered, and management of visitor use would be intensive, including possible closures to facilitate ecological recovery.

Alternative 5. Alternative 5 (agency-preferred and environmentally preferred) would combine elements from alternatives 2, 3 and 4, to balance greater protection of ecological communities while allowing for traditional wilderness-oriented visitor experiences. While most visitor services would remain, the gas station and concessioner trail rides would be eliminated. A small visitor contact station, picnic and parking area would be located across from the Parsons Lodge trailhead on Tioga Road. Glen Aulin High Sierra Camp would be reduced to nearly half its current capacity. Overall, use levels would fall within the middle of the range of alternatives considered, and management of visitor use would be intensive, including possible closures to facilitate ecological recovery.

Since some portions of the DEIS planning area have historic structures or are located in designated wilderness, appendices are included which address (1) role of 1999 and 2008 programmatic agreements between Yosemite NP and the State Historic Preservation Office in protecting and managing historic structures, and (2) the extent to which commercial services are necessary in wilderness.

Public Involvement. On July 10, 2006, the Notice of Intent to prepare an EIS was published in the **Federal Register**, formally initiating a 60-day public scoping period. At that time a letter from the Superintendent was sent to over 6,000 interested members of the public on the park's Planning Mailing list, soliciting ideas, issues, and concerns relating to the scope of this planning effort. Press releases were sent to local and regional newspapers

announcing details of the 60-day public scoping period, including information about public meetings. In July and August 2006, a series of thirteen public scoping meetings were held; in addition, an on-site visit was hosted in Tuolumne Meadows on August 29, 2006. In addition to local and regional press media, public meetings were publicized on the park's Web site, through emailed notices on the park's electronic newsletter, and on various state-wide online bulletin boards. The scoping period was extended for an additional two weeks in deference to public requests.

Overall there were 457 public responses (including letters, faxes, emails, comment forms, and public meeting flip-chart notes), and over 4,000 individual comments. From 2006–2010 over 127 public meetings, presentations, workshops, field visits, and open houses were conducted in support of preparation of the Tuolumne River Plan. These included all-tribes meetings, public work sessions to parallel planning team work sessions (known as ''Planner-for-a-Day'' workshops), socioeconomic workshops held in gateway communities, open houses and other public forums, meetings with park staff, and presentations to other land management agencies and stakeholder groups. The park's Web site served as a central repository for not only information about the plan's status, but various products for public comment—including two separate workbooks devoted to release of preliminary concepts and early alternatives.

How to Comment: All comments must be transmitted or postmarked not later than 60 days from the date the U. S. Environmental Protection Agency publishes their notice of filing of the DEIS in the **Federal Register**. Immediately upon confirmation of this date it will be announced via local and regional news media, through direct mailings, and posted on the project Web sites. Written comments should be mailed to: Superintendent, Yosemite National Park, Attn: Tuolumne River Plan DEIS, P.O. Box 577, Yosemite, California 95389. If preferred, comments also may be transmitted electronically through the *http://parkplanning.nps.gov/yose_trp* Web site.

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.

During the public review period public meetings will be hosted in Yosemite gateway communities, as well as in Yosemite Valley and Tuolumne Meadows; Web-based meetings will also take place. Public site visits may be offered during the public review period, depending upon weather conditions. All meeting and site visit locations and dates will be announced similarly as noted above for the comment due date, and will be included in the Yosemite electronic newsletter and posted on the Yosemite National Park Web site *http://www.nps.gov/yose/parkmgmt/trp.htm.*

Limited printed and CD copies of the TRPCMP/DEIS will be available, and may be requested by email (*yose_planning@nps.gov*) or telephone at (209) 379–1110. The document will be sent directly to congressional delegations, state and local elected officials, federal and state agencies, tribes, organizations, local businesses, public libraries, and the news media. Printed copies can be viewed at local and regional libraries (i.e., El Portal, Mariposa, Oakhurst, Sonora, San Francisco, and Los Angeles). Electronic versions will be available online at *http://parkplanning.nps.gov/yose_trp,* or may be accessed through the Yosemite National Park Web site *http://www.nps.gov/yose/parkmgmt/trp.htm.*

Decision Process: All comments received on the TRPCMP/DEIS will be duly considered in preparing the Final EIS. The Final EIS is expected to be available in early 2013; availability of the document will be announced in a manner similar to that used for the DEIS, including publication of a notice of availability in the **Federal Register.** A Record of Decision would be prepared not sooner than 30 days after release of the Final EIS. Because this is a delegated EIS, the official responsible for approving the final plan is the Regional Director, Pacific West Region, National Park Service; subsequently the official responsible for implementation of the approved Tuolumne Wild and Scenic River Comprehensive Management Plan will be the Superintendent, Yosemite National Park.

Dated: November 26, 2012.

George J. Turnbull,

Acting Regional Director, Pacific West Region.

[FR Doc. 2013–01464 Filed 1–24–13; 8:45 am]

BILLING CODE 4312–FY–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–PWR–PWRO–11522; PX.P0131800B.00.1]

Draft Environmental Impact Statement for Merced Wild and Scenic River Comprehensive Management Plan, Yosemite National Park, Madera and Mariposa Counties, CA

AGENCY: National Park Service, Interior.

ACTION: Notice of availability.

SUMMARY: Pursuant to the National Environmental Policy Act of 1969 (NEPA), 42 U.S.C. 4332(2)(C), and the Council on Environmental Quality Regulations (40 CFR part 1500–1508), the National Park Service (NPS) has prepared a Draft Environmental Impact Statement (DEIS) for the proposed Merced Wild and Scenic River Comprehensive Management Plan (Merced River Plan). The Merced River Plan will fulfill the requirements of the Wild and Scenic Rivers Act, 16 U.S.C. 1271–1287, and will provide long-term protection of river values and a user capacity management program for 81 miles of the Merced River that flow through Yosemite National Park and the El Portal Administrative Site.

Consistent with the Wild and Scenic Rivers Act (WSRA), the purposes of the Merced River Plan/DEIS are to protect the Merced River's free-flowing conditions, and to: (1) Review, and if necessary revise, the river corridor boundaries and segment classifications, and provide a process for protection of the river's free-flowing condition in keeping with the WSRA; (2) Refine descriptions of the river's outstandingly remarkable values (ORVs), which are the unique, rare, or exemplary in a regional or national context, and the river-related/river-dependent characteristics that make the river eligible for inclusion in the national wild and scenic rivers system; (3) Identify management objectives for the river, and specific management measures that will be implemented to achieve protection and enhancement of river values; (4) Establish a user capacity program that addresses the kinds and amounts of public use that the river corridor can sustain while protecting and enhancing the river's ORVs; (5) Commit to a program of ongoing studies and monitoring to ensure that the ORVs are protected and enhanced over the life of the plan.

The Merced River Plan/DEIS evaluates the potential adverse and beneficial environmental consequences of implementing a range of five action

alternatives, including a no action alternative in accordance with NEPA; and for the potential to cause adverse effects to historic properties in accordance with Section 106 of the National Historic Preservation Act. Both the agency preferred and environmentally preferred alternatives are identified. Actions called for in the 1980 Yosemite General Management Plan (GMP) addressing management within the Merced Wild and Scenic River corridor would be amended and are outlined in the Merced River Plan/DEIS.

DATES: The NPS will be accepting public comments on the Merced River Plan/DEIS for 90 days. All comments must be transmitted or postmarked no later than 90 days from the date of publication of the U.S. Environmental Protection Agency's notice of filing for this Draft EIS in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: Please contact Kathleen Morse, Planning Division, Yosemite National Park, P.O. Box 577, Yosemite, CA 95389; telephone (209) 379–1110.

Development of Proposal and Alternatives: On April 11, 2007, the NPS published a Notice of Intent to prepare an EIS in the **Federal Register**. This initial scoping period included three public meetings and resulted in 191 responses. Public scoping was reopened with a **Federal Register** notice on June 30, 2009, and through multiple public notices in newspapers throughout northern California and the Yosemite region. The second scoping period was extended until February 4, 2010 and resulted in 576 responses. Also throughout this period, e-newsletters were sent to 5,700 recipients and postcards to 25,000 Yosemite campers.

The Merced River Plan/DEIS has been developed through consultation with traditionally associated American Indian tribes, the State Historic Preservation Officer, and other federal and state agencies. Gateway communities, organizations, and interested members of the public have provided more than 1,460 pieces of correspondence (including letters, faxes, emails, comment forms, and public meeting flip-chart notes). The NPS has conducted more than 40 public meetings, presentations, workshops, field visits, and open houses in support of the EIS process. Two preliminary alternatives concept workbooks were prepared and distributed for public review and comment prior to completion of the Merced River Plan/DEIS.

Based on a thorough examination of the river's baseline conditions at the time of designation (1986), a multi-faceted approach to river management and stewardship is proposed. To address the WSRA mandate to protect and enhance river values, many of the plan's actions would be common to all the action alternatives, including: (1) All WSRA management elements (boundaries, classifications, § 7 determination process); (2) actions to protect and enhance river values (e.g., ecological restoration components); (3) removal and/or relocation of numerous facilities and services; (4) actions to improve traffic circulation and reduce congestion; (5) implementation of a monitoring program that sets thresholds for when management actions must be taken to protect river values; and (6) numeric limits on use through a user capacity management program.

In keeping with the expressed purpose and need, the DEIS identifies and evaluates five action alternatives for management of the river corridor, and a No-Action alternative. The action alternatives vary primarily in the degree of restoration and the amount of visitor use that could be accommodated by the commensurate level of facilities and services necessary to protect river values under each scenario. The interdisciplinary and public involvement effort provided varying perspectives and experiences that were considered during the alternative development process.

Alternative 1 (No-Action; baseline conditions) would continue current management and trends, including ongoing localized impacts associated with impacts to free flowing condition of the river and connectivity of meadows, permanent facilities in the Merced River floodplain, and pedestrian-vehicle conflicts at major intersections. In 2011, the peak daily visitation recorded for East Yosemite Valley was 20,900 people over a 24-hour period. Under the existing GMP, East Yosemite Valley visitation would be approximately 18,241 people.

Actions Common to Alternatives 2–6: All five action alternatives would protect and enhance river values by improving conditions that threaten sensitive meadows, archeological resources, and scenic vistas, and would differ primarily in the kinds of visitor opportunities available at Yosemite Valley and the Merced Lake High Sierra Camp. Restoration actions common to alternatives 2–6 include the removal of revetments, abandoned infrastructure, informal trails, and encroaching conifers in meadows; restoring riparian areas and meadow hydrology; regulating river access; and cultural resource protection and scenic resource protection. All alternatives would accommodate traditional cultural practices by American Indian tribes and groups. The action alternatives included in the Merced River Plan more closely align capacity with visitation to improve the visitor experience and allow for more extensive resource protection.

Alternative 2: Self-Reliant Visitor Experiences and Extensive Floodplain Restoration would include major restoration within the 100-year floodplain, significant reduction in facilities and services, and significantly lower visitor use than today. Given the conditions in this Alternative, visitation to East Yosemite Valley would be approximately 13,900 people per day over a 24-hour period.

Alternative 3: Dispersed Visitor Experiences and Extensive Riverbank Restoration would include significant restoration within 150 feet of the river, marked reduction in visitor facilities and services, and significantly lower visitor use than today. Given the conditions in this Alternative, East Yosemite Valley visitation would be approximately 13,200 people per day over a 24-hour period.

Alternative 4: Resource-based Visitor Experiences and Targeted Riverbank Restoration would include targeted restoration within 150 feet of the river, reduced commercial services with a significant increase over current camping opportunities, and slightly lower visitor use than today. Given the conditions in this Alternative, East Yosemite Valley visitation would be approximately 17,000 people per day over a 24-hour period.

Alternative 5 (agency-preferred): Enhanced Visitor Experiences and Essential Riverbank Restoration would include essential restoration within 100 feet of the river, reduced commercial services with moderate increases to current camping opportunities, and approximately the same level of visitor use as today. Given the conditions in this Alternative, East Yosemite Valley visitation would be approximately 19,900 people per day over a 24-hour period. This preferred course of action is also identified as the ''environmentally preferred'' alternative.

Alternative 6: Diversified Visitor Experiences and Selective Riverbank Restoration would include limited restoration within 100 feet of the river, expanded facilities and services with the largest increase over current camping opportunities, and some growth in visitor use over time. Given the conditions in this Alternative, East Yosemite Valley visitation would be allowed to increase to approximately

21,800 people per day over a 24-hour period.

How To Comment: At any time during the 90 day public review period, comments may be transmitted electronically through the NPS Planning, Environment and Public Comment Web site at *http://parkplanning.nps.gov/yose_mrp,* or through the Yosemite National Park Web site at *yose_planning@nps.gov.* Alternately, written comments may be mailed to Superintendent, Yosemite National Park, Attn: Merced River Plan DEIS, P.O. Box 577, Yosemite, California 95389, or may be hand-delivered at one of the scheduled public meetings.

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.

Public meetings and site visits will be hosted in Yosemite Valley and in several gateway communities, and San Francisco. Any individual or organization who wants to express an opinion about the effects of the plan on natural or cultural resources and/or the visitor experience is encouraged to attend. All in-park meetings will be available through the park's Web site at *https://yose.webex.com.* All meeting locations and dates will be announced via the Yosemite electronic newsletter, press releases, and posted on the park's Web site *http://www.nps.gov/yose/parkmgmt/mrp.htm.*

Printed or CD format documents may be requested through email (*yose_planning@nps.gov*), or by telephone at (209) 379–1110. In addition, the DEIS will be available at public libraries in local communities. Electronic versions will be available online at *http://parkplanning.nps.gov/yose_mrp,* which can be accessed directly through the Yosemite National Park Web site (noted above).

Decision Process: All comments submitted on the Merced River Plan/DEIS will be duly considered in preparing the Final Environmental Impact Statement (Final EIS). The Final EIS/Merced River Plan is expected to be available in Spring of 2013; availability will be announced similarly as the DEIS, including notice in the **Federal Register**. A Record of Decision will be prepared not sooner than 30 days after release of the FEIS. As a delegated EIS process, the official responsible for final approval is the Regional Director, Pacific West Region, National Park Service; subsequently, the official responsible for implementation of the approved Merced River Plan is the Superintendent, Yosemite National Park.

Dated: November 19, 2012.

Christine S. Lehnertz,

Regional Director, Pacific West Region.

[FR Doc. 2013–01461 Filed 1–24–13; 8:45 am]

BILLING CODE 4312–FF–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–IMR–LAMR–10224; 2310–0091–422]

Off-Road Vehicle Management Plan, Draft Environmental Impact Statement, Lake Meredith National Recreation Area, Texas

AGENCY: National Park Service, Interior.

ACTION: Notice of Availability.

SUMMARY: Pursuant to § 102(2)(C) the National Environmental Policy Act of 1969, 42 U.S.C. 4332(2)(C), the National Park Service (NPS) is releasing a Draft Environmental Impact Statement (DEIS) for the Off-Road Vehicle Management Plan (Plan), Lake Meredith National Recreation Area (LAMR), Texas. The Plan/DEIS evaluates the impacts of four alternatives that address off-road vehicle (ORV) management in the national recreation area. It also assesses the impacts that could result from continuing the current management framework in the no action alternative. The selected alternative will guide ORV management at LAMR for the next 15 years.

DATES: The NPS will accept comments on the DEIS from the public for 60 days following publication by the U.S. Environmental Protection Agency (EPA) of the Notice of the Availability of the DEIS. After the EPA Notice of Availability is published, NPS will schedule public meetings during the comment period. Dates, time, and locations of these meetings will be announced in press releases, a newsletter, and on the NPS Planning, Environment, and Public Comment (PEPC) Web site for the project at *http://www.parkplanning.nps.gov/LAMR.*

ADDRESSES: Information will be available for public review and comment online at: *http://parkplanning.nps.gov/LAMR.* Copies of the Plan/DEIS will be available in the office of the Superintendent, Lake Meredith National Recreation Area, Alibates Flint Quarries National Monument, 419 E. Broadway, Fritch, Texas 79036–1460, or by phone at (806) 857–3151.

FOR FURTHER INFORMATION CONTACT: Cindy Ott-Jones, Superintendent, Lake Meredith National Recreation Area, Alibates Flint Quarries National Monument, P.O. Box 1460, Fritch, Texas 79036–1460, or by phone at (806) 857–3151, or by email at *Cindy_Ott-Jones@nps.gov.*

SUPPLEMENTARY INFORMATION: The purpose of this Plan/DEIS is to manage ORV use in the national recreation area for visitor enjoyment and recreation opportunities, while minimizing and correcting damage to resources. By special regulation (Title 36, Section 7.57 of the Code of Federal Regulations), the national recreation area allows the use of ORVs in two areas: Blue Creek and Rosita Flats. Action is needed at this time to comply with Executive Order 11644, provide for sustainable ORV use areas, address the lack of an approved plan, address resource impacts resulting from ORV use, and address the change in numbers, power, range, and capabilities of ORVs currently using the ORV areas.

The Plan/DEIS evaluates four alternatives: A No Action Alternative (A) and three Action Alternatives (B, C, and D (preferred)). These are summarized briefly here. Other alternatives were explored but dismissed; these are discussed in some detail in the draft Plan/DEIS.

- Alternative A: No Action—The national recreation area would continue to operate under the 2007 Interim ORV Management Plan where ORVs are allowed below the 3,000 foot elevation line in Rosita Flats and from cutbank to cutbank at Blue Creek. Limited facilities are supplied. No additional management tools such as zoning, permits, or use limits would be implemented.
- Alternative B: Under this alternative, ORV use would be managed through a zone system. Uses would be separated into the following zones: Camping, hunting, resource protection, low speed, and beginner. At Rosita Flats, two areas would be established as ORV areas and a number of routes would be designated. At Blue Creek, ORVs would only be allowed on sandy bottom areas designated routes, with ORV use prohibited on vegetated areas. ORV users would be required to obtain a free permit for educational purposes.
- Alternative C: This alternative manages ORV use through a fee permit system and user limits. Permits would

include a fee and initially, there would be no limit on the number of permits. However, additional studies would be required to determine the appropriate use limit, and limits could be set in the future. ORV routes and areas would be designated, including one ORV area and designated routes at Rosita Flats and the sandy bottom area of Blue Creek.

• Alternative D: The preferred alternative manages ORV use through a zone system. Uses would be separated into the following zones: Camping, hunting, resource protection, low speed, and beginner. At Rosita Flats, two areas would be established as ORV areas and a number of routes would be designated. At Blue Creek, ORVs would only be allowed on sandy bottom areas designated routes, with ORV use prohibited on vegetated areas. ORV permits would be required and a fee would apply. Permit fees would be used to recover costs associated with ORV management. New and current education and outreach efforts would also continue under alternative D.

If you wish to comment, you may submit your comments by any one of several methods. You may mail comments to Office of the Superintendent, Lake Meredith National Recreation Area, Alibates Flint Quarries National Monument, P.O. Box 1460, Fritch, Texas 79036–1460. You may also submit your comments online on the PEPC Web site at *http://parkplanning.nps.gov/LAMR.* Finally, you may hand-deliver comments to Lake Meredith National Recreation Area and Alibates Flint Quarries National Monument, 419 E. Broadway, Fritch, Texas 79036. Oral statements and written comments will also be accepted during the public meetings. Comments will not be accepted by fax, email, or in any other way than those specified above. Bulk comments in any format (hard copy or electronic) that do not include a signature and are submitted on behalf of others will not be accepted. 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. We will make all submissions from organizations or businesses, from individuals identifying themselves as representatives or officials, of organizations or businesses, available for public inspection in their entirety.

Dated: December 14, 2012.

John Wessels,

Regional Director, Intermountain Region, National Park Service.

[FR Doc. 2013–01434 Filed 1–24–13; 8:45 am]

BILLING CODE 4310–CB–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 *Certain Sealing Rings for Utility Meters and Components Thereof,* DN 2933; the Commission is soliciting comments on any public interest issues raised by the complaint or complainant's filing under section 210.8(b) of the Commission's Rules of Practice and Procedure (19 CFR 210.8(b)).

FOR FURTHER INFORMATION CONTACT: Lisa R. Barton, 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 and a submission pursuant to section 210.8(b) of the Commission's Rules of Practice and Procedure filed on behalf of E.J. Brooks Company on January 18, 2013. 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 sealing rings for utility meters and components thereof. The complaint names as respondents Mao Dah Enterprise Co., Ltd. of Taiwan.

Proposed respondents, other interested parties, and members of the public are invited to file comments, not to exceed five (5) pages in length, inclusive of attachments, on any public interest issues raised by the complaint or section 210.8(b) filing. Comments should address whether issuance of the relief specifically requested by the complainant in this investigation would 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 requested remedial orders are used in the United States;

(ii) Identify any public health, safety, or welfare concerns in the United States relating to the requested remedial orders;

(iii) Identify like or directly competitive articles that complainant, its licensees, or third parties make in the United States which could replace the subject articles if they were to be excluded;

(iv) Indicate whether complainant, complainant's licensees, and/or third party suppliers have the capacity to replace the volume of articles potentially subject to the requested exclusion order and/or a cease and desist order within a commercially reasonable time; and

(v) Explain how the requested remedial orders would impact United States consumers.

Written submissions must be filed no later than by close of business, eight calendar 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 electronically on or before the deadlines stated above and submit 8 true paper copies to the Office of the Secretary by noon the next day pursuant to section 210.4(f) of the Commission's Rules of Practice and Procedure (19 CFR 210.4(f)). Submissions should refer to the docket number (''Docket No. 2933'')

in a prominent place on the cover page and/or the first page. (*See* Handbook for Electronic Filing Procedures, *http://www.usitc.gov/secretary/fed_reg_notices/rules/handbook_on_electronic_filing.pdf*). Persons with questions regarding 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 and on EDIS.

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 210.8(c) of the Commission's Rules of Practice and Procedure (19 CFR 201.10, 210.8(c)).

By order of the Commission.

Issued: January 18, 2013.

Lisa R. Barton,

Acting Secretary to the Commission.

[FR Doc. 2013–01480 Filed 1–24–13; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Inv. No. 337–TA–863]

Certain Paper Shredders, Certain Processes for Manufacturing or Relating to Same and Certain Products Containing Same and Certain Parts Thereof

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that a complaint was filed with the U.S. International Trade Commission on December 20, 2012, under section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337, on behalf of Fellowes, Inc. of Itasca, Illinois and Fellowes Office Products (Suzhou) Co. Ltd. of China. Letters supplementing the complaint were filed on January 8 and 10, 2013. The complaint alleges violations of section 337 based upon the importation into the United States, the sale for importation, and the sale within the United States after importation of certain paper shredders, certain processes for manufacturing or relating to same and certain products containing same and certain parts thereof by reason of infringement of U.S. Patent No. D583,859 (''the '859 patent'') and U.S. Patent No. D598,048 (''the '048 patent'') and that an industry in the United States exists as required by subsection (a)(2) of section 337. The complaint also alleges violations of section 337 based upon the importation into the United States, the sale for importation, and the sale within the United States after importation of certain paper shredders, certain processes for manufacturing or relating to same and certain products containing same and certain parts thereof by reason of misappropriation of trade secrets, the threat or effect of which is to destroy or substantially injure an industry in the United States.

The complainants request that the Commission institute an investigation and, after the investigation, issue an exclusion order and cease and desist orders.

ADDRESSES: The complaint, except for any confidential information contained therein, is 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., Room 112, Washington, DC 20436, telephone (202) 205–2000. Hearing impaired individuals are advised that information on this matter can be obtained 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 at *http://www.usitc.gov*. The public record for this investigation may be viewed on the Commission's electronic docket (EDIS) at *http://edis.usitc.gov.*

FOR FURTHER INFORMATION CONTACT: The Office of Unfair Import Investigations, U.S. International Trade Commission, telephone (202) 205–2560.

Authority: The authority for institution of this investigation is contained in section 337 of the Tariff Act of 1930, as amended, and in section 210.10 of the Commission's Rules of Practice and Procedure, 19 CFR 210.10 (2012).

Scope of Investigation: Having considered the complaint, the U.S. International Trade Commission, on January 18, 2013, *ordered that*—

(1) Pursuant to subsection (b) of section 337 of the Tariff Act of 1930, as amended, an investigation be instituted to determine:

(a) Whether there is a violation of subsection (a)(1)(B) of section 337 in the importation into the United States, the sale for importation, or the sale within the United States after importation of certain paper shredders, certain processes for manufacturing or relating to same and certain products containing same and certain parts thereof by reason of infringement of the claim of the '859 patent and the claim of the '048 patent, and whether an industry in the United States exists as required by subsection (a)(2) of section 337;

(b) Whether there is a violation of subsection (a)(1)(A) of section 337 in the importation into the United States, the sale for importation, or the sale within the United States after importation of certain paper shredders, certain processes for manufacturing or relating to same and certain products containing same and certain parts thereof by reason of misappropriation of trade secrets, the threat or effect of which is to destroy or substantially injure an industry in the United States;

(2) For the purpose of the investigation so instituted, the following are hereby named as parties upon which this notice of investigation shall be served:

(a) The complainants are:

Fellowes, Inc., 1789 Norwood Avenue, Itasca, IL 60143–1095;

Fellowes Office Products, (Suzhou) Co., Ltd., 1 Shilin Road, Suzhou New District, Jiangsu Province, Suzhou 215151, China.

(b) The respondents are the following entities alleged to be in violation of section 337, and are the parties upon which the complaint is to be served:

New United Co. Group Ltd., No. 18 Qianjia Industrial Park, Yaoguan Town, Wujin District, Changzhou, Jiangsu 213011, China;

Jiangsu New United Office Equipments Co. Ltd., No. 6 Qianjia Industrial Park, Yaoguan, Jiangsu Province 213011, China;

Shenzhen Elite Business, Office Equipment Co. Ltd., No. 88 Fuhuasan Road, Futian District, Unit 11D15, 11th Floor, Fortune Plaza, Shenzhen City, Guangdong Province, China, 518026;

Elite Business Machines Ltd., Unit 1A, 2nd Floor, Fu Tao Building, 98 Argyle Street, Mong Kok, Kowloon, Hong Kong Special Administrative Region, China;

New United Office Equipment USA, Inc., 3701 Commercial Avenue, Northbrook, IL 60062;

Jiangsu Shinri Machinery Co. Ltd., Qianjia Industrial Park, Yaoguan Town, Wujin District, Changzhou, Jiangsu Province, China;

Zhou Licheng, No. 45, Miaotou Natural Village, Qianjia Administrative Village, Yaoguan Town, Wujin District, Changzhou City, Jiangsu Province, China, 213102;

Randall Graves, Apartment 1201, Unit C, Block 320, Nandu Section, Hutang New City Complex, Wujin District, Changzhou City, Jiangsu Province, China, 213161;

''Jessica'' Wang Chongge, Group 1, Tonguyan Village, Tongyuan Town, Gaoling County, Xi'an City, Shaanzi Province, China 710202.

(c) The Office of Unfair Import Investigations, U.S. International Trade Commission, 500 E Street SW., Suite 401, Washington, DC 20436; and

(3) For the investigation so instituted, the Chief Administrative Law Judge, U.S. International Trade Commission, shall designate the presiding Administrative Law Judge.

Responses to the complaint and the notice of investigation must be submitted by the named respondents in accordance with section 210.13 of the Commission's Rules of Practice and Procedure, 19 CFR 210.13. Pursuant to 19 CFR 201.16(d)–(e) and 210.13(a), such responses will be considered by the Commission if received not later than 20 days after the date of service by the Commission of the complaint and the notice of investigation. Extensions of time for submitting responses to the complaint and the notice of investigation will not be granted unless good cause therefor is shown.

Failure of a respondent to file a timely response to each allegation in the complaint and in this notice may be deemed to constitute a waiver of the right to appear and contest the allegations of the complaint and this notice, and to authorize the administrative law judge and the Commission, without further notice to the respondent, to find the facts to be as alleged in the complaint and this notice and to enter an initial determination and a final determination containing such findings, and may result in the issuance of an exclusion order or a cease and desist order or both directed against the respondent.

By order of the Commission.

Issued: January 22, 2013.

William R. Bishop,

Supervisory Hearings and Information Officer.

[FR Doc. 2013–01553 Filed 1–24–13; 8:45 am]

BILLING CODE 7020–02–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Importer of Controlled Substances; Notice of Registration; Fisher Clinical Services, Inc.

By Notice dated November 1, 2012, and published in the **Federal Register** on November 9, 2012, 77 FR 67396, Fisher Clinical Services, Inc., 7554 Schantz Road, Allentown, Pennsylvania 18106, made application to the Drug Enforcement Administration (DEA) to be registered as an importer of Tapentadol (9780), a basic class of controlled substance listed in schedule II.

The company plans to import the listed controlled substance to conduct clinical trials.

No comments or objections have been received. DEA has considered the factors in 21 U.S.C. 823(a) and 952(a), and determined that the registration of Fisher Clinical Services, Inc., to import the basic class of controlled substance is consistent with the public interest, and with United States obligations under international treaties, conventions, or protocols in effect on May 1, 1971. DEA has investigated Fisher Clinical Services, Inc., to ensure that the company's registration is consistent with the public interest. The investigation has included inspection and testing of the company's physical security systems, verification of the company's compliance with state and local laws, and a review of the company's background and history.

Therefore, pursuant to 21 U.S.C. 952(a) and 958(a), and in accordance with 21 CFR 1301.34, the above named company is granted registration as an importer of the basic class of controlled substance listed.

Dated: January 16, 2013.

Joseph T. Rannazzisi,

Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration.

[FR Doc. 2013–01532 Filed 1–24–13; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Importer of Controlled Substances; Notice of Application

Pursuant to 21 U.S.C. 958(i), the Attorney General shall, prior to issuing a registration under this Section to a bulk manufacturer of a controlled substance in schedules I or II, and prior to issuing a regulation under 21 U.S.C. 952(a)(2) authorizing the importation of such a substance, provide manufacturers holding registrations for the bulk manufacture of the substance an opportunity for a hearing.

Therefore, in accordance with 21 CFR 1301.34(a), this is notice that on September 21, 2012, Nebraska State Penitentiary, 4201 South 14th Street, Lincoln, Nebraska 68502, made application to the Drug Enforcement Administration (DEA) to be registered as an importer of Pentobarbital (2270), a basic class of controlled substance listed in schedule II.

The facility intends to import the above listed controlled substance for legitimate use. Supplies of this particular controlled substance are inadequate and are not available in the form needed within the current domestic supply of the United States.

Any bulk manufacturer who is presently, or is applying to be, registered with DEA to manufacture such basic class of controlled substance may file comments or objections to the issuance of the proposed registration, and may, at the same time, file a written request for a hearing on such application pursuant to 21 CFR 1301.43, and in such form as prescribed by 21 CFR 1316.47.

Any such written comments or objections should be addressed, in quintuplicate, to the Drug Enforcement Administration, Office of Diversion Control, Federal Register Representative (ODL), 8701 Morrissette Drive, Springfield, Virginia 22152; and must be filed no later than February 25, 2013.

This procedure is to be conducted simultaneously with, and independent of, the procedures described in 21 CFR 1301.34(b), (c), (d), (e), and (f). As noted in a previous notice published in the **Federal Register** on September 23, 1975, 40 FR 43745–46, all applicants for registration to import a basic class of any controlled substance in schedule I or II are, and will continue to be, required to demonstrate to the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, that the requirements for such registration pursuant to 21 U.S.C. 958(a), 21 U.S.C. 823(a), and 21 CFR 1301.34(b), (c), (d), (e), and (f) are satisfied.

Dated: January 16, 2013.

Joseph T. Rannazzisi,

Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration.

[FR Doc. 2013–01536 Filed 1–24–13; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Importer of Controlled Substances; Notice of Registration; R & D Systems, Inc.

By Notice dated August 17, 2012, and published in the **Federal Register** on August 20, 2012, 77 FR 50162, R & D Systems, Inc., 614 McKinley Place NE., Minneapolis, Minnesota 55413, made application to the Drug Enforcement Administration (DEA) to be registered as an importer of the following basic classes of controlled substances:

Drug	Schedule
1-Pentyl-3-(1-naphthoyl)indole (7118).	I
5-(1,1-Dimethylheptyl)-2-[(1R,3S)-3- hydroxycyclohexyl]- phenol (7297).	I
Marihuana (7360)	I
Tetrahydrocannabinols (7370)	I
4-Bromo-2,5-dimethoxyamphetamine (7391).	I
3,4-Methylenedioxymethamphetamine (7405).	I
Dimethyltryptamine (7435)	I
Amphetamine (1100)	II
Methylphenidate (1724)	II
Phencyclidine (7471)	II
Cocaine (9041)	II
Oxycodone (9143)	II
Thebaine (9333)	II
Fentanyl (9801)	II

The company plans to import the listed controlled substances in dosage form to distribute to researchers.

In reference to drug codes 7360 and 7370, the company plans to import a synthetic cannabidiol and a synthetic Tetrahydrocannabinol. No other activity for this drug code is authorized for this registration.

No comments or objections have been received. DEA has considered the factors in 21 U.S.C. 823(a) and 952(a), and determined that the registration of R & D Systems, Inc., to import the basic classes of controlled substances is consistent with the public interest, and with United States obligations under international treaties, conventions, or protocols in effect on May 1, 1971, at this time. DEA has investigated R & D Systems, Inc., to ensure that the company's registration is consistent with the public interest. The investigation has included inspection and testing of the company's physical security systems, verification of the company's compliance with state and local laws, and a review of the company's background and history.

Therefore, pursuant to 21 U.S.C. 952(a) and 958(a), and in accordance with 21 CFR § 1301.34, the above named company is granted registration as an importer of the basic classes of controlled substances listed.

Dated: January 15, 2013.

Joseph T. Rannazzisi,

Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration.

[FR Doc. 2013–01554 Filed 1–24–13; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Importer of Controlled Substances, Notice of Registration, Myoderm

By Notice dated June 28, 2012, and published in the **Federal Register** on July 5, 2012, 77 FR 39741, Myoderm, 48 East Main Street, Norristown, Pennsylvania 19401, made application to the Drug Enforcement Administration (DEA) to be registered as an importer of the following basic classes of controlled substances:

Drug	Schedule
Amphetamine (1100)	II
Lisdexamfetamine (1205)	II
Methylphenidate (1724)	II
Pentobarbital (2270)	II
Nabilone (7379)	II
Codeine (9050)	II
Oxycodone (9143)	II
Hydromorphone (9150)	II
Hydrocodone (9193)	II
Levomethorphan (9210)	II
Meperidine (9230)	II
Methadone (9250)	II
Methadone intermediate (9254)	II
Morphine (9300)	II
Oxymorphone (9652)	II
Fentanyl (9801)	II

The company plans to import the listed controlled substances in finished dosage form for clinical trials, and research.

The import of the above listed basic classes of controlled substances is granted only for analytical testing and clinical trials. This authorization does not extend to the import of a finished FDA approved or non-approved dosage form for commercial distribution in the United States.

No comments or objections have been received. DEA has considered the factors in 21 U.S.C. 823(a) and 952(a), and determined that the registration of Myoderm, to import the basic classes of controlled substances is consistent with the public interest, and with United States obligations under international treaties, conventions, or protocols in effect on May 1, 1971, at this time. DEA has investigated Myoderm, to ensure that the company's registration is consistent with the public interest. The investigation has included inspection and testing of the company's physical security systems, verification of the company's compliance with state and local laws, and a review of the company's background and history. Therefore, pursuant to 21 U.S.C. 952(a) and 958(a), and in accordance with 21 CFR 1301.34, the above named company is granted registration as an importer of the basic classes of controlled substances listed.

Dated: January 15, 2013.

Joseph T. Rannazzisi,

Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration.

[FR Doc. 2013–01540 Filed 1–24–13; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Importer of Controlled Substances; Notice of Registration; Chattem Chemicals, Inc.

By Notice dated June 28, 2012, and published in the **Federal Register** on July 6, 2012, 77 FR 40086, Chattem Chemicals, Inc., 3801 St. Elmo Avenue, Chattanooga, Tennessee 37409, made application by renewal to the Drug Enforcement Administration (DEA) to be registered as an importer of the following basic classes of controlled substances:

Drug	Schedule
Methamphetamine (1105)	II
4-Anilino-N-phenethyl-4-piperidine (8333).	II
Phenylacetone (8501)	II
Opium, raw (9600)	II
Poppy Straw Concentrate (9670)	II
Tapentadol (9780)	II

The company plans to import the listed controlled substances to manufacture bulk controlled substances for sale to its customers.

The company plans to import an intermediate form of Tapentadol (9780), to bulk manufacture Tapentadol for distribution to its customers.

Comments and requests for hearing on applications to import narcotic raw material are not appropriate, 72 FR 3417(2007).

Regarding all other basic classes of controlled substances, no comments or objections have been received. DEA has considered the factors in 21 U.S.C. 823(a) and 952(a), and determined that

the registration of Chattem Chemicals, Inc., to import the basic classes of controlled substances is consistent with the public interest, and with United States obligations under international treaties, conventions, or protocols in effect on May 1, 1971. DEA has investigated Chattem Chemicals, Inc., to ensure that the company's rgistration is consistent with the public interest. The investigation has included inspection and testing of the company's physical security systems, verification of the company's compliance with state and local laws, and a review of the company's background and history.

Therefore, pursuant to 21 U.S.C. 952(a) and 958(a), and in accordance with 21 CFR 1301.34, the above named company is granted registration as an importer of the basic classes of controlled substances listed.

Dated: January 15, 2013.

Joseph T. Rannazzisi,

Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration.

[FR Doc. 2013–01530 Filed 1–24–13; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Manufacturer of Controlled Substances; Notice of Application; Cerilliant Corporation

Pursuant to § 1301.33(a), Title 21 of the Code of Federal Regulations (CFR), this is notice that on October 4, 2012, Cerilliant Corporation, 811 Paloma Drive, Suite A, Round Rock, Texas 78665–2402, made application to the Drug Enforcement Administration (DEA) to be registered as a bulk manufacturer of the following basic classes of controlled substances:

Drug	Schedule
JWH-250 (6250)	I
SR-18 also known as RCS-8 (7008).	I
JWH-019 (7019)	I
JWH-081 (7081)	I
SR-19 also known as RCS-4 (7104).	I
JWH-122 (7122)	I
AM-2201 (7201)	I
JWH-203 (7203)	I
2C-T-2 (7385)	I
JWH-398 (7398)	I
N-Ethyl-1-phenylcyclohexylamine (7455).	I
2C-D (7508)	I
2C-E (7509)	I
2C-H (7517)	I
2C-I (7518)	I
2C-C (7519)	I
2C-N (7521)	I
2C-P (7524)	I
2C-T-4 (7532)	I
AM-694 (7694)	I
Metazocine (9240)	II

The company plans to manufacture the listed controlled substances for distribution to their research and forensic customers conducting drug testing and analysis.

Any other such applicant, and any person who is presently registered with DEA to manufacture such substances, may file comments or objections to the issuance of the proposed registration pursuant to 21 CFR 1301.33(a).

Any such written comments or objections should be addressed, in quintuplicate, to the Drug Enforcement Administration, Office of Diversion Control, Federal Register Representative (ODL), 8701 Morrissette Drive, Springfield, Virginia 22152; and must be filed no later than March 26, 2013.

Dated: January 14, 2013.

Joseph T. Rannazzisi,

Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration.

[FR Doc. 2013–01556 Filed 1–24–13; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Manufacturer of Controlled Substances, Notice of Registration; Sigma Aldrich Research Biochemicals, Inc.

By Notice dated September 20, 2012, and published in the **Federal Register** on October 2, 2012, 77 FR 60145, Sigma Aldrich Research Biochemicals, Inc., 1–3 Strathmore Road, Natick, Massachusetts 01760–2447, made application by letter to the Drug Enforcement Administration (DEA) to be registered as a bulk manufacturer of the following basic classes of controlled substances:

Drug	Schedule
4-Methyl-2,5-dimethoxyamphetamine (7395).	I
Dimethyltryptamine (7435)	I

The company plans to manufacture reference standards.

No comments or objections have been received. DEA has considered the factors in 21 U.S.C. 823(a), and determined that the registration of Sigma Aldrich Research Biochemicals, Inc., to manufacture the listed basic classes of controlled substances is consistent with the public interest at this time. DEA has investigated Sigma Aldrich Research Biochemicals, Inc., to ensure that the company's registration is consistent with the public interest. The investigation has included inspection and testing of the company's physical security systems; verification of the company's compliance with state and local laws; and a review of the company's background and history.

Therefore, pursuant to 21 U.S.C. 823(a), and in accordance with 21 CFR 1301.33, the above named company is granted registration as a bulk manufacturer of the basic classes of controlled substances listed.

Dated: January 14, 2013.

Joseph T. Rannazzisi,

Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration.

[FR Doc. 2013–01588 Filed 1–24–13; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Manufacturer of Controlled Substances; Notice of Registration; Johnson Matthey, Inc.

By Notice dated May 9, 2012, and published in the **Federal Register** on May 21, 2012, 77 FR 30026, Johnson Matthey, Inc., Custom Pharmaceuticals Department, 2003 Nolte Drive, West Deptford, New Jersey 08066–1742, made application by letter to the Drug Enforcement Administration (DEA) to be registered as a bulk manufacturer of Tapentadol (9780), a basic class of controlled substance listed in schedule II.

The company plans to manufacture the listed controlled substance for sale to its customers.

One comment objecting to the granting of registration as a bulk manufacturer of the basic class of controlled substance listed to this applicant was received. However, after a thorough review of this matter, DEA has concluded that the issues raised in the comment and objection do not warrant the denial of this application.

DEA has considered the factors in 21 U.S.C. 823(a) and determined that the registration of Johnson Matthey, Inc., to manufacture the listed basic class of controlled substance is consistent with the public interest at this time. DEA has investigated Johnson Matthey, Inc., to ensure that the company's registration is consistent with the public interest. The

investigation has included inspection and testing of the company's physical security systems, verification of the company's compliance with state and local laws, and a review of the company's background and history. Therefore, pursuant to 21 U.S.C. 823(a), and in accordance with 21 CFR 1301.33, the above named company is granted registration as a bulk manufacturer of the basic class of controlled substance listed.

Dated: January 15, 2013.

Joseph T. Rannazzisi,

Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration.

[FR Doc. 2013–01603 Filed 1–24–13; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Manufacturer of Controlled Substances; Notice of Registration; Ampac Fine Chemicals, LLC

By Notice dated September 20, 2012, and published in the **Federal Register** on October 2, 2012, 77 FR 60145, AMPAC Fine Chemicals, LLC, Highway 50 and Hazel Avenue, Building 05001, Rancho Cordova, California 95670, made application by letter to the Drug Enforcement Administration (DEA) to be registered as a bulk manufacturer of Tapentadol (9780), a basic class of controlled substance listed in schedule II.

The company plans to manufacture the listed controlled substance for distribution to its customers.

No comments or objections have been received. DEA has considered the factors in 21 U.S.C. 823(a), and determined that the registration of AMPAC Fine Chemicals, LLC to manufacture the listed basic class of controlled substance is consistent with the public interest at this time. DEA has investigated AMPAC Fine Chemicals, LLC to ensure that the company's registration is consistent with the public interest. The investigation has included inspection and testing of the company's physical security systems; verification of the company's compliance with state and local laws; and a review of the company's background and history.

Therefore, pursuant to 21 U.S.C. 823(a), and in accordance with 21 CFR 1301.33, the above named company is granted registration as a bulk manufacturer of the basic class of controlled substance listed.

Dated: January 14, 2013.

Joseph T. Rannazzisi,

Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration.

[FR Doc. 2013–01534 Filed 1–24–13; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Manufacturer of Controlled Substances, Notice of Application; Siegfried (USA)

Pursuant to § 1301.33(a), Title 21 of the Code of Federal Regulations (CFR), this is notice that on June 19, 2012, Siegfried (USA), 33 Industrial Park Road, Pennsville, New Jersey 08070, made application by letter to the Drug Enforcement Administration (DEA) to be registered as a bulk manufacturer of Tapentadol (9780), a basic class of controlled substance listed in schedule II.

The company plans to manufacturer the listed controlled substance for distribution to its customers.

Any other such applicant, and any person who is presently registered with DEA to manufacture such substances, may file comments or objections to the issuance of the proposed registration pursuant to 21 CFR 1301.33(a).

Any such written comments or objections should be addressed, in quintuplicate, to the Drug Enforcement Administration, Office of Diversion Control, Federal Register Representative (ODL), 8701 Morrissette Drive, Springfield, Virginia 22152; and must be filed no later than March 26, 2013.

Dated: January 15, 2013.

Joseph T. Rannazzisi,

Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration.

[FR Doc. 2013–01591 Filed 1–24–13; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Manufacturer of Controlled Substances; Notice of Registration; Chemic Laboratories, Inc.

By Notice dated September 25, 2012, and published in the **Federal Register** on October 2, 2012, 77 FR 60144, Chemic Laboratories, Inc., 480 Neponset Street, Building 7, Canton, Massachusetts 02021, made application by renewal to the Drug Enforcement Administration (DEA) to be registered as a bulk manufacturer of Cocaine (9041), a basic class of controlled substance listed in schedule II.

The company plans to manufacture small quantities of the above listed controlled substance for distribution to its customers for the purpose of research.

No comments or objections have been received. DEA has considered the factors in 21 U.S.C. 823(a), and determined that the registration of Chemic Laboratories, Inc., to manufacture the listed basic class of controlled substance is consistent with the public interest at this time. DEA has investigated Chemic Laboratories, Inc., to ensure that the company's registration is consistent with the public interest. The investigation has included inspection and testing of the company's physical security systems; verification of the company's compliance with state and local laws; and a review of the company's background and history.

Therefore, pursuant to 21 U.S.C. 823(a), and in accordance with 21 CFR 1301.33, the above named company is granted registration as a bulk manufacturer of the basic class of controlled substance listed.

Dated: January 14, 2013.

Joseph T. Rannazzisi,

Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration.

[FR Doc. 2013–01535 Filed 1–24–13; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Manufacturer of Controlled Substances; Notice of Registration; Noramco, Inc.

By Notice dated October 9, 2012, and published in the **Federal Register** on October 18, 2012, 77 FR 64143, Noramco, Inc., 500 Swedes Landing Road, Wilmington, Delaware 19801–4417, made application by renewal to the Drug Enforcement Administration (DEA) to be registered as a bulk manufacturer of the following basic classes of controlled substances:

Drug	Schedule
Codeine-N-oxide (9053)	I
Dihydromorphine (9145)	I
Morphine-N-oxide (9307)	I
Amphetamine (1100)	II
Methylphenidate (1724)	II
Phenylacetone (8501)	II
Codeine (9050)	II
Dihydrocodeine (9120)	II
Oxycodone (9143)	II

Drug	Schedule
Hydromorphone (9150)	II
Hydrocodone (9193)	II
Morphine (9300)	II
Oripavine (9330)	II
Thebaine (9333)	II
Opium extracts (9610)	II
Opium fluid extract (9620)	II
Opium tincture (9630)	II
Opium, powdered (9639)	II
Opium, granulated (9640)	II
Oxymorphone (9652)	II
Noroxymorphone (9668)	II
Tapentadol (9780)	II

The company plans to manufacture the listed controlled substances in bulk for distribution to its customers.

No comments or objections have been received. DEA has considered the factors in 21 U.S.C. 823(a) and determined that the registration of Noramco, Inc., to manufacture the listed basic classes of controlled substances is consistent with the public interest at this time. DEA has investigated Noramco, Inc., to ensure that the company's registration is consistent with the public interest. The investigation has included inspection and testing of the company's physical security systems, verification of the company's compliance with state and local laws, and a review of the company's background and history. Therefore, pursuant to 21 U.S.C. 823(a), and in accordance with 21 CFR 1301.33, the above named company is granted registration as a bulk manufacturer of the basic classes of controlled substances listed.

Dated: January 15, 2013.

Joseph T. Rannazzisi,

Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration.

[FR Doc. 2013–01600 Filed 1–24–13; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Manufacturer of Controlled Substances; Notice of Registration; Cerilliant Corporation

By Notice dated August 17, 2012, and published in the **Federal Register** on August 29, 2012, 77 FR 52366, Cerilliant Corporation, 811 Paloma Drive, Suite A, Round Rock, Texas 78665–2402, made application by renewal to the Drug Enforcement Administration (DEA) to be registered as a bulk manufacturer of the following basic classes of controlled substances:

Drug	Schedule
Cathinone (1235)	I
Methcathinone (1237)	I
4-Methyl-N-methylcathinone (1248)	I
N-Ethylamphetamine (1475)	I
N,N-Dimethylamphetamine (1480)	I
Fenethylline (1503)	I
Aminorex (1585)	I
4-Methylaminorex (cis isomer) (1590)	I
Gamma Hydroxybutyric Acid (2010)	I
Methaqualone (2565)	I
1-Pentyl-3-(1-naphthoyl)indole (7118)	I
1-Butyl-3-(1-naphthoyl)indole (7173)	I
1-[2-(4-Morpholinyl)ethyl]-3-(1-naphthoyl) indole (7200)	I
Alpha-ethyltryptamine (7249)	I
5-(1,1-Dimethylheptyl)-2-[(1R,3S)-3-hydroxycyclohexyl-phenol] (7297)	I
5-(1,1-Dimethyloctyl)-2-[(1R,3S)3-hydroxycyclohexyl-phenol] (7298)	I
Lysergic acid diethylamide (7315)	I
2,5-Dimethoxy-4-(n)-propylthiophenethylamine (7348)	I
Marihuana (7360)	I
Tetrahydrocannabinols (7370)	I
Parahexyl (7374)	I
Mescaline (7381)	I
3,4,5-Trimethoxyamphetamine (7390)	I
4-Bromo-2,5-dimethoxyamphetamine (7391)	I
4-Bromo-2,5-dimethoxyphenethylamine (7392)	I
4-Methyl-2,5-dimethoxyamphetamine (7395)	I
2,5-Dimethoxyamphetamine (7396)	I
2,5-Dimethoxy-4-ethylamphetamine (7399)	I
3,4-Methylenedioxyamphetamine (7400)	I
5-Methoxy-3,4-methylenedioxyamphetamine (7401)	I
N-Hydroxy-3,4-methylendioxyamphetamine (7402)	I
3,4-Methylendioxy-N-ethylamphetamine (7404)	I
3,4-Methylenedioxymethamphetamine (7405)	I
4-Methoxyamphetamine (7411)	I
5-Methoxy-N-N-dimethyltryptamine (7431)	I
Alpha-methyltryptamine (7432)	I
Bufotenine (7433)	I
Diethyltryptamine (7434)	I
Dimethyltryptamine (7435)	I
Psilocybin (7437)	I
Psilocyn (7438)	I
5-Methoxy-N,N-diisopropyltryptamine (7439)	I
N-Ethyl-1-phenylcyclohexylamine (7455)	I
1-(1-Phenylcyclohexyl)pyrrolidine (7458)	I
1-[1-(2-Thienyl)cyclohexyl]piperidine (7470)	I
N-Benzylpiperazine (7493)	I

Drug	Schedule
Acetyldihydrocodeine (9051)	I
Benzylmorphine (9052)	I
Codeine-N-oxide (9053)	I
Codeine methylbromide (9070)	I
Dihydromorphine (9145)	I
Heroin (9200)	I
Hydromorphinol (9301)	I
Methyldesorphine (9302)	I
Methyldihydromorphine (9304)	I
Morphine methylbromide (9305)	I
Morphine methylsulfonate (9306)	I
Morphine-N-oxide (9307)	I
Normorphine (9313)	I
Pholcodine (9314)	I
Acetylmethadol (9601)	I
Allylprodine (9602)	I
Alphacetylmethadol except levo-alphacetylmethadol (9603)	I
Alphameprodine (9604)	I
Alphamethadol (9605)	I
Betacetylmethadol (9607)	I
Betameprodine (9608)	I
Betamethadol (9609)	I
Betaprodine (9611)	I
Dipipanone (9622)	I
Hydroxypethidine (9627)	I
Noracymethadol (9633)	I
Norlevorphanol (9634)	I
Normethadone (9635)	I
Trimeperidine (9646)	I
Phenomorphan (9647)	I
1-Methyl-4-phenyl-4-propionoxypiperidine (9661)	I
Tilidine (9750)	I
Para-Fluorofentanyl (9812)	I
3-Methylfentanyl (9813)	I
Alpha-Methylfentanyl (9814)	I
Acetyl-alpha-methylfentanyl (9815)	I
Beta-hydroxyfentanyl (9830)	I
Beta-hydroxy-3-methylfentanyl (9831)	I
Alpha-methylthiofentanyl (9832)	I
3-Methylthiofentanyl (9833)	I
Thiofentanyl (9835)	I
Amphetamine (1100)	II
Methamphetamine (1105)	II
Lisdexamfetamine (1205)	II
Phenmetrazine (1631)	II
Methylphenidate (1724)	II
Amobarbital (2125)	II
Pentobarbital (2270)	II
Secobarbital (2315)	II
Glutethimide (2550)	II
Nabilone (7379)	II
1-Phenylcyclohexylamine (7460)	II
Phencyclidine (7471)	II
1-Piperidinocyclohexanecarbonitrile (8603)	II
Alphaprodine (9010)	II
Cocaine (9041)	II
Codeine (9050)	II
Dihydrocodeine (9120)	II
Oxycodone (9143)	II
Hydromorphone (9150)	II
Diphenoxylate (9170)	II
Benzoylecgonine (9180)	II
Ethylmorphine (9190)	II
Hydrocodone (9193)	II
Levomethorphan (9210)	II
Levorphanol (9220)	II
Isomethadone (9226)	II
Meperidine (9230)	II
Meperidine intermediate-A (9232)	II
Meperidine intermediate-B (9233)	II
Meperidine intermediate-C (9234)	II
Metazocine (9240)	II
Methadone (9250)	II
Methadone intermediate (9254)	II

Drug	Schedule
Dextropropoxyphene, bulk (non-dosage forms) (9273)	II
Morphine (9300)	II
Thebaine (9333)	II
Levo-alphacetylmethadol (9648)	II
Oxymorphone (9652)	II
Noroxymorphone (9668)	II
Racemethorphan (9732)	II
Alfentanil (9737)	II
Remifentanil (9739)	II
Sufentanil (9740)	II
Carfentanil (9743)	II
Tapentadol (9780)	II
Fentanyl (9801)	II

The company plans to manufacture small quantities of the listed controlled substances to make reference standards which will be distributed to their customers.

No comments or objections have been received. DEA has considered the factors in 21 U.S.C. 823(a) and determined that the registration of Cerilliant Corporation to manufacture the listed basic classes of controlled substances is consistent with the public interest at this time. DEA has investigated Cerilliant Corporation to ensure that the company's registration is consistent with the public interest. The investigation has included inspection and testing of the company's physical security systems; verification of the company's compliance with state and local laws; and a review of the company's background and history. Therefore, pursuant to 21 U.S.C. 823(a), and in accordance with 21 CFR 1301.33, the above named company is granted registration as a bulk manufacturer of the basic classes of controlled substances listed.

Dated: January 15, 2013.

Joseph T. Rannazzisi,

Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration.

[FR Doc. 2013–01533 Filed 1–24–13; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Manufacturer of Controlled Substances, Notice of Registration; Morton Grove Pharmaceuticals

By Notice dated September 25, 2012, and published in the **Federal Register** on October 2, 2012, 77 FR 60144, Morton Grove Pharmaceuticals, 6451 Main Street, Morton Grove, Illinois 60053–2633, made application by letter to the Drug Enforcement Administration (DEA) to be registered as a bulk manufacturer of Gamma Hydroxybutyric Acid (2010), a basic class of controlled substance listed in schedule I.

The company plans to manufacture the listed controlled substance for distribution to its customers.

No comments or objections have been received. DEA has considered the factors in 21 U.S.C. 823(a), and determined that the registration of Morton Grove Pharmaceuticals to manufacture the listed basic class of controlled substance is consistent with the public interest at this time. DEA has investigated Morton Grove Pharmaceuticals to ensure that the company's registration is consistent with the public interest. The investigation has included inspection and testing of the company's physical security systems; verification of the company's compliance with state and local laws; and a review of the company's background and history.

Therefore, pursuant to 21 U.S.C. 823(a), and in accordance with 21 CFR 1301.33, the above named company is granted registration as a bulk manufacturer of the basic class of controlled substance listed.

Dated: January 14, 2013.

Joseph T. Rannazzisi,

Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration.

[FR Doc. 2013–01592 Filed 1–24–13; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF LABOR

Office of the Secretary

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Statement of Expenditures and Financial Adjustment of Federal Funds for Unemployment Compensation for Federal Employees and Ex-Servicemembers

ACTION: Notice.

SUMMARY: The Department of Labor (DOL) is submitting the Employment and Training Administration (ETA) sponsored information collection request (ICR) titled, ''Statement of Expenditures and Financial Adjustment of Federal Funds for Unemployment Compensation for Federal Employees and Ex-Servicemembers,'' (Reporting Form ETA–191) to the Office of Management and Budget (OMB) for review and approval for continued use in accordance with the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501 et seq.).

DATES: Submit comments on or before February 25, 2013.

ADDRESSES: A copy of this ICR with applicable supporting documentation; including a description of the likely respondents, proposed frequency of response, and estimated total burden may be obtained from the RegInfo.gov Web site, *http://www.reginfo.gov/public/do/PRAMain,* on the day following publication of this notice or by contacting Michel Smyth by telephone at 202–693–4129 (this is not a toll-free number) or sending an email to *DOL_PRA_PUBLIC@dol.gov.*

Submit comments about this request to the Office of Information and Regulatory Affairs, Attn: OMB Desk Officer for DOL–ETA, Office of Management and Budget, Room 10235, 725 17th Street NW., Washington, DC 20503, Fax: 202–395–6881 (this is not a

toll-free number), email: *OIRA_submission@omb.eop.gov.*

FOR FURTHER INFORMATION CONTACT: Contact Michel Smyth by telephone at 202–693–4129 (this is not a toll-free number) or by email at *DOL_PRA_PUBLIC@dol.gov.*

Authority: 44 U.S.C. 3507(a)(1)(D).

SUPPLEMENTARY INFORMATION: Federal civilian and military agencies must reimburse the Federal Employees Compensation Account for the amount expended for benefits to former Federal civilian employees and ex-servicemembers. The ETA–191 report informs the ETA of the amount to bill such agencies.

This information collection is subject to the PRA. A Federal agency generally cannot conduct or sponsor a collection of information, and the public is generally not required to respond to an information collection, unless it is approved by the OMB under the PRA and displays a currently valid OMB Control Number. In addition, notwithstanding any other provisions of law, no person shall generally be subject to penalty for failing to comply with a collection of information that does not display a valid Control Number. *See* 5 CFR 1320.5(a) and 1320.6. The DOL obtains OMB approval for this information collection under Control Number 1205–0162. The current approval is scheduled to expire on January 31, 2013; however, it should be noted that existing information collection requirements submitted to the OMB receive a month-to-month extension while they undergo review. For additional information, see the related notice published in the **Federal Register** on September 18, 2012.

Interested parties are encouraged to send comments to the OMB, Office of Information and Regulatory Affairs at the address shown in the **ADDRESSES** section within 30 days of publication of this notice in the **Federal Register**. In order to help ensure appropriate consideration, comments should mention OMB Control Number 1205–0162. The OMB is particularly interested in comments that:

- 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.

Agency: DOL–ETA.

Title of Collection: Statement of Expenditures and Financial Adjustment of Federal Funds for Unemployment Compensation for Federal Employees and Ex-Servicemembers.

OMB Control Number: 1205–0162.

Affected Public: State, Local, and Tribal Governments.

Total Estimated Number of Respondents: 53.

Total Estimated Number of Responses: 212.

Total Estimated Annual Burden Hours: 1,272.

Total Estimated Annual Other Costs Burden: $0.

Dated: January 17, 2013.

Michel Smyth,

Departmental Clearance Officer.

[FR Doc. 2013–01513 Filed 1–24–13; 8:45 am]

BILLING CODE 4510–FW–P

OFFICE OF THE DIRECTOR OF NATIONAL INTELLIGENCE

Agency Information Collection Activities: Extension of Information Collection; Comment Request

AGENCY: Office of the Director of National Intelligence (ODNI).

ACTION: Notice and comment.

SUMMARY: In December 2011, the ODNI accepted responsibility from the Information Security Oversight Office (ISOO) for the maintenance of Standard Form 312: Classified Information Nondisclosure Agreement; Standard Form 713: Consent For Access to Records; and Standard Form 714: Financial Disclosure Report, which are directly related to responsibilities assigned to the Director of National Intelligence (DNI) as Security Executive Agent. Accordingly, ODNI is giving public notice regarding extension of the currently approved information collection, Financial Disclosure Report, Standard Form 714, which candidates for national security clearance must submit as a condition of access to specifically designated classified information along with a favorably adjudicated personnel security background investigation or reinvestigation that results in the granting or updating of a security clearance. ODNI is proposing no changes to the Standard Form 714 and its instructions at this time. The public is invited to comment on the information collection pursuant to the Paperwork Reduction Act of 1995.

DATES: Written comments must be received on or before March 26, 2013 to be assured of consideration.

ADDRESSES: Comments should be sent to: *dni-foia@dni.gov.*

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the information collection and supporting statement should be directed to Mr. John Hackett, Office of the Chief Information Officer, Information and Data Management Group, Office of the Director of National Intelligence, Washington, DC 20511.

SUPPLEMENTARY INFORMATION: Pursuant to the Paperwork Reduction Act of 1995 (Pub. L. 104–13), ODNI invites the general public and other Federal agencies to comment on Standard Form 714. The comments and suggestions should address one or more of the following points: (a) Whether the proposed information collection reflected in the Standard Form 714 meets the intent of § 1.3 (''Financial Disclosure'') of Executive Order 12968 (''Access to Classified Information''); (b) the accuracy of the estimated burden of the proposed information collection for Standard Form 714; (c) ways to enhance the quality, utility, and clarity of the information to be collected in the Standard Form 714; (d) ways, including the use of information technology, to minimize the burden of the collection of information on all respondents to the Standard Form 714; and (e) whether small businesses are affected by this collection. The comments that are submitted will be summarized and included in the ODNI request for Office of Management and Budget (OMB) approval. All comments will become a matter of public record.

Abstract: The National Security Act of 1947, as amended by the Intelligence Reform and Terrorism Prevention Act of 2004, and Executive Order 13467, ''Reforming Processes Related to Suitability for Government Employment, Fitness for Contractor Employees, and Eligibility for Access to Classified National Security Information,'' authorizes the DNI as the Security Executive Agent to develop standard forms that promote uniformity and consistency in the implementation

of the Government's security clearance program.

The Financial Disclosure Report contains information that is used to assist in making eligibility determinations for access to specifically designated classified information pursuant to Executive Order 12968, ''Access to Classified Information.'' The data may later be used as part of a review process to evaluate continued eligibility for access to such specifically designated classified information or as evidence in legal proceedings. In addition, law enforcement entities may use this data where pertinent to appropriate investigatory activity.

Respondent burden data follows below:

Title: Financial Disclosure Report.

OMB number: 3440–0001.

Agency form number: Standard Form 714.

Type of review: Regular.

Affected public: Business or other for-profit.

Estimated number of respondents: 86,000.

Estimated time per response: 2 hours.

Frequency of response: Annually.

Estimated total annual burden hours: 172,000 hours.

Dated: January 11, 2013.

Mark W. Ewing,

Chief Management Officer.

[FR Doc. 2013–01544 Filed 1–24–13; 8:45 am]

BILLING CODE P

NATIONAL SCIENCE FOUNDATION

Proposal Review Panel for Materials Research; Notice of Meeting

In accordance with the Federal Advisory Committee Act (Pub. L. 92–463 as amended), the National Science Foundation announces the following meeting:

Name: Site Visit review of the Materials Research Science and Engineering Center (MRSEC) at Yale University, also called Center for Research on Interface Structures and Phenomena, by NSF Division of Materials Research (DMR) #1203

Dates and Times: February 20, 2013 7:45 a.m.–5:00 p.m.

Place: Yale University, New Haven, CT.

Type of Meeting: Part-open.

Contact Person: Dr. Charles Bouldin, Program Director, Materials Research Science and Engineering Centers Program, Division of Materials Research, Room 1065, National Science Foundation, 4201 Wilson Boulevard, Arlington, VA 22230, Telephone (703) 292–4920.

Purpose of Meeting: To provide advice and recommendations concerning further support of the MRSEC at Yale University.

Agenda:

Monday, February 20

7:45 a.m.–9:00 a.m. Closed—Executive Session

9:00 a.m.–4:15 p.m. Open—Review of the Yale MRSEC

4:15 p.m.–5:00 p.m. Closed—Executive Session

Reason for Closing: The work being reviewed may include information of a proprietary or confidential nature, including technical information; financial data, such as salaries and personal information concerning individuals associated with the proposals. These matters are exempt under 5 U.S.C. 552b(c), (4) and (6) of the Government in the Sunshine Act.

Dated: January 18, 2013.

Susanne Bolton,

Committee Management Officer.

[FR Doc. 2013–01426 Filed 1–24–13; 8:45 am]

BILLING CODE 7555–01–P

NUCLEAR REGULATORY COMMISSION

[Docket Nos.: 50–250 and 50–251; NRC–2013–0015]

Turkey Point, Units 3 and 4; Application and Amendment to Facility Operating License Involving Proposed No Significant Hazards Consideration Determination

AGENCY: Nuclear Regulatory Commission.

ACTION: License amendment request; opportunity to comment, request a hearing and petition for leave to intervene.

DATES: Comments must be filed by February 25, 2013. A request for a hearing must be filed by March 26, 2013.

ADDRESSES: You may access information and comment submissions related to this document, which the NRC possesses and are publicly available, by searching on *http://www.regulations.gov* under Docket ID NRC–2013–0015. You may submit comments by any of the following methods:

- *Federal Rulemaking Web site:* Go to *http://www.regulations.gov* and search for Docket ID NRC–2013–0015. Address questions about NRC dockets to Carol Gallagher; telephone: 301–492–3668; email: *Carol.Gallagher@nrc.gov.*
- *Mail comments to:* Cindy Bladey, Chief, Rules, Announcements, and Directives Branch (RADB), Office of Administration, Mail Stop: TWB–05–B01M, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.
- *Fax comments to:* RADB at 301–492–3446.

For additional direction on accessing information and submitting comments, see ''Accessing Information and Submitting Comments'' in the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Tracy J. Orf, Project Manager, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington, DC 20555; telephone: 301–415–2788; email: *Tracy.Orf@nrc.gov.*

SUPPLEMENTARY INFORMATION:

I. Accessing Information and Submitting Comments

A. Accessing Information

Please refer to Docket ID NRC–2013–0015 when contacting the NRC about the availability of information regarding this document. You may access information related to this document, which the NRC possesses and are publicly available, by any of the following methods:

- *Federal Rulemaking Web site:* Go to *http://www.regulations.gov* and search for Docket ID NRC–2013–0015.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may access publicly available documents online in the NRC Library at *http://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''*ADAMS Public Documents*'' and then select ''*Begin Web-based ADAMS Search.*'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *pdr.resource@nrc.gov.* The ADAMS accession number for each document referenced in this notice (if that document is available in ADAMS) is provided the first time that a document is referenced. The application for amendments, dated September 6, 2012, is available in ADAMS under Accession No. ML12251A249.
- *NRC's PDR:* You may examine and purchase copies of public documents at the NRC's PDR, Room O1–F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

B. Submitting Comments

Please include Docket ID NRC–2013–0015 in the subject line of your comment submission, in order to ensure that the NRC is able to make your comment submission available to the public in this docket.

The NRC cautions you not to include identifying or contact information in comment submissions that you do not want to be publicly disclosed. The NRC posts all comment submissions at *http://www.regulations.gov* as well as

enters the comment submissions into ADAMS. The NRC does not edit comment submissions to remove identifying or contact information.

If you are requesting or aggregating comments from other persons for submission to the NRC, then you should inform those persons not to include identifying or contact information in their comment submissions that they do not want to be publicly disclosed. Your request should state that the NRC will not edit comment submissions to remove such information before making the comment submissions available to the public or entering the comment submissions into ADAMS.

II. Introduction

The U.S. Nuclear Regulatory Commission (NRC) is considering issuance of amendments to Renewed Facility Operating License Nos. 50–250 and 50–251, issued to Florida Power & Light Company (the licensee), for operation of the Turkey Point plant located in Miami-Dade County, Florida.

The proposed amendments would reduce the minimum sodium tetraborate basket loading to 7,500 pounds mass (lbm) in order to lessen the long term sump pH profile, recover design margin, and facilitate sodium tetraborate basket loading and maintenance activities.

Before issuance of the proposed license amendments, the Commission will have made findings required by the Atomic Energy Act of 1954, as amended (the Act), and the Commission's regulations.

The Commission has made a proposed determination that the amendment request involves no significant hazards consideration. Under the Commission's regulations in section 50.92 of Title 10 of the *Code of Federal Regulations* (10 CFR), this means that operation of the facility in accordance with the proposed amendments would not (1) involve a significant increase in the probability or consequences of an accident previously evaluated; or (2) create the possibility of a new or different kind of accident from any accident previously evaluated; or (3) involve a significant reduction in a margin of safety. As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. Do the proposed amendments involve a significant increase in the probability or consequences of an accident previously evaluated?

No. The proposed amendments do not affect any precursors to any accident previously evaluated. The proposed amendments do affect the passive recirculation pH control system consisting of ten stainless steel baskets loaded with NaTB [sodium tetraborate] but do *not* adversely affect the system performance or its contribution to the mitigation strategy for a design basis large break loss of coolant accident (LBLOCA). The proposed TS [technical specification] change, when implemented, will reduce the minimum required NaTB basket loading from 11,061 lbm to 7,500 lbm in TS 3/4.6.2.3. This change will also lessen the long term sump pH profile, allow recovery of design margin and facilitate NaTB basket loading and maintenance activities.

Therefore, the proposed amendments do not involve a significant increase in the probability or consequences of an accident previously evaluated.

2. Do the proposed amendments create the possibility of a new or different kind of accident from any accident previously evaluated?

No. The proposed amendments do not directly or indirectly affect any recognized accident initiators. The proposed amendments do affect the passive recirculation pH control system consisting of ten stainless steel baskets loaded with NaTB but do *not* adversely affect the system performance or its contribution to the mitigation strategy for a design basis LBLOCA. The proposed TS change, when implemented, will reduce the minimum required NaTB basket loading from 11,061 lbm to 7,500 lbm in TS 3/4.6.2.3. This change will lessen the long term sump pH profile, allow recovery of design margin to upper pH limits and facilitate NaTB basket loading and maintenance activities while it continues to ensure that the design basis minimum sump pH of 7.0 is maintained throughout the recirculation phase of a LOCA.

Therefore, the proposed amendments do not create the possibility of a new or different kind of accident from any accident previously evaluated.

3. Do the proposed amendments involve a significant reduction in the margin of safety?

No. The proposed amendments will reduce the minimum required NaTB basket loading from 11,061 lbm to 7,500 lbm in TS 3/4.6.2.3. This change, when implemented, will also lessen the long term sump pH profile, allow recovery of design margin to upper pH limits and facilitate NaTB basket loading and maintenance activities. This change continues to assure that containment sump pH reaches 7.0 by onset of containment spray recirculation phase in response to a LBLOCA and lessens the peak and long-term sump pH such that post-accident chemical precipitate generation and the potential for stainless steel stress corrosion cracking is reduced.

Therefore, the proposed amendments do not involve a significant reduction in the margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

The Commission is seeking public comments on this proposed determination. Any comments received within 30 days after the date of publication of this notice will be considered in making any final determination.

Normally, the Commission will not issue the amendments until the expiration of 60 days after the date of publication of this notice. The Commission may issue the license amendments before expiration of the 60-day period provided that its final determination is that the amendments involve no significant hazards consideration. In addition, the Commission may issue the amendments prior to the expiration of the 30-day comment period should circumstances change during the 30-day comment period such that failure to act in a timely way would result, for example, in derating or shutdown of the facility. Should the Commission take action prior to the expiration of either the comment period or the notice period, it will publish in the **Federal Register** a notice of issuance. Should the Commission make a final No Significant Hazards Consideration Determination, any hearing will take place after issuance. The Commission expects that the need to take this action will occur very infrequently.

III. Opportunity To Request a Hearing; Petition for Leave To Intervene

Within 60 days after the date of publication of this notice, any person(s) whose interest may be affected by this action may file a request for a hearing and a petition to intervene with respect to issuance of the amendments to the subject facility operating licenses. Requests for a hearing and a petition for leave to intervene shall be filed in accordance with the Commission's ''Rules of Practice for Domestic Licensing Proceedings'' in 10 CFR part 2. Interested person(s) should consult a current copy of 10 CFR 2.309, which is available at the NRC's PDR, located at O1F21, 11555 Rockville Pike (first floor), Rockville, Maryland 20852. The NRC regulations are available electronically from the NRC Library on the NRC's Web site at *http://www.nrc.gov/reading-rm/doc-collections/cfr/*. If a request for a hearing or petition for leave to intervene is filed by the above date, the Commission or a presiding officer designated by the Commission or by the Chief Administrative Judge of the Atomic Safety and Licensing Board Panel, will rule on the request and/or petition; and the Secretary or the Chief Administrative Judge of the Atomic

Safety and Licensing Board will issue a notice of a hearing or an appropriate order.

As required by 10 CFR 2.309, a petition for leave to intervene shall set forth with particularity the interest of the petitioner in the proceeding, and how that interest may be affected by the results of the proceeding. The petition should specifically explain the reasons why intervention should be permitted with particular reference to the following general requirements: (1) The name, address and telephone number of the requestor or petitioner; (2) the nature of the requestor's/petitioner's right under the Act to be made a party to the proceeding; (3) the nature and extent of the requestor's/petitioner's property, financial, or other interest in the proceeding; and (4) the possible effect of any decision or order which may be entered in the proceeding on the requestor's/petitioner's interest. The petition must also identify the specific contentions which the requestor/petitioner seeks to have litigated at the proceeding.

Each contention must consist of a specific statement of the issue of law or fact to be raised or controverted. In addition, the requestor/petitioner shall provide a brief explanation of the bases for the contention and a concise statement of the alleged facts or expert opinion which support the contention and on which the petitioner intends to rely in proving the contention at the hearing. The requestor/petitioner must also provide references to those specific sources and documents of which the petitioner is aware and on which the petitioner intends to rely to establish those facts or expert opinion. The petition must include sufficient information to show that a genuine dispute exists with the applicant on a material issue of law or fact. Contentions shall be limited to matters within the scope of the amendments under consideration. The contention must be one which, if proven, would entitle the petitioner to relief. A requestor/petitioner who fails to satisfy these requirements with respect to at least one contention will not be permitted to participate as a party.

Those permitted to intervene become parties to the proceeding, subject to any limitations in the order granting leave to intervene, and have the opportunity to participate fully in the conduct of the hearing.

If a hearing is requested, the Commission will make a final determination on the issue of no significant hazards consideration. The final determination will serve to decide when the hearing is held. If the final determination is that the amendment request involves no significant hazards consideration, the Commission may issue the amendments and make them immediately effective, notwithstanding the request for a hearing. Any hearing held would take place after issuance of the amendments. If the final determination is that the amendment request involves a significant hazards consideration, then any hearing held would take place before the issuance of the amendments.

IV. Electronic Submissions (E-Filing)

All documents filed in NRC adjudicatory proceedings, including a request for hearing, a petition for leave to intervene, any motion or other document filed in the proceeding prior to the submission of a request for hearing or petition to intervene, and documents filed by interested governmental entities participating under 10 CFR 2.315(c), must be filed in accordance with the NRC's E-Filing rule (72 FR 49139; August 28, 2007). The E-Filing process requires participants to submit and serve all adjudicatory documents over the Internet, or in some cases to mail copies on electronic storage media. Participants may not submit paper copies of their filings unless they seek an exemption in accordance with the procedures described below.

To comply with the procedural requirements of E-Filing, at least ten 10 days prior to the filing deadline, the participant should contact the Office of the Secretary by email at *hearing.docket@nrc.gov,* or by telephone at 301–415–1677, to request (1) a digital identification (ID) certificate, which allows the participant (or its counsel or representative) to digitally sign documents and access the E-Submittal server for any proceeding in which it is participating; and (2) advise the Secretary that the participant will be submitting a request or petition for hearing (even in instances in which the participant, or its counsel or representative, already holds an NRC-issued digital ID certificate). Based upon this information, the Secretary will establish an electronic docket for the hearing in this proceeding if the Secretary has not already established an electronic docket.

Information about applying for a digital ID certificate is available on the NRC's public Web site at *http://www.nrc.gov/site-help/e-submittals/apply-certificates.html.* System requirements for accessing the E-Submittal server are detailed in the NRC's ''Guidance for Electronic Submission,'' which is available on the NRC's public Web site at *http://www.nrc.gov/site-help/e-submittals.html.* Participants may attempt to use other software not listed on the Web site, but should note that the NRC's E-Filing system does not support unlisted software, and the NRC Meta System Help Desk will not be able to offer assistance in using unlisted software.

If a participant is electronically submitting a document to the NRC in accordance with the E-Filing rule, the participant must file the document using the NRC's online, Web-based submission form. In order to serve documents through the Electronic Information Exchange System, users will be required to install a Web browser plug-in from the NRC's Web site. Further information on the Web-based submission form, including the installation of the Web browser plug-in, is available on the NRC's public Web site at *http://www.nrc.gov/site-help/e-submittals.html.*

Once a participant has obtained a digital ID certificate and a docket has been created, the participant can then submit a request for hearing or petition for leave to intervene. Submissions should be in Portable Document Format (PDF) in accordance with the NRC guidance available on the NRC's public Web site at *http://www.nrc.gov/site-help/e-submittals.html.* A filing is considered complete at the time the documents are submitted through the NRC's E-Filing system. To be timely, an electronic filing must be submitted to the E-Filing system no later than 11:59 p.m. Eastern Time on the due date. Upon receipt of a transmission, the E-Filing system time-stamps the document and sends the submitter an email notice confirming receipt of the document. The E-Filing system also distributes an email notice that provides access to the document to the NRC's Office of the General Counsel and any others who have advised the Office of the Secretary that they wish to participate in the proceeding, so that the filer need not serve the documents on those participants separately. Therefore, applicants and other participants (or their counsel or representative) must apply for and receive a digital ID certificate before a hearing request/petition to intervene is filed so that they can obtain access to the document via the E-Filing system.

A person filing electronically using the NRC's adjudicatory E-Filing system may seek assistance by contacting the NRC Meta System Help Desk through the ''Contact Us'' link located on the NRC's public Web site at *http://www.nrc.gov/site-help/e-*

submittals.html, by email to *MSHD.Resource@nrc.gov,* or by a toll-free call to 1–866–672–7640. The NRC Meta System Help Desk is available between 8 a.m. and 8 p.m., Eastern Time, Monday through Friday, excluding government holidays.

Participants who believe that they have a good cause for not submitting documents electronically must file an exemption request, in accordance with 10 CFR 2.302(g), with their initial paper filing requesting authorization to continue to submit documents in paper format. Such filings must be submitted by: (1) First class mail addressed to the Office of the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, Attention: Rulemaking and Adjudications Staff; or (2) courier, express mail, or expedited delivery service to the Office of the Secretary, Sixteenth Floor, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852, Attention: Rulemaking and Adjudications Staff. Participants filing a document in this manner are responsible for serving the document on all other participants. Filing is considered complete by first-class mail as of the time of deposit in the mail, or by courier, express mail, or expedited delivery service upon depositing the document with the provider of the service. A presiding officer, having granted an exemption request from using E-Filing, may require a participant or party to use E-Filing if the presiding officer subsequently determines that the reason for granting the exemption from use of E-Filing no longer exists.

Documents submitted in adjudicatory proceedings will appear in the NRC's electronic hearing docket which is available to the public at *http://ehd1.nrc.gov/ehd/,* unless excluded pursuant to an order of the Commission, or the presiding officer. Participants are requested not to include personal privacy information, such as social security numbers, home addresses, or home phone numbers in their filings, unless an NRC regulation or other law requires submission of such information. With respect to copyrighted works, except for limited excerpts that serve the purpose of the adjudicatory filings and would constitute a Fair Use application, participants are requested not to include copyrighted materials in their submission.

Petitions for leave to intervene must be filed no later than 60 days from January 25, 2013. Requests for hearing, petitions for leave to intervene, and motions for leave to file new or amended contentions that are filed after the 60-day deadline will not be entertained absent a determination by the presiding officer that the filing demonstrates good cause by satisfying the following three factors in 10 CFR 2.309(c)(1): (i) The information upon which the filing is based was not previously available; (ii) the information upon which the filing is based is materially different from information previously available; and (iii) the filing has been submitted in a timely fashion based on the availability of the subsequent information.

For further details with respect to this action, see the application for amendments dated September 6, 2012.

Attorney for licensee: James Petro, Managing Attorney—Nuclear, Florida Power & Light, P.O. Box 14000, Juno Beach, Florida 33408–0420.

Dated at Rockville, Maryland, this 16th day of January 2013.

For the Nuclear Regulatory Commission.

Tracy J. Orf,

Project Manager, Plant Licensing Branch II–2, Division of Operating Reactor Licensing, Office of Nuclear Reactor Regulation.

[FR Doc. 2013–01585 Filed 1–24–13; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[Docket Nos. 052–00025 and 052–00026; NRC–2008–0252]

Vogtle Electric Generating Plant, Units 3 and 4; Application and Amendment to Combined Licenses Involving Proposed No Significant Hazards Consideration Determination

AGENCY: Nuclear Regulatory Commission.

ACTION: License amendment request; opportunity to comment, request a hearing and petition for leave to intervene.

DATES: Comments must be filed by February 25, 2013. A request for a hearing must be filed by March 26, 2013.

ADDRESSES: You may access information and comment submissions related to this document, which the NRC possesses and are publicly available, by searching on *http://www.regulations.gov* under Docket ID NRC–2008–0252. You may submit comments by any of the following methods:

- *Federal Rulemaking Web site:* Go to *http://www.regulations.gov* and search for Docket ID NRC–2008–0252. Address questions about NRC dockets to Carol Gallagher; telephone: 301–492–3668; email: *Carol.Gallagher@nrc.gov.*
- *Mail comments to:* Cindy Bladey, Chief, Rules, Announcements, and Directives Branch (RADB), Office of Administration, Mail Stop: TWB–05–B01M, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.
- *Fax comments to:* RADB at 301–492–3446.

For additional direction on accessing information and submitting comments, see ''Accessing Information and Submitting Comments'' in the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Ravindra Joshi, Office of New Reactors, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–6191; email: *ravindra.joshi@nrc.gov.*

SUPPLEMENTARY INFORMATION:

I. Accessing Information and Submitting Comments

A. Accessing Information

Please refer to Docket ID NRC–2008–0252 when contacting the NRC about the availability of information regarding this document. You may access information related to this document, which the NRC possesses and are publicly available, by any of the following methods:

- *Federal Rulemaking Web site:* Go to *http://www.regulations.gov* and search for Docket ID NRC–2008–0252.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may access publicly available documents online in the NRC Library at *http://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''*ADAMS Public Documents*'' and then select ''Begin Web-based ADAMS Search.'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *pdr.resource@nrc.gov.* The ADAMS accession number for each document referenced in this notice (if that document is available in ADAMS) is provided the first time that a document is referenced. The application for amendment, dated January 15, 2013, is available in ADAMS under Accession No. ML13016A169.
- *NRC's PDR:* You may examine and purchase copies of public documents at the NRC's PDR, Room O1–F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

B. Submitting Comments

Please include Docket ID NRC–2008–0252 in the subject line of your comment submission, in order to ensure

that the NRC is able to make your comment submission available to the public in this docket.

The NRC cautions you not to include identifying or contact information that that you do not want to be publicly disclosed in your comment submission. The NRC will post all comment submissions at *http://www.regulations.gov* as well as enter the comment submissions into ADAMS. The NRC does not routinely edit comment submissions to remove identifying or contact information.

If you are requesting or aggregating comments from other persons for submission to the NRC, then you should inform those persons not to include identifying or contact information that they do not want to be publicly disclosed in their comment submission. Your request should state that the NRC does not routinely edit comment submissions to remove such information before making the comment submissions available to the public or entering the comment submissions into ADAMS.

II. Introduction

The U.S. Nuclear Regulatory Commission (NRC) is considering issuance of an amendment to Combined Licenses (NPF–91 and NPF–92), issued to Southern Nuclear Operating Company, Inc. (SNC), and Georgia Power Company, Oglethorpe Power Corporation, Municipal Electric Authority of Georgia, and the City of Dalton, Georgia (the licensee), for construction and operation of the Vogtle Electric Generating Plant (VEGP), Units 3 and 4 located in Burke County, Georgia.

The proposed amendment would depart from VEGP Units 3 and 4 plant-specific Design Control Document (DCD) Tier 2* material incorporated into the Updated Final Safety Analysis Report (UFSAR) to clarify the requirements for shear reinforcement spacing in the nuclear island basemat below the auxiliary building. The proposed change would modify the provisions for maximum spacing of the shear reinforcement in the basemat below the auxiliary building.

Before issuance of the proposed license amendment, the Commission will have made findings required by the Atomic Energy Act of 1954, as amended (the Act), and the Commission's regulations.

The Commission has made a proposed determination that the amendment request involves no significant hazards consideration. Under the Commission's regulations in section 50.92 of Title 10 of the *Code of Federal Regulations* (10 CFR), this means that operation of the facility in accordance with the proposed amendment would not (1) involve a significant increase in the probability or consequences of an accident previously evaluated; or (2) create the possibility of a new or different kind of accident from any accident previously evaluated; or (3) involve a significant reduction in a margin of safety. As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. Does the proposed amendment involve a significant increase in the probability or consequences of an accident previously evaluated?

Response: No.

The design function of the basemat is to provide the interface between the nuclear island structures and the supporting soil or rock. The basemat transfers the load of nuclear island structures to the supporting soil or rock and transmits seismic motions from the supporting soil or rock to the nuclear island.

The clarification of the requirements for shear reinforcement spacing in the AP1000 basemat does not have an adverse impact on the response of the basemat and nuclear island structures to safe shutdown earthquake ground motions or loads due to anticipated transients or postulated accident conditions. The clarification of the requirements for shear reinforcement spacing in the AP1000 basemat does not impact the support, design, or operation of mechanical and fluid systems. There is no change to plant systems or the response of systems to postulated accident conditions. There is no change to the predicted radioactive releases due to normal operation or postulated accident conditions. The plant response to previously evaluated accidents or external events is not adversely affected, nor does the change described create any new accident precursors. Therefore, there is no significant increase in the probability or consequences of an accident previously evaluated.

2. Does the proposed amendment create the possibility of a new or different kind of accident from any accident previously evaluated?

Response: No.

The proposed change is to clarify the requirements for shear reinforcement spacing in the nuclear island basemat. The clarification of the requirements for shear reinforcement spacing in the nuclear island basemat does not change the design of the basemat or nuclear island structures. The clarification of the requirements for shear reinforcement spacing in the nuclear island basemat does not change the design function, support, design, or operation of mechanical and fluid systems. The clarification of the requirements for shear reinforcement spacing in the nuclear island basemat does not result in a new failure mechanism for the basemat or new accident precursors. As a result, the design function of the basemat is not adversely affected by the proposed change. Therefore, the proposed change will not create the possibility of a new or different kind of accident from any accident previously evaluated.

3. Does the proposed amendment involve a significant reduction in a margin of safety?

Response: No.

No safety analysis or design basis acceptance limit/criterion is challenged or exceeded by the proposed changes, thus, no margin of safety is reduced. Therefore, the proposed amendment does not involve a significant reduction in a margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

The Commission is seeking public comments on this proposed determination. Any comments received within 30 days after the date of publication of this notice will be considered in making any final determination.

Normally, the Commission will not issue the amendment until the expiration of 60 days after the date of publication of this notice. The Commission may issue the license amendment before expiration of the 60-day period provided that its final determination is that the amendment involves no significant hazards consideration. In addition, the Commission may issue the amendment prior to the expiration of the 30-day comment period should circumstances change during the 30-day comment period such that failure to act in a timely way would result, for example, in derating or shutdown of the facility. Should the Commission take action prior to the expiration of either the comment period or the notice period, it will publish in the **Federal Register** a notice of issuance. Should the Commission make a final No Significant Hazards Consideration Determination, any hearing will take place after issuance. The Commission expects that the need to take this action will occur very infrequently.

III. Opportunity To Request a Hearing; Petition for Leave To Intervene

Within 60 days after the date of publication of this notice, any person(s) whose interest may be affected by this action may file a request for a hearing and a petition to intervene with respect to issuance of the amendment to the subject combined licenses. Requests for a hearing and a petition for leave to intervene shall be filed in accordance with the Commission's ''Rules of Practice for Domestic Licensing

Proceedings'' in 10 CFR Part 2. Interested person(s) should consult a current copy of 10 CFR 2.309, which is available at the NRC's PDR, located at O1F21, 11555 Rockville Pike (first floor), Rockville, Maryland 20852. NRC regulations are accessible electronically from the NRC Library on the NRC Web site at *http://www.nrc.gov/reading-rm/doc-collections/cfr/.* If a request for a hearing or petition for leave to intervene is filed by the above date, the Commission or a presiding officer designated by the Commission or by the Chief Administrative Judge of the Atomic Safety and Licensing Board Panel, will rule on the request and/or petition; and the Secretary or the Chief Administrative Judge of the Atomic Safety and Licensing Board will issue a notice of a hearing or an appropriate order.

As required by 10 CFR 2.309, a petition for leave to intervene shall set forth with particularity the interest of the petitioner in the proceeding, and how that interest may be affected by the results of the proceeding. The petition should specifically explain the reasons why intervention should be permitted with particular reference to the following general requirements: (1) The name, address and telephone number of the requestor or petitioner; (2) the nature of the requestor's/petitioner's right under the Act to be made a party to the proceeding; (3) the nature and extent of the requestor's/petitioner's property, financial, or other interest in the proceeding; and (4) the possible effect of any decision or order which may be entered in the proceeding on the requestor's/petitioner's interest. The petition must also identify the specific contentions which the requestor/petitioner seeks to have litigated at the proceeding.

Each contention must consist of a specific statement of the issue of law or fact to be raised or controverted. In addition, the requestor/petitioner shall provide a brief explanation of the bases for the contention and a concise statement of the alleged facts or expert opinion which support the contention and on which the petitioner intends to rely in proving the contention at the hearing. The requestor/petitioner must also provide references to those specific sources and documents of which the petitioner is aware and on which the petitioner intends to rely to establish those facts or expert opinion. The petition must include sufficient information to show that a genuine dispute exists with the applicant on a material issue of law or fact. Contentions shall be limited to matters within the scope of the amendment under consideration. The contention must be one which, if proven, would entitle the petitioner to relief. A requestor/petitioner who fails to satisfy these requirements with respect to at least one contention will not be permitted to participate as a party.

Those permitted to intervene become parties to the proceeding, subject to any limitations in the order granting leave to intervene, and have the opportunity to participate fully in the conduct of the hearing.

If a hearing is requested, the Commission will make a final determination on the issue of no significant hazards consideration. The final determination will serve to decide when the hearing is held. If the final determination is that the amendment request involves no significant hazards consideration, the Commission may issue the amendment and make it immediately effective, notwithstanding the request for a hearing. Any hearing held would take place after issuance of the amendment. If the final determination is that the amendment request involves a significant hazards consideration, then any hearing held would take place before the issuance of any amendment.

IV. Electronic Submissions (E-Filing)

All documents filed in NRC adjudicatory proceedings, including a request for hearing, a petition for leave to intervene, any motion or other document filed in the proceeding prior to the submission of a request for hearing or petition to intervene, and documents filed by interested governmental entities participating under 10 CFR 2.315(c), must be filed in accordance with the NRC E-Filing rule (72 FR 49139; August 28, 2007). The E-Filing process requires participants to submit and serve all adjudicatory documents over the Internet, or in some cases to mail copies on electronic storage media. Participants may not submit paper copies of their filings unless they seek an exemption in accordance with the procedures described below.

To comply with the procedural requirements of E-Filing, at least ten 10 days prior to the filing deadline, the participant should contact the Office of the Secretary by email at *hearing.docket@nrc.gov,* or by telephone at 301–415–1677, to request (1) a digital identification (ID) certificate, which allows the participant (or its counsel or representative) to digitally sign documents and access the E-Submittal server for any proceeding in which it is participating; and (2) advise the Secretary that the participant will be submitting a request or petition for hearing (even in instances in which the participant, or its counsel or representative, already holds an NRC-issued digital ID certificate). Based upon this information, the Secretary will establish an electronic docket for the hearing in this proceeding if the Secretary has not already established an electronic docket.

Information about applying for a digital ID certificate is available on the NRC's public Web site at *http://www.nrc.gov/site-help/e-submittals/apply-certificates.html.* System requirements for accessing the E-Submittal server are detailed in the NRC's ''Guidance for Electronic Submission,'' which is available on the NRC's public Web site at *http://www.nrc.gov/site-help/e-submittals.html.* Participants may attempt to use other software not listed on the Web site, but should note that the NRC's E-Filing system does not support unlisted software, and the NRC Meta System Help Desk will not be able to offer assistance in using unlisted software.

If a participant is electronically submitting a document to the NRC in accordance with the E-Filing rule, the participant must file the document using the NRC's online, Web-based submission form. In order to serve documents through the Electronic Information Exchange System, users will be required to install a Web browser plug-in from the NRC's Web site. Further information on the Web-based submission form, including the installation of the Web browser plug-in, is available on the NRC's public Web site at *http://www.nrc.gov/site-help/e-submittals.html.*

Once a participant has obtained a digital ID certificate and a docket has been created, the participant can then submit a request for hearing or petition for leave to intervene. Submissions should be in Portable Document Format (PDF) in accordance with the NRC guidance available on the NRC's public Web site at *http://www.nrc.gov/site-help/e-submittals.html.* A filing is considered complete at the time the documents are submitted through the NRC's E-Filing system. To be timely, an electronic filing must be submitted to the E-Filing system no later than 11:59 p.m. Eastern Time on the due date. Upon receipt of a transmission, the E-Filing system time-stamps the document and sends the submitter an email notice confirming receipt of the document. The E-Filing system also distributes an email notice that provides access to the document to the NRC's Office of the General Counsel and any others who

have advised the Office of the Secretary that they wish to participate in the proceeding, so that the filer need not serve the documents on those participants separately. Therefore, applicants and other participants (or their counsel or representative) must apply for and receive a digital ID certificate before a hearing request/petition to intervene is filed so that they can obtain access to the document via the E-Filing system.

A person filing electronically using the NRC's adjudicatory E-Filing system may seek assistance by contacting the NRC Meta System Help Desk through the ''Contact Us'' link located on the NRC's public Web site at *http://www.nrc.gov/site-help/e-submittals.html,* by email to *MSHD.Resource@nrc.gov,* or by a toll-free call to 1–866–672–7640. The NRC Meta System Help Desk is available between 8 a.m. and 8 p.m., Eastern Time, Monday through Friday, excluding government holidays.

Participants who believe that they have a good cause for not submitting documents electronically must file an exemption request, in accordance with 10 CFR 2.302(g), with their initial paper filing requesting authorization to continue to submit documents in paper format. Such filings must be submitted by: (1) First class mail addressed to the Office of the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, Attention: Rulemaking and Adjudications Staff; or (2) courier, express mail, or expedited delivery service to the Office of the Secretary, Sixteenth Floor, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852, Attention: Rulemaking and Adjudications Staff. Participants filing a document in this manner are responsible for serving the document on all other participants. Filing is considered complete by first-class mail as of the time of deposit in the mail, or by courier, express mail, or expedited delivery service upon depositing the document with the provider of the service. A presiding officer, having granted an exemption request from using E-Filing, may require a participant or party to use E-Filing if the presiding officer subsequently determines that the reason for granting the exemption from use of E-Filing no longer exists.

Documents submitted in adjudicatory proceedings will appear in the NRC's electronic hearing docket which is available to the public at *http://ehd1.nrc.gov/ehd/,* unless excluded pursuant to an order of the Commission, or the presiding officer. Participants are requested not to include personal privacy information, such as social security numbers, home addresses, or home phone numbers in their filings, unless an NRC regulation or other law requires submission of such information. With respect to copyrighted works, except for limited excerpts that serve the purpose of the adjudicatory filings and would constitute a Fair Use application, participants are requested not to include copyrighted materials in their submission.

Petitions for leave to intervene must be filed no later than 60 days from January 25, 2013. Requests for hearing, petitions for leave to intervene, and motions for leave to file new or amended contentions that are filed after the 60-day deadline will not be entertained absent a determination by the presiding officer that the filing demonstrates good cause by satisfying the following three factors in 10 CFR 2.309(c)(1): (i) The information upon which the filing is based was not previously available; (ii) the information upon which the filing is based is materially different from information previously available; and (iii) the filing has been submitted in a timely fashion based on the availability of the subsequent information.

For further details with respect to this action, see the application for amendment dated January 15, 2013.

Attorney for licensee: Mr. M. Stanford Blanton, Balch & Bingham LLP, 1710 Sixth Avenue North, Birmingham, AL 35203–2015.

Dated at Rockville, Maryland, this 18th day of January, 2013.

For the Nuclear Regulatory Commission.

Denise L. McGovern,

Project Manager, Licensing Branch 4, Division of New Reactor Licensing, Office of New Reactors.

[FR Doc. 2013–01590 Filed 1–24–13; 8:45 am]

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NUCLEAR REGULATORY COMMISSION

[Docket Nos. 052–00027 and 052–00028; NRC–2008–0441]

Virgil C. Summer Nuclear Station, Units 2 and 3; Application and Amendment to Facility Combined Licenses Involving Proposed No Significant Hazards Consideration Determination

AGENCY: Nuclear Regulatory Commission.

ACTION: License amendment request; opportunity to comment, request a hearing and petition for leave to intervene.

DATES: Comments must be filed by February 25, 2013. A request for a hearing must be filed by March 26, 2013.

ADDRESSES: You may access information and comment submissions related to this document, which the NRC possesses and are publicly available, by searching on *http://www.regulations.gov* under Docket ID NRC–2008–0441. You may submit comments by any of the following methods:

- *Federal rulemaking Web site:* Go to *http://www.regulations.gov* and search for Docket ID NRC–2008–0441. Address questions about NRC dockets to Carol Gallagher; telephone: 301–492–3668; email: *Carol.Gallagher@nrc.gov.*
- *Mail comments to:* Cindy Bladey, Chief, Rules, Announcements, and Directives Branch (RADB), Office of Administration, Mail Stop: TWB–05–B01M, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.
- *Fax comments to:* RADB at 301–492–3446.

For additional direction on accessing information and submitting comments, see ''Accessing Information and Submitting Comments'' in the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Denise McGovern, Office of New Reactors, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–0681; email: *denise.mcgovern@nrc.gov.*

SUPPLEMENTARY INFORMATION:

I. Accessing Information and Submitting Comments

A. Accessing Information

Please refer to Docket ID NRC–2008–0441 when contacting the NRC about the availability of information regarding this document. You may access information related to this document, which the NRC possesses and are publicly available, by any of the following methods:

- *Federal Rulemaking Web site:* Go to *http://www.regulations.gov* and search for Docket ID NRC–2008–0441.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may access publicly available documents online in the NRC Library at *http://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''*ADAMS Public Documents*'' and then select ''*Begin Web-based ADAMS Search.*'' For problems with ADAMS,

please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *pdr.resource@nrc.gov.* The ADAMS accession number for each document referenced in this notice (if that document is available in ADAMS) is provided the first time that a document is referenced. The application for amendment, dated January 15, 2013, is available in ADAMS under Accession No. ML13017A082.

• *NRC's PDR:* You may examine and purchase copies of public documents at the NRC's PDR, Room O1–F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

B. Submitting Comments

Please include Docket ID NRC–2008–0441 in the subject line of your comment submission, in order to ensure that the NRC is able to make your comment submission available to the public in this docket.

The NRC cautions you not to include identifying or contact information that you do not want to be publicly disclosed in your comment submission. The NRC will post all comment submissions at *http://www.regulations.gov* as well as enter the comment submissions into ADAMS. The NRC does not routinely edit comment submissions to remove identifying or contact information.

If you are requesting or aggregating comments from other persons for submission to the NRC, then you should inform those persons not to include identifying or contact information that they do not want to be publicly disclosed in their comment submission. Your request should state that the NRC does not routinely edit comment submissions to remove such information before making the comment submissions available to the public or entering the comment submissions into ADAMS.

II. Introduction

The U.S. Nuclear Regulatory Commission (NRC) is considering issuance of an amendment to Combined Licenses (NPF–93 and NPF–94), issued to South Carolina Electric and Gas (SCE&G) and South Carolina Public Service Authority (Santee Cooper) (the licensee), for construction and operation of the Virgil C. Summer Nuclear Station (VCSNS), Units 2 and 3 located in Fairfield County, South Carolina.

The proposed amendment would depart from VCSNS Units 2 and 3 plant-specific Design Control Document (DCD) Tier 2* material incorporated into the Updated Final Safety Analysis Report (UFSAR) to clarify the requirements for shear reinforcement spacing in the nuclear island basemat below the auxiliary building. The proposed change would modify the provisions for maximum spacing of the shear reinforcement in the basemat below the auxiliary building.

Before issuance of the proposed license amendment, the Commission will have made findings required by the Atomic Energy Act of 1954, as amended (the Act), and the Commission's regulations.

The Commission has made a proposed determination that the amendment request involves no significant hazards consideration. Under the Commission's regulations in section 50.92 of Title 10 of the *Code of Federal Regulations* (10 CFR), this means that operation of the facility in accordance with the proposed amendment would not (1) involve a significant increase in the probability or consequences of an accident previously evaluated; or (2) create the possibility of a new or different kind of accident from any accident previously evaluated; or (3) involve a significant reduction in a margin of safety. As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. Does the proposed amendment involve a significant increase in the probability or consequences of an accident previously evaluated?

Response: No.

The design function of the basemat is to provide the interface between the nuclear island structures and the supporting soil or rock. The basemat transfers the load of nuclear island structures to the supporting soil or rock and transmits seismic motions from the supporting soil or rock to the nuclear island.

The clarification of the requirements for shear reinforcement spacing in the AP1000 basemat does not have an adverse impact on the response of the basemat and nuclear island structures to safe shutdown earthquake ground motions or loads due to anticipated transients or postulated accident conditions. The clarification of the requirements for shear reinforcement spacing in the AP1000 basemat does not impact the support, design, or operation of mechanical and fluid systems. There is no change to plant systems or the response of systems to postulated accident conditions. There is no change to the predicted radioactive releases due to normal operation or postulated accident conditions. The plant response to previously evaluated accidents or external events is not adversely affected, nor does the change described create any new accident precursors. Therefore, there is no significant increase in the probability or consequences of an accident previously evaluated.

2. Does the proposed amendment create the possibility of a new or different kind of accident from any accident previously evaluated?

Response: No.

The proposed change is to clarify the requirements for shear reinforcement spacing in the nuclear island basemat. The clarification of the requirements for shear reinforcement spacing in the nuclear island basemat does not change the design of the basemat or nuclear island structures. The clarification of the requirements for shear reinforcement spacing in the nuclear island basemat does not change the design function, support, design, or operation of mechanical and fluid systems. The clarification of the requirements for shear reinforcement spacing in the nuclear island basemat does not result in a new failure mechanism for the basemat or new accident precursors. As a result, the design function of the basemat is not adversely affected by the proposed change. Therefore, the proposed change will not create the possibility of a new or different kind of accident from any accident previously evaluated.

3. Does the proposed amendment involve a significant reduction in a margin of safety?

Response: No.

No safety analysis or design basis acceptance limit/criterion is challenged or exceeded by the proposed changes, thus, no margin of safety is reduced. Therefore, the proposed amendment does not involve a significant reduction in a margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

The Commission is seeking public comments on this proposed determination. Any comments received within 30 days after the date of publication of this notice will be considered in making any final determination.

Normally, the Commission will not issue the amendment until the expiration of 60 days after the date of publication of this notice. The Commission may issue the license amendment before expiration of the 60-day period provided that its final determination is that the amendment involves no significant hazards consideration. In addition, the Commission may issue the amendment prior to the expiration of the 30-day comment period should circumstances change during the 30-day comment period such that failure to act in a timely way would result, for example, in derating or shutdown of the facility. Should the Commission take action prior to the expiration of either the comment period or the notice period, it will publish in the **Federal Register** a notice of issuance. Should the Commission make a final No Significant

Hazards Consideration Determination, any hearing will take place after issuance. The Commission expects that the need to take this action will occur very infrequently.

III. Opportunity To Request a Hearing; Petition for Leave To Intervene

Within 60 days after the date of publication of this notice, any person(s) whose interest may be affected by this action may file a request for a hearing and a petition to intervene with respect to issuance of the amendment to the subject combined licenses. Requests for a hearing and a petition for leave to intervene shall be filed in accordance with the Commission's ''Rules of Practice for Domestic Licensing Proceedings'' in 10 CFR part 2. Interested person(s) should consult a current copy of 10 CFR 2.309, which is available at the NRC's PDR, located at O1F21, 11555 Rockville Pike (first floor), Rockville, Maryland 20852. The NRC regulations are accessible electronically from the NRC Library on the NRC's Web site at *http://www.nrc.gov/reading-rm/doc-collections/cfr/.* If a request for a hearing or petition for leave to intervene is filed by the above date, the Commission or a presiding officer designated by the Commission or by the Chief Administrative Judge of the Atomic Safety and Licensing Board Panel, will rule on the request and/or petition; and the Secretary or the Chief Administrative Judge of the Atomic Safety and Licensing Board will issue a notice of a hearing or an appropriate order.

As required by 10 CFR 2.309, a petition for leave to intervene shall set forth with particularity the interest of the petitioner in the proceeding, and how that interest may be affected by the results of the proceeding. The petition should specifically explain the reasons why intervention should be permitted with particular reference to the following general requirements: (1) The name, address and telephone number of the requestor or petitioner; (2) the nature of the requestor's/petitioner's right under the Act to be made a party to the proceeding; (3) the nature and extent of the requestor's/petitioner's property, financial, or other interest in the proceeding; and (4) the possible effect of any decision or order which may be entered in the proceeding on the requestor's/petitioner's interest. The petition must also identify the specific contentions which the requestor/petitioner seeks to have litigated at the proceeding.

Each contention must consist of a specific statement of the issue of law or fact to be raised or controverted. In addition, the requestor/petitioner shall provide a brief explanation of the bases for the contention and a concise statement of the alleged facts or expert opinion which support the contention and on which the petitioner intends to rely in proving the contention at the hearing. The requestor/petitioner must also provide references to those specific sources and documents of which the petitioner is aware and on which the petitioner intends to rely to establish those facts or expert opinion. The petition must include sufficient information to show that a genuine dispute exists with the applicant on a material issue of law or fact. Contentions shall be limited to matters within the scope of the amendment under consideration. The contention must be one which, if proven, would entitle the petitioner to relief. A requestor/petitioner who fails to satisfy these requirements with respect to at least one contention will not be permitted to participate as a party.

Those permitted to intervene become parties to the proceeding, subject to any limitations in the order granting leave to intervene, and have the opportunity to participate fully in the conduct of the hearing.

If a hearing is requested, the Commission will make a final determination on the issue of no significant hazards consideration. The final determination will serve to decide when the hearing is held. If the final determination is that the amendment request involves no significant hazards consideration, the Commission may issue the amendment and make it immediately effective, notwithstanding the request for a hearing. Any hearing held would take place after issuance of the amendment. If the final determination is that the amendment request involves a significant hazards consideration, then any hearing held would take place before the issuance of any amendment.

IV. Electronic Submissions (E-Filing)

All documents filed in the NRC adjudicatory proceedings, including a request for hearing, a petition for leave to intervene, any motion or other document filed in the proceeding prior to the submission of a request for hearing or petition to intervene, and documents filed by interested governmental entities participating under 10 CFR 2.315(c), must be filed in accordance with the NRC's E-Filing rule (72 FR 49139; August 28, 2007). The E-Filing process requires participants to submit and serve all adjudicatory documents over the Internet, or in some cases to mail copies on electronic storage media. Participants may not submit paper copies of their filings unless they seek an exemption in accordance with the procedures described below.

To comply with the procedural requirements of E-Filing, at least ten 10 days prior to the filing deadline, the participant should contact the Office of the Secretary by email at *hearing.docket@nrc.gov,* or by telephone at 301–415–1677, to request (1) a digital identification (ID) certificate, which allows the participant (or its counsel or representative) to digitally sign documents and access the E-Submittal server for any proceeding in which it is participating; and (2) advise the Secretary that the participant will be submitting a request or petition for hearing (even in instances in which the participant, or its counsel or representative, already holds an NRC-issued digital ID certificate). Based upon this information, the Secretary will establish an electronic docket for the hearing in this proceeding if the Secretary has not already established an electronic docket.

Information about applying for a digital ID certificate is available on the NRC's public Web site at *http://www.nrc.gov/site-help/e-submittals/apply-certificates.html.* System requirements for accessing the E-Submittal server are detailed in the NRC's ''Guidance for Electronic Submission,'' which is available on the NRC's public Web site at *http://www.nrc.gov/site-help/e-submittals.html.* Participants may attempt to use other software not listed on the Web site, but should note that the NRC's E-Filing system does not support unlisted software, and the NRC Meta System Help Desk will not be able to offer assistance in using unlisted software.

If a participant is electronically submitting a document to the NRC in accordance with the E-Filing rule, the participant must file the document using the NRC's online, Web-based submission form. In order to serve documents through the Electronic Information Exchange System, users will be required to install a Web browser plug-in from the NRC's Web site. Further information on the Web-based submission form, including the installation of the Web browser plug-in, is available on the NRC's public Web site at *http://www.nrc.gov/site-help/e-submittals.html.*

Once a participant has obtained a digital ID certificate and a docket has been created, the participant can then submit a request for hearing or petition

for leave to intervene. Submissions should be in Portable Document Format (PDF) in accordance with the NRC guidance available on the NRC's public Web site at *http://www.nrc.gov/site-help/e-submittals.html.* A filing is considered complete at the time the documents are submitted through the NRC's E-Filing system. To be timely, an electronic filing must be submitted to the E-Filing system no later than 11:59 p.m. Eastern Time on the due date. Upon receipt of a transmission, the E-Filing system time-stamps the document and sends the submitter an email notice confirming receipt of the document. The E-Filing system also distributes an email notice that provides access to the document to the NRC's Office of the General Counsel and any others who have advised the Office of the Secretary that they wish to participate in the proceeding, so that the filer need not serve the documents on those participants separately. Therefore, applicants and other participants (or their counsel or representative) must apply for and receive a digital ID certificate before a hearing request/petition to intervene is filed so that they can obtain access to the document via the E-Filing system.

A person filing electronically using the NRC's adjudicatory E-Filing system may seek assistance by contacting the NRC Meta System Help Desk through the ''Contact Us'' link located on the NRC's public Web site at *http://www.nrc.gov/site-help/e-submittals.html,* by email to *MSHD.Resource@nrc.gov,* or by a toll-free call to 1–866–672–7640. The NRC Meta System Help Desk is available between 8 a.m. and 8 p.m., Eastern Time, Monday through Friday, excluding government holidays.

Participants who believe that they have a good cause for not submitting documents electronically must file an exemption request, in accordance with 10 CFR 2.302(g), with their initial paper filing requesting authorization to continue to submit documents in paper format. Such filings must be submitted by: (1) First class mail addressed to the Office of the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, Attention: Rulemaking and Adjudications Staff; or (2) courier, express mail, or expedited delivery service to the Office of the Secretary, Sixteenth Floor, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852, Attention: Rulemaking and Adjudications Staff. Participants filing a document in this manner are responsible for serving the document on all other participants. Filing is considered complete by first-class mail as of the time of deposit in the mail, or by courier, express mail, or expedited delivery service upon depositing the document with the provider of the service. A presiding officer, having granted an exemption request from using E-Filing, may require a participant or party to use E-Filing if the presiding officer subsequently determines that the reason for granting the exemption from use of E-Filing no longer exists.

Documents submitted in adjudicatory proceedings will appear in the NRC's electronic hearing docket which is available to the public at *http://ehd1.nrc.gov/ehd/,* unless excluded pursuant to an order of the Commission, or the presiding officer. Participants are requested not to include personal privacy information, such as social security numbers, home addresses, or home phone numbers in their filings, unless an NRC regulation or other law requires submission of such information. With respect to copyrighted works, except for limited excerpts that serve the purpose of the adjudicatory filings and would constitute a Fair Use application, participants are requested not to include copyrighted materials in their submission.

Petitions for leave to intervene must be filed no later than 60 days from January 25, 2013. Requests for hearing, petitions for leave to intervene, and motions for leave to file new or amended contentions that are filed after the 60-day deadline will not be entertained absent a determination by the presiding officer that the filing demonstrates good cause by satisfying the following three factors in 10 CFR 2.309(c)(1): (i) The information upon which the filing is based was not previously available; (ii) the information upon which the filing is based is materially different from information previously available; and (iii) the filing has been submitted in a timely fashion based on the availability of the subsequent information.

For further details with respect to this action, see the application for amendment dated January 15, 2013.

Attorney for licensee: Ms. Kathryn M. Sutton, Morgan, Lewis & Bockius LLC, 1111 Pennsylvania Avenue NW., Washington, DC 20004–2514.

Dated at Rockville, Maryland, this 18th day of January, 2013.

For the Nuclear Regulatory Commission.

Denise L. McGovern,

Project Manager, Licensing Branch 4, Division of New Reactor Licensing, Office of New Reactors.

[FR Doc. 2013–01594 Filed 1–24–13; 8:45 am]

BILLING CODE P

NUCLEAR REGULATORY COMMISSION

[Docket No. 040–08502; NRC–2009–0036]

Supplemental Environmental Assessment and Finding of No Significant Impact for License Renewal for Uranium One USA, Inc., Willow Creek Uranium In-Situ Recovery Project, Johnson and Campbell Counties, WY, License SUA–1341

AGENCY: Nuclear Regulatory Commission.

ACTION: Notice of availability.

ADDRESSES: Please refer to Docket ID NRC–2009–0036 when contacting the NRC about the availability of information regarding this document. You may access information related to this document, which the NRC possesses and are publicly-available, using any of the following methods:

- *Federal Rulemaking Web site:* Go to *http://www.regulations.gov* and search for Docket ID NRC–2009–0036. Address questions about NRC dockets to Carol Gallagher; telephone: 301–492–3668; email: *Carol.Gallagher@nrc.gov.*
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may access publicly-available documents online in the NRC Library at *http://www.nrc.gov/reading-rm/adams.html.* To begin the search, select *''ADAMS Public Documents''* and then select *''Begin Web-based ADAMS Search.''* For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *pdr.resource@nrc.gov.* The ADAMS accession number for each document referenced in this notice (if that document is available in ADAMS) is provided the first time that a document is referenced. In addition, for the convenience of the reader, the ADAMS accession numbers are provided in a table in Section IV of this notice.
- *NRC's PDR:* You may examine and purchase copies of public documents at the NRC's PDR, Room O1–F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

FOR FURTHER INFORMATION CONTACT: Ron C. Linton, Project Manager, Office of

Federal and State Materials and Environmental Management Programs, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–7777; email: *Ron.Linton@nrc.gov.*

SUPPLEMENTARY INFORMATION:

I. Introduction

The U.S. Nuclear Regulatory Commission (NRC) is considering the renewal of Source Materials License SUA–1341 for continued uranium production operations and *in-situ* recovery (*IS*R) of uranium at the Willow Creek Project (formally known as Irigaray and Christensen Ranch Project) in Johnson and Campbell Counties, Wyoming. The NRC has prepared a Supplemental Environmental Assessment (SEA) to the Environmental Assessment (EA) published in July 2011, in support of this proposed license renewal in accordance with the requirements in part 51 of Title 10 of the *Code of Federal Regulations* (10 CFR). Based on the SEA, the NRC has concluded that a Finding of No Significant Impact (FONSI) is appropriate. The NRC is also conducting a safety evaluation of the proposed license renewal, pursuant to 10 CFR part 40. The results of the safety evaluation will be documented in a separate Safety Evaluation Report. If approved, the NRC will issue the renewed license following the publication of this notice.

II. Supplemental Environmental Assessment Summary

On May 30, 2008, Cogema Mining, Inc. submitted an application to the NRC, requesting license renewal of Source Materials License SUA–1341. On December 17, 2009, the NRC consented to a change of control of the license and Uranium One, USA, Inc. (Uranium One) became the licensee for Source Materials License SUA–1341. The NRC completed a Final EA and FONSI for the license renewal request on July 7, 2011. This SEA was prepared after publication of the EA due to the licensee's request to increase the flow rate of operations from 4,000 gallons per minute (gpm) to 9,000 gpm. The proposed action in this SEA is to increase the Christensen Ranch satellite plant throughput from 4,000 gpm to 9,000 gpm.

The NRC staff has determined that this increase in flow rate will not change the licensed boundary, and will only require minor modifications to the satellite plant resulting in an increase in the satellite plant footprint of approximately 660 square feet. The increase in flow rate will allow the licensee to operate more wellfields simultaneously, but will not change production rates from already approved wellfields because the production unit geologic properties control the flow rate at which each wellfield can be operated, which has not changed from previous evaluations. In the SEA, the staff considered the following environmental resource areas in its evaluation: Air quality, public and occupational doses; soil and groundwater; waste management and transportation. Public and occupational exposures are expected to remain below the limits established in 10 CFR part 20. Soil and groundwater are not expected to be impacted beyond what has already been evaluated, as the proposed action will allow the licensee to produce at a faster rate, but not from more production areas. Uranium One maintains acceptable waste management practices and procedures and even with the increase in flow rate, the waste management impacts are expected to be small. The increase in flow rate will result in one additional transfer of resin daily and one additional truck transporting resin daily to the Irigaray central processing plant. This increase does not affect the previous analysis discussed in the EA. The staff concluded that the proposed 10-year renewal of Source Materials License SUA–1341 will not result in a significant impact to the environment.

During development of the SEA, NRC staff requested comments from the Wyoming Department of Environmental Quality (WDEQ) on the increase in flow rate; none were provided.

III. Finding of No Significant Impact

The NRC staff has prepared an SEA in support of the proposed action. On the basis of this SEA, the NRC finds that there are no significant environmental impacts from the proposed action, and that the preparation of an environmental impact statement is not warranted. Accordingly, the NRC has determined that a Finding of No Significant Impact is appropriate.

IV. Further Information

Documents related to this action, including the application for amendment and supporting documentation, are available electronically at the NRC Library at *http://www.nrc.gov/reading-rm/adams.html.* From this site, you can access the NRC's Agencywide Document Access and Management System (ADAMS), which provides text and image files of NRC's public documents. The ADAMS accession numbers for the documents related to this notice are provided in the following table:

Document	ADAMS Accession No.
Final Environmental Assessment, July 7, 2011	ML103270681
License Renewal Revision (LRA), Revision and Request for Flow Rate Increase, March 7, 2012	ML120820095
Acceptance For Review And Request For Additional Information, Supplemental Information to 2008 License Renewal Application, June 7, 2012.	ML12152A159
Response to RAIs for Supplemental Information to 2008 License Renewal Application, July 7, 2012	ML12206A436
LRA Revision, July 10, 2012	ML12206A436
Letter to WDEQ, Request for Comments	ML12230A086
Email response from WDEQ	ML12285A074
Supplemental Environmental Assessment	ML12289A522

If you do not have access to ADAMS or if there are problems in accessing the documents located in ADAMS, contact the NRC Public Document Room (PDR) Reference staff at 1–800–397–4209, 301–415–4737 or by email to *pdr.resource@nrc.gov.*

These documents may also be viewed electronically on the public computers located at the NRC's Public Document Room (PDR), O 1 F21, One White Flint North, 11555 Rockville Pike, Rockville, MD 20852. The PDR reproduction contractor will copy documents for a fee.

Dated at Rockville, Maryland, 16th day of January 2013.

For the Nuclear Regulatory Commission.

Andrew Persinko,

Deputy Director, Decommissioning and Uranium Recovery Licensing Directorate, Division of Waste Management and Environmental Protection, Office of Federal and State Materials and Environmental Management Programs.

[FR Doc. 2013–01581 Filed 1–24–13; 8:45 am]

BILLING CODE 7590–01–P

OCCUPATIONAL SAFETY AND HEALTH REVIEW COMMISSION

Senior Executive Service Performance Review Board Membership

AGENCY: Occupational Safety and Health Review Commission.

ACTION: Annual notice.

SUMMARY: Notice is given under 5 U.S.C. 4314(c)(4) of the appointment of members to the Performance Review Board (PRB) of the Occupational Safety and Health Review Commission.

DATES: Membership is effective on January 25, 2013.

FOR FURTHER INFORMATION CONTACT: Linda M. Beard, Human Resources Specialist, U.S. Occupational Safety and Health Review Commission, 1120 20th Street NW., Washington, DC 20036, (202) 606–5393.

SUPPLEMENTARY INFORMATION: The Review Commission, as required by 5 U.S.C. 4314(c)(1) through (5), has established a Senior Executive Service PRB. The PRB reviews and evaluates the initial appraisal of a senior executive's performance by the supervisor, and makes recommendations to the Chairman of the Review Commission regarding performance ratings, performance awards, and pay-for-performance adjustments. Members of the PRB serve for a period of 24 months. In the case of an appraisal of a career appointee, more than half of the members shall consist of career appointees, pursuant to 5 U.S.C. 4314(c)(5). The names and titles of the PRB members are as follows:

- Nicholas M. Inzeo, Director, Office of Field Programs, U.S. Equal Employment Opportunity Commission;
- Jeffrey Risinger, Human Resources Director, Federal Housing Finance Agency; and
- Joel R. Schapira, Deputy General Counsel, Defense Nuclear Facilities Safety Board.

Dated: January 16, 2013.

Thomasina V. Rogers,

Chairman.

[FR Doc. 2013–01517 Filed 1–24–13; 8:45 am]

BILLING CODE 7600–01–P

OVERSEAS PRIVATE INVESTMENT CORPORATION

Sunshine Act: OPIC Annual Public Hearing

TIME AND DATE: 2 p.m., Wednesday, March 13, 2013.

PLACE: Offices of the Corporation, Twelfth Floor Board Room, 1100 New York Avenue NW., Washington, DC.

STATUS: Hearing open to the public at 2 p.m.

PURPOSE: Annual Public Hearing to afford an opportunity for any person to present views regarding the activities of the Corporation.

PROCEDURES:

Individuals wishing to address the hearing orally must provide advance notice to OPIC's Corporate Secretary no later than 5 p.m. Monday, February 25, 2013. The notice must include the individual's name, title, organization, address, email, telephone number, and a concise summary of the subject matter to be presented.

Oral presentations may not exceed ten (10) minutes. The time for individual presentations may be reduced proportionately, if necessary, to afford all participants who have submitted a timely request an opportunity to be heard.

Participants wishing to submit a written statement for the record must submit a copy of such statement to OPIC's Corporate Secretary no later than 5 p.m. Monday, February 25, 2013. Such statement must be typewritten, double-spaced, and may not exceed twenty-five (25) pages.

Upon receipt of the required notice, OPIC will prepare an agenda for the hearing identifying speakers, setting forth the subject on which each participant will speak, and the time allotted for each presentation. The agenda will be available at the hearing.

A written summary of the hearing will be compiled, and such summary will be made available, upon written request to OPIC's Corporate Secretary, at the cost of reproduction.

CONTACT PERSON FOR INFORMATION: Information on the hearing may be obtained from Connie M. Downs at (202) 336–8438, via email at *connie.downs@opic.gov,* or via facsimile at (202) 408–0297.

SUPPLEMENTARY INFORMATION: OPIC is a U.S. Government agency that provides, on a commercial basis, political risk insurance and financing in friendly developing countries and emerging democracies for environmentally sound projects that confer positive developmental benefits upon the project country while creating employment in the U.S. OPIC is required by section 231A(c) of the Foreign Assistance Act of 1961, as amended (the ''Act'') to hold at least one public hearing each year.

Dated: January 22, 2013.

Connie M. Downs,

OPIC Corporate Secretary.

[FR Doc. 2013–01605 Filed 1–23–13; 11:15 am]

BILLING CODE 3210–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–68690; File No. SR–DTC–2012–810]

Self-Regulatory Organizations; The Depository Trust Company; Notice of Filing Advance Notice To Reduce Liquidity Risk Relating to Its Processing of Maturity and Income Presentments and Issuances of Money Market Instruments

January 18, 2013.

Pursuant to Section 806(e)(1) of the Payment, Clearing, and Settlement Supervision Act of 2010 (''Clearing Supervision Act'') [1] and Rule 19b–4(n)(1)(i) [2] thereunder, notice is hereby given that on December 28, 2012, The Depository Trust Company (''DTC'') filed with the Securities and Exchange Commission (''Commission'') the advance notice described in Items I, II and III below, which Items have been prepared primarily by DTC. The Commission is publishing this notice to solicit comments on the advance notice from interested persons.

I. Clearing Agency's Statement of the Terms of Substance of the Advance Notice

DTC is proposing to change the current Largest Provisional Net Credit (''LPNC'') risk management control in order to increase withholding from one to two largest provisional credits (on an acronym [3] basis). DTC is also proposing to modify its Rules as they relate to the Issuing/Paying Agent's (''IPA's'') refusal to pay process. DTC is proposing not to process a reversal of a transaction initiated by an IPA when issuances of Money Market Instruments (''MMIs'') in an acronym exceed, in dollar value, the maturity or income presentments (''Maturity Obligations'') of MMIs in the

[1] 12 U.S.C. 5465(e)(1).

[2] 17 CFR 240.19b–4(n)(i).

[3] DTC employs a four-character acronym to designate an issuer's Money Market Instrument program. An issuer can have multiple acronyms. The Issuing/Paying Agent's bank uses the acronym(s) when submitting an instruction for a given issuer's Money Market Instrument securities.

same acronym on the same day. As a result, at the point in time when issuances of MMIs in an acronym exceed, in dollar value, the Maturity Obligations of the MMIs in the same acronym on that day, DTC will remove the LPNC control with respect to the affected acronym.

II. Clearing Agency's Statement of Purpose of, and Statutory Basis for, the Advance Notice

In its filing with the Commission, DTC included statements concerning the purpose of and basis for the advance notice and discussed any comments it received on the advance notice. The text of these statements may be examined at the places specified in Item IV below. DTC has prepared summaries, set forth in sections (A) and (B) below, of the most significant aspects of such statements.[4]

(A) Advance Notices Filed Pursuant to Section 806(e) of the Payment, Clearing and Settlement Supervision Act

Description of Change

MMI presentment processing is initiated automatically by DTC each morning for MMIs maturing that day. The automatic process electronically sweeps all maturing positions of MMI CUSIPs from DTC Participant accounts and creates the Maturity Obligations. The matured MMIs are, subject to DTC Rules, delivered to the applicable IPA, a DTC Participant, and DTC debits the IPA's account for the amount of the Maturity Obligations. In accordance with DTC Rules, payment will be due from the IPA for net settlement to the extent, if any, that the IPA has a net debit balance in its settlement account at end-of-day.

Without regard to DTC net settlement, MMI issuers and IPAs commonly view the primary source of funding of payments for Maturity Obligations of MMIs as flowing from new issuances of MMIs in the same acronym by that issuer on that day. In a situation where those new issuances exceed the Maturity Obligations, the issuer would have no net funds payment due to the IPA on that day. However, because Maturity Obligations of MMIs are processed automatically at DTC, IPAs currently operationally have the ability to pay for all of an issuer's maturities. An IPA that refuses payment on an MMI must communicate its intention to DTC using the DTC Participant Terminal/Browser Service (''PTS/PBS'') MMRP function. This communication is referred to as an Issuer Failure/Refusal to Pay (''RTP'') and it allows the Paying Agent to enter a refusal to pay instruction for a particular issuer acronym up to 3:00 p.m. Eastern Time (''ET'') on the date of the affected maturity or income presentment. Such an instruction will cause DTC, pursuant to its Rules, to reverse all transactions related to that issuer's acronym, including Maturity Obligations and any new issuances, posing a potential for systemic risk since the reversals may override DTC's risk management controls (e.g., collateral monitor[5] and net debit cap[6]).

To mitigate the risks associated with an RTP, DTC employs the LPNC risk management control. On each processing day, DTC withholds intraday credit from each MMI Participant for the largest credit with respect to an issuer's acronym, for purposes of calculating the Participant's net settlement balance and collateral monitor. As such, this single largest credit is provisional and is not included in the calculation of the Participant's collateral monitor or in the settlement balance measured against its net debit cap. DTC believes that the LPNC control will help protect DTC against either (i) the single largest issuer failure on a business day, or (ii) multiple failures on a business day that, taken together, do not exceed the largest provisional net credit.

Maturity payment procedures were designed to limit credit, liquidity, and operational risk for DTC and Participants in the MMI program. In an effort to further mitigate these risks, DTC is proposing the following changes to current processing associated with (1) the LPNC control and (2) limiting intraday MMI reversals under specified conditions:

(1) Increase Withholding From One to Two LPNCs

DTC is proposing to change the current LPNC risk management control in order to increase withholding from one to two largest provisional credits (on an acronym basis). DTC believes this will provide increased risk protection in the event of transaction reversals due to multiple issuer defaults or a single issuer default with two or more MMI programs.

DTC has conducted a simulation analysis to measure the impact to IPAs and custodians/dealers of an increase in LPNC controls from one to two on settlement blockage[7] intraday during peak processing periods. DTC analyzed the blockage level for both the IPAs and custodians/dealers as separate segments since each react to the additional blockage in different ways. DTC believes the results of the simulation analysis indicated that there will be no material change in settlement blockage.

(2) Eliminate Intraday Reversals When MMI Issuances Exceed Maturity Obligations

DTC is also proposing to modify its Rules as they relate to the refusal to pay process. As planned, DTC will not process a reversal of a transaction initiated by an IPA when issuances of MMIs in an acronym exceed, in dollar value, the Maturity Obligations of MMIs in the same acronym on the same day. In such instances, DTC will not process a reversal of the transaction because the IPA would have no reason to exercise the refusal to pay for that acronym on that settlement day. As a result, because the LPNC control is designed to protect against transaction reversals, at the point in time when issuances of MMIs in an acronym exceed, in dollar value, the Maturity Obligations of the MMIs in the same acronym on that day, DTC proposes not to apply the LPNC control with respect to the affected acronym.

Anticipated Effect on and Management of Risk

DTC believes that the proposed changes will mitigate the systemic risk associated with MMI transaction reversals due to an IPA refusal to pay instruction by increasing withholding from one to two largest provisional credits (on an acronym basis). DTC believes that this will provide increased risk protection in the event of transaction reversals due to multiple issuer defaults or a single issuer default with two or more MMI programs. By

[4] The Commission has modified the text of the summaries prepared by DTC.

[5] DTC tracks collateral in a Participant's account through the Collateral Monitor (''CM''). At all times, the CM reflects the amount by which the collateral value in the account exceeds the net debit balance in the account. When processing a transaction, DTC verifies that the CM of each of the deliverer and receiver will not become negative when the transaction is processed. If the transaction would cause either party to have a negative CM, the transaction will recycle until the deficient account has sufficient collateral to proceed or until the applicable cutoff occurs.

[6] The net debit cap control is designed so that DTC may complete settlement, even if a Participant fails to settle. Before completing a transaction in which a Participant is the receiver, DTC calculates the effect the transaction would have on such Participant's account, and determines whether any resulting net debit balance would exceed the Participant's net debit cap. Any transaction that would cause the net debit balance to exceed the net debit cap is placed on a pending (recycling) queue until the net debit cap will not be exceeded by processing the transaction.

[7] Settlement blockage refers to transactions that cannot be completed due to a receiver's net debit cap or collateral monitor controls.

mitigating DTC's and the financial systems exposure to this systemic risk, DTC believes that the proposed change will contribute to the goal of financial stability in the event of a default, and is consistent with the CPSS-IOSCO Recommendations for Securities Settlement Systems [8] applicable to DTC.

DTC has discussed this proposal with various industry groups, including the Participants that transact in MMIs, none of whom objected, according to DTC. According to DTC, the Participants understand that the elimination of intraday reversals when issuances exceed Maturity Obligations will result in no material change in settlement blockage and will mitigate systemic risk as a whole. DTC believes the proposed changes should promote settlement finality by precluding reversals for those issuances.

(B) Clearing Agency's Statement on Comments on the Advance Notice Received From Members, Participants, or Others

The subject proposal regarding MMIs was developed in consultation with various industry organizations. Written comments relating to the proposed changes contained in the advance notice have not yet been solicited or received. DTC will notify the Commission of any written comments received by DTC.

III. Date of Effectiveness of the Advance Notice and Timing for Commission Action

The clearing agency may implement the proposed change pursuant to Section 806(e)(1)(G) of the Clearing Supervision Act [9] if it has not received an objection to the proposed change within 60 days of the later of (i) the date that the Commission received the advance notice or (ii) the date the Commission receives any further information it requested for consideration of the notice. The clearing agency shall not implement the proposed change if the Commission has any objection to the proposed change.

The Commission may extend the period for review by an additional 60 days if the proposed change raises novel or complex issues, subject to the Commission providing the clearing agency with prompt written notice of the extension. A proposed change may be implemented in less than 60 days from the date of receipt of the advance notice, or the date the Commission receives any further information it requested, if the Commission notifies the clearing agency in writing that it does not object to the proposed change and authorizes the clearing agency to implement the proposed change on an earlier date, subject to any conditions imposed by the Commission. The clearing agency shall post notice on its Web site of proposed changes that are implemented.

The proposal shall not take effect until all regulatory actions required with respect to the proposal are completed.[10]

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the advance notice is consistent with the Clearing Supervision Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–DTC–2012–810 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–DTC–2012–810. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the advance notice that are filed with the Commission, and all written communications relating to the advance notice between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filings also will be available for inspection and copying at the principal office of DTC and on DTC's Web site at *http://dtcc.com/downloads/legal/rule_filings/2012/dtc/Advance_Notice_SR_2012_810.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–DTC–2012–810 and should be submitted on or before February 15, 2013.

By the Commission.

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2013–01484 Filed 1–24–13; 8:45 am]

BILLING CODE 8011–01–P

[8] Principles for Financial Market Infrastructures of the Committee on Payment and Settlement Systems and the Technical Committee of the International Organization of Securities Commissions (''CPSS-IOSCO'') (April 2012), available at *http://www.bis.org/publ/cpss101a.pdf.*

[9] 12 U.S.C. 5465(e)(1)(G).

[10] DTC also filed the proposals contained in this advance notice as a proposed rule change under Section 19(b)(1) of the Act and Rule 19b–4 thereunder. 15 U.S.C. 78s(b)(1); 17 CFR 240.19b–4. Pursuant to Section 19(b)(2) of the Act, within 45 days of the date of publication of the proposed rule change in the **Federal Register** or within such longer period up to 90 days if the Commission designates or the self-regulatory organization consents the Commission will either: (i) By order approve or disapprove the proposed rule change or (ii) institute proceedings to determine whether the proposed rule change should be disapproved. 15 U.S.C. 78s(b)(2)(A). *See* Release No. 34–68548 (December 28, 2012), 78 FR 795 (January 4, 2013).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–68689; File No. SR–Phlx–2013–03]

Self-Regulatory Organizations; NASDAQ OMX PHLX LLC; Notice of Filing of Proposed Rule Change To Amend Exchange Rules 507 and 1014 To Establish Remote Streaming Quote Trader Organizations

January 18, 2013.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 [2] thereunder, notice is hereby given that on January 4, 2013, NASDAQ OMX PHLX LLC (''Phlx'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II, and III, below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange is filing with the Commission a proposal to amend Phlx Rules 507 (Application for Approval as an SQT or RSQT and Assignment in Options) and 1014 (Obligations and Restrictions Applicable to Specialists and Registered Options Traders) to establish that member organizations may qualify to be Remote Streaming Quote Trader Organizations with which as many as three Remote Streaming Quote Traders may be affiliated.

The text of the proposed rule change is available on the Exchange's Web site at *http://nasdaqomxphlx.cchwallstreet.com/NASDAQOMXPHLX/Filings/,* 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 Phlx Rules 507 and 1014 to establish that member organizations may qualify to be Remote Streaming Quote Trader Organizations (''RSQTOs'') with which as many as three Remote Streaming Quote Traders may be affiliated.

Background

Remote Streaming Quote Traders (''RSQTs'') are, along with specialists, one of several types of Registered Option Traders (''ROTs'') on the Exchange. ROTs are market makers that include Streaming Quote Traders (''SQTs''),[3] RSQTs,[4] Directed Streaming Quote Traders (''DSQTs''), and Directed Remote Streaming Quote Traders (''DRSQTs'') [5] (SQTs, DSQTs, and DRSQTs are together known as the ''Other Streaming Quote Traders'').

Rule 507 is one of the numerous rules administered by the Exchange that deal with allocation and assignment of securities (the ''Allocation and Assignment Rules''). The Allocation and Assignment Rules generally describe the process for: Application for becoming and appointment of specialists; allocation of classes of options to specialist units and individual specialists; application for becoming and approval of SQTs and RQTs and assignment of options to them; and performance evaluations. The Allocation and Assignment Rules also indicate, among other things, under what circumstances new allocations to specialists and assignments to Streaming Quote Traders may not be made.[6]

Rule 1014 is the principal rule that deals with the obligations and restrictions that are applicable to specialists and Registered Option Traders. Rule 1014 states that, in addition to other requirements, on a daily basis RSQTs and Other Streaming Quote Traders are responsible to quote two-sided markets in not less than a specified percentage of options assigned by the Exchange at the request of such traders,[7] unless specifically exempted from such quoting (market-making) responsibility.

Remote Streaming Quote Trader Organizations and Affiliated Remote Streaming Quote Traders

Rule 507 discusses the process of applying for approval as an RSQT or SQT on the Exchange and assignment of options to them. Under Rule 507, RSQTs are actually Exchange member organizations while SQTs are Exchange members; therefore, options are assigned to RSQTs as firms (member organizations) and to SQTs as individual members (permit holders). The criteria for successfully applying to be an RSQT or an SQT is currently, with two exceptions, the same for both types of streaming quoters: (1) Significant market-making and/or specialist experience in a broad array of securities; (2) superior resources, including capital, technology and personnel; (3) demonstrated history of stability, superior electronic capacity, and superior operational capacity; (4) proven ability to interact with order flow in all types of markets; and (5) willingness and ability to make competitive markets on the Exchange and otherwise to promote the Exchange in a manner that is likely to enhance the ability of the Exchange to compete successfully for order flow in the options it trades (together the ''readiness requirements'').[8] Only RSQTs need to demonstrate two additional criteria for successful approval as remote streaming quoters: (1) Existence of order flow commitments; and (2) willingness to accept allocations as an RSQT in options overlying 400 or more securities.[9] The Exchange continues to believe that the existence of order floor commitments and the willingness to accept options allocations overlying hundreds of securities are criteria that belong at the firm level. As such, the Exchange proposes that all of the current RSQT application criteria will become the application criteria for RSQTOs (the ''RSQTO readiness requirements''), and all of the current SQT application criteria will become application criteria for both RSQTs and SQTs.[10]

[3] An SQT is an ROT who has received permission from the Exchange to generate and submit option quotations electronically in eligible options to which such SQT is assigned. An SQT may only submit such quotations while such SQT is physically present on the floor of the Exchange. *See* Rule 1014(b)(ii)(A).

[4] An RSQT is an ROT that is a member or member organization with no physical trading floor presence who has received permission from the Exchange to generate and submit option quotations electronically in eligible options to which such RSQT has been assigned. An RSQT may only submit such quotations electronically from off the floor of the Exchange. *See* Rule 1014(b)(ii)(B).

[5] A DSQT is an SQT and a DRSQT is an RSQT that receives a Directed Order. Exchange Rule 1080(l)(i)(A) defines Directed Order as any customer order (other than a stop or stop-limit order as defined in Rule 1066) to buy or sell which has been directed to a particular specialist, RSQT, or SQT by an Order Flow Provider and delivered to the Exchange via its electronic quoting, execution and trading system.

[6] *See,* for example, Supplementary Material .01 to Rule 506 (specialist may not apply for a new allocation for a period of six months after an option allocation was taken away from the specialist in a disciplinary proceeding or an involuntary reallocation proceeding). *See also* Commentaries .01 to .05 to Rule 507 setting forth procedures regarding the Maximum Number of Quoters (''MNQ'') allowed in equity options.

[7] Regarding RSQT and Other Streaming Quote Trader quoting obligations, *see* Rule 1014(b)(ii)(D)(1). Regarding specialist quoting obligations, *see* Rule 1014(b)(ii)(D)(2). *See also* Rule 1014 generally.

[8] *See* Rule 507(a)(i)(A) through (D) and (G) and Rule 507(a)(ii).

[9] *See* Rule 507(a)(i)(E) and (F). *See also* 1014(b)(ii)(B), which indicates that an RSQT is an ROT that is a member with no physical trading floor presence who has received permission from the Exchange to generate and submit option quotations electronically.

[10] *See* proposed Rule 507(a)(ii). RSQTs will, in addition, have to demonstrate that they have an

Continued

The Proposal

Proposed Rule 507 adds the concept of RSQTOs, which does not currently exist in Exchange rules. Any member organization of the Exchange in good standing that satisfies the RSQTO readiness requirements will be approved as an RSQTO.[11] No limit is placed on the number of member organizations that may become RSQTOs. Moreover, as many as three RSQT applicants affiliated with an RSQTO may be approved as an RSQT, to the extent that each such RSQT applicant is qualified as an ROT in good standing, and satisfies the five readiness requirements that are set out in Rule 507. The Exchange would continue to assign options to RSQTs, but these RSQTs would no longer be corporate entities but would be as many as three individual members per each Exchange-approved RSQTO. Rule 507 would continue to indicate that there is no limit on the number of qualifying ROTs that may be approved as RSQTs, as long as the applicants are qualified as ROTs in good standing and satisfy the readiness requirements.[12]

The process for applying for RSQTO and applying for and assigning options to RQSTs and SQTs is set out in Rule 507. The Exchange proposes in subsection (b)(i) that each RSQTO application is submitted to the Exchange's designated staff in writing (electronically or otherwise as specified by the Exchange) in a form and/or format prescribed by the Exchange and shall include, at a minimum: (1) The name of the RSQTO applicant, (2) the appropriate Exchange account number, and (3) the name of each RSQT associated with the RSQTO applicant. The Exchange proposes to also add that each RSQT application, in addition to other currently-requested minimum information,[13] state the name of the RSQTO with whom the RSQT is affiliated. If the Exchange does not have applications from SQTs or RSQTs for assignment in a particular option or options that it desires to assign or reassign, the Exchange may request such applications.[14]

The Exchange also clarifies in subsection (b)(ii) of Rule 507 that the technological readiness and testing requirements are applicable to RSQTO applicants just as they are applicable to RSQTs and SQTs. Thus, no application for being RSQTO or assignment in an option will be approved without verification that: (1) The RSQTO, SQT or RSQT applicant has sufficient technological ability to support his/her continuous quoting requirements as set forth in Rule 1014(b)(ii), and (2) the RSQTO, SQT or RSQT applicant has successfully completed, or is scheduled to complete, testing of its quoting system with the Exchange.

The Exchange also proposes in subsection (a) of Rule 507 a procedure to facilitate the process of RSQTs (currently, member organizations) to convert to an RSQTO structure with associated RSQTs. Upon approval of the proposal establishing RSQTOs and Exchange notification via OTA of such approval, each member organization operating as an RSQT pursuant this rule will automatically be deemed an RSQTO. After this designation the RSQTO will have twenty one (21) days to notify the Exchange of no more than three RSQTs to be affiliated with the RSQTO (the ''Conversion Period''), each of whom is an ROT in good standing and satisfies the technological readiness and testing requirements described in sub-paragraph (b)(ii) of Rule 507.

After the Conversion Period, per proposed subsection (a) of Rule 507 a member organization that is not currently qualified as an RSQTO may apply to the Exchange to be an RSQTO with up to three affiliated RSQTs. Each RSQTO application shall be submitted to the Exchange's designated staff in writing (electronically or otherwise as specified by the Exchange) in a form and/or format prescribed by the Exchange and shall include, at a minimum, the name of the RSQTO applicant, the appropriate Exchange account number, and the name of each RSQT affiliated with the RSQTO applicant (the ''Application Process''). The purpose for the sequential Conversion Period followed by the Application Process is to use the Exchange's current administrative process to ensure an accurate conversion from the existing RSQT methodology to the proposed RSQTO concept with three associated RSQTs.[15]

Subsection (d) of Rule 507 indicates that once an RSQTO, SQT or RSQT is approved for initial assignment in an option, he may not withdraw from such option assignment for ten (10) or fewer business days after the effective date of assignment. However, the Exchange may, in exceptional circumstances, approve withdrawal from an option assignment in ten (10) or fewer business days. If an RSQTO, SQT or RSQT seeks to withdraw from assignment in an option, it should so notify the Exchange at least one business day prior to the desired effective date of such withdrawal.

Finally, market makers may appeal if they believe that the Exchange's determination in respect of Rule 507 was improper.[16] The current appeal rights provided in subsection (e) of Rule 507 are not changed. Thus, an appeal to the Exchange's Board of Directors (''Board'') from a decision of the Exchange may be requested by a member or member organization interested therein by filing with the Secretary of the Exchange written notice of appeal within ten (10) days after the decision has been rendered. Any appeal from a decision pursuant to Rule 507 shall be heard by a special committee of the Board composed of three (3) Directors, of whom at least one (1) shall be an Independent Director.[17]

Restrictions Applicable to Remote Streaming Quote Traders and Remote Streaming Quote Trader Organizations

Rule 1014 describes, among other things, certain electronic quoting obligations via the Exchange's electronic

ongoing affiliation with an Exchange-approved RSQTO. Rule 507(a)(ii)(F).

[11] RSQTOs may also be referred to as Remote Market Maker Organizations (''RMOs'') and RSQTs may also be referred to as Remote Market Markers (''RMMs''). Proposed Rule 507(a).

[12] Rule 507 provides, however, that based on system constraints, capacity restrictions or other factors relevant to the maintenance of a fair and orderly market, the Board may defer, for a period to be determined in the Board's discretion, approval of qualifying applications for SQT or RSQT status pending any action required to address the issue of concern to the Board; where the basis for such deferral has been objectively determined by the Board, subject to Commission approval or effectiveness pursuant to a rule change filing under Section 19(b) of the Act.

[13] Other minimum information required of RSQT and SQT applicants includes: (1) The name of the SQT or RSQT applicant, (2) the appropriate Exchange account number, and (3) the requested start date for each option applied for. Rule 507(b)(i).

[14] The Exchange is deleting obsolete language from 507(b)(i) that it request (solicit) applications for all assignments, as such language is no longer necessary or desirable in light of the updated application process.

[15] There are currently 28 member organizations that will be converted to RSQTOs pursuant to this proposal.

[16] Decision concerning applications for assignment in options shall be in writing and shall be distributed to all applicants. Proposed Rule 507(c).

[17] Rule 507(e) states also that the person requesting review shall be permitted to submit a written statement to and/or appear before this special committee. The Secretary of the Exchange shall certify the record of the proceeding, if any and the written decision and shall submit these documents to the special committee. The special committee's review of the action shall be based solely on the record, the written decision and any statement submitted by the person requesting the review. The special committee shall prepare and deliver to such person a written decision and reasons therefore. If the special committee affirms the action, the action shall become effective ten (10) days from the date of the special committee's decision. There shall be no appeal to the Board of Directors from any decision of the special committee.

quoting and trading system,[18] as well as restrictions, pertaining to the current market makers on the Exchange. One of these restrictions in Rule 1014 indicates that no person who is either directly or indirectly affiliated with an RSQT (''affiliated RSQT'') is allowed to submit quotations as a specialist, SQT, RSQT or non-SQT ROT in options in which such affiliated RSQT is assigned.[19] In light of customer requests, the establishment of RSQTOs and inherent RSQT affiliation(s), and established quoting procedures, the Exchange proposes to clarify the quoting restriction applicable to RSQTs.

In particular, the Exchange proposes to amend subsection (b)(ii)(B) of Rule 1014 to remove the provision that states that no person who is either directly or indirectly affiliated with an RSQT shall submit quotations as a specialist, SQT, RSQT or non-SQT ROT in options in which such affiliated RSQT is assigned. This allows more than one RSQT to submit a quote in an assigned option, to the extent that each RSQT applies for and is approved as an RSQT affiliated with an RSQTO pursuant to Rule 507. The Exchange notes that this proposal does not otherwise affect the quoting responsibilities of RSQTs or other aspects of Rule 1014.[20] The Exchange also proposes to clarify subsection (b)(ii)(A) of Rule 1014 to state that an SQT may only trade in a market making capacity in classes of options in which the SQT is assigned.[21]

The Exchange represents that it has an adequate surveillance program in place for options that are quoted and traded on the Exchange and intends to continue application of those program procedures as necessary.[22] The Exchange also represents that it has the systems capacity to continue to support quoting and trading options subsequent to the effectiveness of this proposal.

The Exchange believes that the proposed rule change establishing RSQTOs and affiliated RSQTs and enabling the submission of more than one quotation in the same option class should encourage competition, create additional trading opportunities and outlets and increase the depth of markets, and promote a more robust system with specific standards for member organizations that are RSQTOs, electronic market makers that are affiliated with RSQTOs as RSQTs, and floor-based SQTs. This should lead to tighter, more efficient markets to the benefit of market participants including public investors that engage in trading and hedging on the Exchange.

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act[23] in general, and furthers the objectives of Section 6(b)(5) of the Act[24] 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, by enabling approval of RSQTOs with whom as many as three RSQTs may be affiliated, and enabling multiple quotes in the same option.

The Exchange believes that its rule change proposal does not engender unfair discrimination among specialists, specialist units, SQTs and RSQTs in that it proposes to amend rules and procedures that are equally applicable to all members and member organizations at the Exchange. Moreover, the Exchange believes that the proposal will promote a more robust system with specific standards for member organizations that are RSQTOs, electronic market makers that are affiliated with RSQTOs as RSQTs, and floor-based SQTs. By engendering more competition among market makers, the proposal may also lead to tighter, more efficient markets to the benefit of market participants including public investors that engage in trading and hedging on the Exchange.

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. To the contrary, the proposal further promotes competition on the Exchange which should lead to tighter, more efficient markets to the benefit of market participants including public investors that engage in trading and hedging on the Exchange, and thereby make the Exchange a desirable market vis a vis other options exchanges.

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

Within 45 days of the date of publication of this notice in the **Federal Register** or within such longer period (i) as the Commission may designate up to 90 days of such date if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the Exchange consents, the Commission shall: (a) By order approve or disapprove such proposed rule change, or (b) institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–Phlx–2013–03 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.

[18] The Exchange's electronic quoting and trading system, which has been denoted in Exchange rules as XL II, XL and AUTOM, has been updated with recent enhancements and configurations. *See* Exchange Act Release No. 59995 (May 28, 2009), 74 FR 26750 (June 3, 2009) (SR–Phlx–2009–32) (approval order regarding current electronic quoting and trading system known as XL II).

[19] *See* Rule 1014(b)(ii)(B).

[20] The proposed rule change will not, for example, impact the allocation received by a Directed RSQT or Directed SQT pursuant to rule 1014(viii)(B)(2). Thus, if an order is directed to a member organization that has more than one affiliated SQT or RSQT assigned in an option, only one SQT or RSQT may receive an allocation as Directed RSQT or Directed SQT, and the remaining non-Directed market makers will simply receive the standard RSQT or SQT allocation. Each RSQT and SQT would need to maintain Directed SQT and Directed RSQT quoting requirements because it is possible that they could receive a Directed Order, albeit only one market maker could be Directed per order.

[21] The language regarding when an SQT may trade in a market making capacity is exactly the same as what is currently applicable to RSQTs. *See* Rule 1014(b)(ii)(B).

[22] Additionally, the Exchange is a member of the Intermarket Surveillance Group (''ISG'') under the Intermarket Surveillance Group Agreement, dated June 20, 1994. ISG members generally work together to coordinate surveillance and investigative information sharing in the stock and options markets. Moreover, the major futures exchanges are affiliated members of the ISG, which allows for the sharing of surveillance information for potential intermarket trading abuses.

[23] 15 U.S.C. 78f(b).

[24] 15 U.S.C. 78f(b)(5).

All submissions should refer to File Number SR–Phlx–2013–03. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filing also will be available for inspection and copying at the principal 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–2013–03 and should be submitted on or before February 15, 2013.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[25]

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2013–01483 Filed 1–24–13; 8:45 am]

BILLING CODE 8011–01–P

[25] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–68692; File No. SR–FINRA–2013–004]

Self-Regulatory Organizations; Financial Industry Regulatory Authority, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Delay the Implementation Date of FINRA Rule 5350 (Stop Orders)

January 18, 2013.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'')[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on January 9, 2013, Financial Industry Regulatory Authority, Inc. (''FINRA'') filed with the Securities and Exchange Commission (''SEC'' or ''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by FINRA. FINRA has designated the proposed rule change as constituting a ''non-controversial'' rule change under paragraph (f)(6) of Rule 19b–4 under the Act,[3] which renders the proposal effective upon receipt of this filing by the Commission. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

FINRA is proposing to delay the implementation date of FINRA Rule 5350 (Stop Orders), as approved in SR–FINRA–2012–026, until March 4, 2013.

The text of the proposed rule change is available on FINRA's Web site at *http://www.finra.org,* at the principal office of FINRA 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, FINRA 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. FINRA has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

On September 4, 2012, the Commission approved FINRA Rule 5350 (Stop Orders),[4] a new rule that replaces the stop order provisions of FINRA Rule 6140(h) and that generally provides that any order labeled as a ''stop order'' or a ''stop limit order'' must be triggered based upon a transaction at the stop price, but permits firms to offer alternative order types with different triggers (*e.g.,* a stop order triggered by a quotation at the stop price) so long as, among other things, the order type is not labeled as a stop order and is clearly distinguishable from a stop order.

In SR–FINRA–2012–026, FINRA stated that the implementation date of new Rule 5350 would be no more than 150 days following Commission approval,[5] which requires FINRA to designate an effective date of no later than February 1, 2013. Consistent with this timeframe, on November 2, 2012 and following industry consultation, FINRA announced an effective date for new Rule 5350 of January 21, 2013.[6]

FINRA recently has received requests from industry participants for additional time to prepare for compliance with the new rule. Members have indicated that, among other things, Hurricane Sandy and code freezes occurred during the preparation timeframe, which contributed to delays in members' efforts to finalize standard order nomenclature and order messaging standards. Thus, in light of recent events and in response to members' requests for additional time, FINRA is extending the January 21, 2013 effective date announced in *Regulatory Notice* 12–50 until March 4, 2013.[7]

FINRA has filed the proposed rule change for immediate effectiveness and has requested that the Commission waive the requirement that the proposed rule change not become operative for 30 days after the date of the filing, such that FINRA may immediately announce a revised effective date of March 4, 2013.

2. Statutory Basis

FINRA believes that the proposed rule change is consistent with the provisions of Section 15A(b)(6) of the Act,[8] which requires, among other things, that FINRA rules must be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade and, in general, to protect investors and the public interest.

FINRA understands that Hurricane Sandy and code freezes that occurred during the preparation timeframe contributed to delays in members' efforts to finalize standard order nomenclature and order messaging standards. Thus, in light of recent events and in response to members' requests for additional time, FINRA is

[3] 17 CFR 240.19b–4(f)(6).

[4] *See* Securities Exchange Act Release No. 67778 (September 4, 2012), 77 FR 55517 (September 10, 2012) (Order Approving File No. SR–FINRA–2012–026).

[5] *See* Securities Exchange Act Release No. 67085 (May 31, 2012), 77 FR 33537 (June 6, 2012) (Notice of Filing File No. SR–FINRA–2012–026).

[6] *See Regulatory Notice* 12–50 (November 2012).

[7] An effective date of March 4, 2013 is 181 days from Commission approval of SR–FINRA–2012–026.

[8] 15 U.S.C. 78*o*–3(b)(6).

extending the effective date until March 4, 2013. FINRA, therefore, believes that the proposed rule change will promote the orderly coordination and implementation of technological and other changes to facilitate compliance with new FINRA Rule 5350.

B. Self-Regulatory Organization's Statement on Burden on Competition

FINRA does not believe that the proposed rule change will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

FINRA has filed the proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act [9] and Rule 19b–4(f)(6) thereunder.[10] Because the proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative prior to 30 days from the date on which it was filed, or such shorter time as the Commission may designate, if consistent with the protection of investors and the public interest, the proposed rule change has become effective pursuant to Section 19(b)(3)(A) of the Act [11] and Rule 19b–4(f)(6)(iii) thereunder.[12]

A proposed rule change filed under Rule 19b–4(f)(6) [13] normally does not become operative prior to 30 days after the date of the filing. However, pursuant to Rule 19b–4(f)(6)(iii),[14] the Commission may designate a shorter time if such action is consistent with the protection of investors and the public interest. FINRA has indicated that its members have been delayed in their efforts to finalize standard order nomenclature and order messaging standards, and have requested additional time to prepare for compliance with the new rule. The Commission notes that the proposed rule change does not present any new, unique, or substantive issues, but rather is merely delaying the implementation date of a proposed rule change the Commission previously approved, and that waiver of the 30-day operative delay will allow FINRA to announce the delayed implementation date to members immediately. The Commission believes that waiving the 30-day operative delay is consistent with the protection of investors and the public interest and, therefore, designates the proposed rule change as operative upon filing.[15]

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 email to *rule-comments@sec.gov*. Please include File Number SR–FINRA–2013–004 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–FINRA–2013–004. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filing also will be available for inspection and copying at the principal office of FINRA. 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–FINRA–2013–004 and should be submitted on or before February 15, 2013.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[16]

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2013–01486 Filed 1–24–13; 8:45 am]

BILLING CODE 8011–01–P

[9] 15 U.S.C. 78s(b)(3)(A)(iii).

[10] 17 CFR 240.19b–4(f)(6).

[11] 15 U.S.C. 78s(b)(3)(A).

[12] 17 CFR 240.19b–4(f)(6)(iii). FINRA has requested that the Commission waive the requirement that FINRA provide the Commission written notice of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date on which FINRA filed the proposed rule change pursuant to Rule 19b–4(f)(6)(iii). The Commission hereby grants this request.

[13] 17 CFR 240.19b–4(f)(6).

[14] 17 CFR 240.19b–4(f)(6)(iii).

[15] For purposes only of waiving the 30-day operative delay, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[16] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–68697; File No. SR–C2–2013–001]

Self-Regulatory Organizations; C2 Options Exchange, Incorporated; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change Relating to the BBO Data Feed for C2 Listed Options

January 18, 2013.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the ''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on January 11, 2013, C2 Options Exchange, Incorporated (the ''Exchange'' or ''C2'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I, II and III below, which Items

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

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 identify certain additional market data made available by Market Data Express, LLC (''MDX''), an affiliate of C2, as part of the BBO Data Feed for C2 listed options (''C2 BBO Data Feed''). The text of the proposed rule change is available on the Exchange's Web site (*http://www.cboe.com/AboutCBOE/CBOELegalRegulatoryHome.aspx*), at the Exchange's Office of the Secretary, and at the Commission.

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 reflect MDX's current practice of making certain additional market data available as part of the C2 BBO Data Feed.[3]

The C2 BBO Data Feed is a real-time, low latency data feed that includes C2 ''BBO data'' and last sale data.[4] The BBO and last sale data contained in the C2 BBO Data Feed is identical to the data that C2 sends to the Options Price Reporting Authority (''OPRA'') for redistribution to the public.[5]

The C2 BBO Data Feed also includes certain data that is not included in the data sent to OPRA, namely, totals of customer versus non-customer contracts at the BBO, All-or-None contingency orders priced better than or equal to the BBO, and BBO data and last sale data for complex strategies (e.g., spreads, straddles, buy-writes, etc.). MDX charges Customers a ''direct connect fee'' of $1,000 per connection per month and a ''per user fee'' of $25 per month per ''Authorized User'' or ''Device'' for receipt of the C2 BBO Data Feed by Subscribers.[6] Either a C2 Permit Holder or a non-C2 Permit Holder may be a Customer. All Customers are assessed the same fees.

MDX currently makes available an additional set of data as part of the C2 BBO Data Feed at no additional charge to Customers. Specifically, the C2 BBO Data Feed also includes expected opening price (''EOP'') and expected opening size (''EOS'') information that is disseminated prior to the opening of the market and during trading rotations (collectively, ''EOP/EOS data''). EOP/EOS data is calculated by the C2 System based on resting orders in the Book that remain from the prior business day and any orders and quotes submitted before the opening.[7] The EOP is the price at which the greatest number of orders and quotes in the Book are expected to trade.[8] EOP/EOS data is not offered separate from the C2 BBO Data Feed.

2. Statutory Basis

The Exchange believes the proposed rule change is consistent with the provisions of Section 6 of the Securities Exchange Act of 1934 (the ''Act'')[9] in general and with Section 6(b)(5) of the Act[10] in particular in that it is designed to prevent fraudulent and manipulative acts and practices, promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system and, in general, to protect investors and the public interest, and is not designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

In adopting Regulation NMS, the Commission granted self-regulatory organizations and broker-dealers increased authority and flexibility to offer new and unique market data to the public. It was believed that this authority would expand the amount of data available to consumers, and also spur innovation and competition for the provision of market data. The Exchange believes that the proposed rule change is in keeping with those principles by promoting increased transparency through the dissemination of more useful proprietary data and also by clarifying its availability to market participants.

Additionally, the Exchange believes the proposed rule change would not permit unfair discrimination because the C2 BBO Data Feed, including EOP/EOS data, is made equally available by MDX to any market participant that wishes to subscribe to it. The Exchange notes that other exchanges make information relating to the market opening available to members and non-members.[11]

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The Exchange believes the C2 BBO Data Feed, including EOP/EOS data, offered

[3] The C2 BBO Data Feed and the fees charged by MDX for the C2 BBO Data Feed were established in March 2011. *See* Securities Exchange Act Release No. 63996 (March 1, 2011), 76 FR 12386 (March 7, 2011).

[4] The BBO Data Feed includes the ''best bid and offer,'' or ''BBO'', consisting of all outstanding quotes and standing orders at the best available price level on each side of the market, with aggregate size (''BBO data,'' sometimes referred to as ''top of book data''). Data with respect to executed trades is referred to as ''last sale'' data.

[5] The Exchange notes that MDX makes available to ''Customers'' the BBO data and last sale data that is included in the C2 BBO Data Feed no earlier than the time at which the Exchange sends that data to OPRA. A ''Customer'' is any entity that receives the C2 BBO Data Feed directly from MDX's system and then distributes it either internally or externally to Subscribers. A ''Subscriber'' is a person (other than an employee of a Customer) that receives the C2 BBO Data Feed from a Customer for its own internal use.

[6] An ''Authorized User'' is defined as an individual user (an individual human being) who is uniquely identified (by user ID and confidential password or other unambiguous method reasonably acceptable to MDX) and authorized by a Customer to access the C2 BBO Data Feed supplied by the Customer. A ''Device'' is defined as any computer, workstation or other item of equipment, fixed or portable, that receives, accesses and/or displays data in visual, audible or other form.

[7] *See* C2 Rule 6.11(a)(2). The Exchange has filed a separate proposed rule change to amend C2 Rule 6.11(a)(2) to provide that such pre-opening information will be disseminated to users that have elected to receive such information and to remove the existing reference to such pre-opening information being disseminated to Participants. The term ''Participant'' means a Permit Holder as defined in C2 Rule 1.1. *See* SR–C2–2013–002.

[8] Id.

[9] 15 U.S.C. 78f(b).

[10] 15 U.S.C. 78f(b)(4) and (5). [sic]

[11] *See* e.g., Securities Exchange Act Release No. 66967 (May 11, 2012), 77 FR 29440 (May 17, 2012) (SR–PHLX–2012–60); and Securities Exchange Act Release No. 67720 (August 23, 2012), 77 FR 52769 (August 30, 2012) (SR–NYSEARCA–2012–89). In addition, the Nasdaq Options Market (''NOM'') disseminates certain pre-opening order imbalance information every five seconds for a period of time prior to the open and this information is made available via subscription. *See* NOM Chapter VI, Section 8(b)(1) and Chapter XV, Section 4(e); *see also http://www.nasdaqtrader.com/trader.aspx?id=openclose.*

by MDX will help attract new users and new order flow to the Exchange, thereby improving the Exchange's ability to compete in the market for options order flow and executions.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

The Exchange neither solicited nor received comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not:

A. Significantly affect the protection of investors or the public interest;

B. Impose any significant burden on competition; and

C. Become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A) [12] of the Act and Rule 19b–4(f)(6) [13] thereunder.

At any time within 60 days of the filing of this proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–C2–2013–001 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–C2–2013–001. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filing also will be available for inspection and copying at the principal offices of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–C2–2013–001, and should be submitted on or before February 15, 2013.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[14]

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2013–01491 Filed 1–24–13; 8:45 am]

BILLING CODE 8011–01–P

[12] 15 U.S.C. 78s(b)(3)(A).

[13] 17 CFR 240.19b–4(f)(6).

[14] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–68693; File No. SR–ISE–2013–04]

Self-Regulatory Organizations; International Securities Exchange, LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend the Exchange's Obvious and Catastrophic Error Rule

January 18, 2013.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the ''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on January 8, 2013, the International Securities Exchange, LLC (the ''Exchange'' or the ''ISE'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I and II below, which items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend ISE Rule 720, Obvious and Catastrophic Errors, to address obvious and catastrophic errors involving complex orders. The text of the proposed rule change is available on the Exchange's Web site *www.ise.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The self-regulatory organization has prepared summaries, set forth in Sections A, B and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The purpose of this proposed rule change is to amend ISE Rule 720 regarding Obvious and Catastrophic Errors to mitigate the risk to parties using complex orders, where part or all of a complex order traded at an erroneous price. Specifically, this proposed rule change addresses situations where one component (or leg) of a complex order is deemed an obvious (or catastrophic) error but the other component(s) is (are) not.

Complex orders are orders involving the simultaneous purchase and/or sale of two or more different options series in the same underlying security, for the same account, in a ratio that is equal to or greater than one-to-three (.333) and less than or equal to three-to-one (3.00) and for the purpose of executing a particular investment strategy.[3] With this proposed rule change, the Exchange is proposing to amend Rule 720 to

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* ISE Rule 722(a)(1).

address complex orders that have at least one leg that trades at an erroneous price. Rule 720 is the Exchange's rule that governs obvious and catastrophic errors in options. Most options exchanges have similar but not identical rules; this proposal would adopt a new process of determining how to deal with obvious/catastrophic errors when a complex order trades with another complex order on the Exchange.

Rule 720 provides a framework for reviewing the price of a transaction to determine whether that price was an ''obvious error''[4] pursuant to objective standards. When a Member believes it received one or more executions at an erroneous price, that Member may notify designated members of the Exchange's market control center (''Market Control'') within the prescribed timeframe so Market Control can determine whether the Member participated in a transaction that was the result of an obvious or catastrophic error.[5] Such an error will be deemed to have occurred when the execution price of a transaction is higher or lower than the theoretical price for a series by a certain amount depending on the type of option. Market Control use one of two criteria when determining the theoretical price of an options execution, which is enumerated in ISE Rule 720(a)(3). The theoretical price is then compared to an obvious/catastrophic error chart within Rule 720(a). If the transaction price meets this threshold, the transaction may be adjusted or nullified.

This proposed rule change would permit all legs of a complex order execution to be nullified when one leg can be nullified under Rule 720, only if the execution was a complex order versus a complex order.[6] This occurs when a complex order executes against another complex order. For example, assume a customer trades a call spread at a net price of $0.50 by buying the January 50 calls at $3.00 and selling the January 55 calls at $2.50. If the January 50 calls should have been trading at $7.00 and thus meet the obvious error threshold in Rule 720, then the entire complex trade will be nullified only if the January 50 and 55 calls traded as a complex order against another complex order, rather than as two separate trades. Currently, once the trade involving the January 50 calls is nullified, both parties are stuck with a transaction in the January 55 calls, which was not intended by either. This proposed rule change, therefore, provides an important benefit to both parties of a complex order, i.e., nullification of all the components of a complex order that traded with another complex order, because neither party intended to end up with just one component of a complex order. With this proposed rule change, a complex order execution where part or all of a complex order traded at an erroneous price would be nullified, not adjusted. The Exchange believes that if any one leg of a complex order is adjusted to a price other than its stated price, the trade no longer serves its purpose because complex orders are intended to serve a particular trading strategy but only if the order is executed at its stated price.

This proposal does not address complex orders that do not trade against other complex orders. This proposal is intended to mitigate risk for parties of a complex order where a complex order traded with another complex order at an erroneous price. By creating uniformity for all trades that are ''complex to complex,'' parties will have less trading risk because all of the components will be nullified under this proposed rule change.

The Exchange believes that the proposed rule change is reasonable and objective, and would serve to enhance the application of the Exchange's Obvious and Catastrophic Error rule by extending it to erroneous executions in complex orders. The purpose of this proposed rule change is to align the Exchange's rule with rules currently in place at other exchanges that address erroneous executions in complex orders.[7] The proposed rule change will provide members with similar opportunities for trade nullification that are available on PHLX which also has a rule in place to address obvious and catastrophic errors involving executions in complex orders.

2. Basis

The Exchange believes that this proposed rule change is consistent with Section 6(b) of the Securities Exchange Act of 1934 (''Exchange Act'')[8] in general, and furthers the objectives of Section 6(b)(5) of the Exchange Act[9] in particular, in that it is designed to promote just and equitable principles of trade, and to remove impediments to and perfect the mechanism for a free and open market and a national market system, and in general, to protect investors and the public interest.

The Exchange understands that, in approving proposals related to adjusting and nullifying option trades involving obvious and catastrophic errors, the Commission has focused on the need for specificity and objectivity with respect to exchange determinations and processes for reviewing such determinations.[10] In this regard, the Exchange believes that the proposed rule change provides specific and objective procedures for determining whether a trade should be nullified. The Exchange believes the proposed rule change will improve the obvious error process for complex orders that trade with another complex order. Recognition that a trade is part of a complex order should help add more certainty to the obvious/catastrophic error process and reduce the risk to parties trading complex orders on the Exchange because neither party to a complex order expects or intends to end up with just a piece of a complex order.

The Exchange also believes that the proposed rule change would benefit investors and market participants that are members of multiple exchanges by more closely aligning the Exchange's rules with respect to obvious and catastrophic errors involving executions in complex orders with those of other exchanges. In this respect, the proposed rule change helps foster certainty for market participants trading on multiple exchanges. Accordingly, the Exchange believes that the increased specificity resulting from the proposed rule change, combined with the continued objective nature of the Exchange's process for rendering and reviewing trade nullification determinations, is consistent with prior guidance from the Commission, is consistent with the Exchange Act and is consistent with the maintenance of a fair and orderly market and the protection of investors and the public interest.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act, but rather this proposal will promote competition as it is designed to improve the treatment of complex orders where part or all of a complex order is traded at an erroneous price.

[4] This proposed rule change also covers catastrophic errors.

[5] *See,* ISE Rules 720(b)(1) and 720(d)(1).

[6] *See,* proposed ISE Rule 720, Supplementary Material .06.

[7] *See,* for example, NASDAQ OMX PHLX LLC (''PHLX'') Rule 1092(c)(v).

[8] 15 U.S.C. 78f(b).

[9] 15 U.S.C. 78f(b)(5).

[10] *See* Securities Exchange Act Release No. 54228 (July 27, 2006), 71 FR 44066 (August 3, 2006) (SR–ISE–2006–14).

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

The Exchange has not solicited, and does not intend to solicit, comments on this proposed rule change. The Exchange has not received any unsolicited written comments from members or other interested parties.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not significantly affect the protection of investors or the public interest, does not impose any significant burden on competition, and, by its terms, does not become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A) [11] of the Act and Rule 19b–4(f)(6) [12] thereunder. The Exchange provided the Commission with written notice of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing the proposed rule change.

The Exchange has asked the Commission to waive the 30-day operative delay so that the proposal may become operative immediately upon filing. The Commission believes that waiver of the operative delay is consistent with the protection of investors and the public interest because this rule will offer Exchange members the same potential for relief that is available at other options exchanges for certain obvious and catastrophic errors involving complex orders. Therefore, the Commission designates the proposal operative upon filing.[13]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–ISE–2013–04 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–ISE–2013–04. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filing also will be available for inspection and copying at the principal offices of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–ISE–2013–04, and should be submitted on or before February 15, 2013.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[14]

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2013–01487 Filed 1–24–13; 8:45 am]

BILLING CODE 8011–01–P

[11] 15 U.S.C. 78s(b)(3)(A).

[12] 17 CFR 240.19b–4(f)(6).

[13] For purposes only of waiving the 30-day operative delay, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[14] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–68696; File No. SR–CBOE–2013–005]

Self-Regulatory Organizations; Chicago Board Options Exchange, Incorporated; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change Relating to the BBO Data Feed for CBOE Listed Options and a BBO Data Feed for Flexible Exchange Options

January 18, 2013.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the ''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on January 11, 2013, Chicago Board Options Exchange, Incorporated (the ''Exchange'' or ''CBOE'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to identify certain additional market data made available by Market Data Express, LLC (''MDX''), an affiliate of CBOE, as part of the BBO Data Feed for CBOE listed options (''BBO Data Feed'') and as a separate data feed. The text of the proposed rule change is available on the Exchange's Web site (*http://www.cboe.com/AboutCBOE/CBOELegalRegulatoryHome.aspx*), at the Exchange's Office of the Secretary, and at the Commission.

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

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

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 reflect MDX's current practice of making certain additional market data available as part of the BBO Data Feed [3] and as a separate data feed.

The BBO Data Feed is a real-time, low latency data feed that includes CBOE ''BBO data'' and last sale data.[4] The BBO and last sale data contained in the BBO Data Feed is identical to the data that CBOE sends to the Options Price Reporting Authority (''OPRA'') for redistribution to the public.[5]

The BBO Data Feed also includes certain data that is not included in the data sent to OPRA, namely, totals of customer versus non-customer contracts at the BBO, All-or-None contingency orders priced better than or equal to the BBO, and BBO data and last sale data for complex strategies (e.g., spreads, straddles, buy-writes, etc.). MDX charges Customers a ''direct connect fee'' of $3,500 per connection per month and a ''per user fee'' of $25 per month per ''Authorized User'' or ''Device'' for receipt of the BBO Data Feed by Subscribers.[6] Either a CBOE Trading Permit Holder or a non-CBOE Trading Permit Holder may be a Customer. All Customers are assessed the same fees.

MDX currently makes available two additional sets of data as part of the BBO Data Feed at no additional charge to Customers. Specifically, the BBO Data Feed also includes (i) BBO data and last sale data for Flexible Exchange (''FLEX'') options traded on the CBOE FLEX Hybrid Trading System,[7] including BBO data and last sale data for FLEX complex strategies (collectively, ''FLEX BBO data''), and (ii) expected opening price (''EOP'') and expected opening size (''EOS'') information that is disseminated prior to the opening of the market and during trading rotations (collectively, ''EOP/EOS data''). EOP/EOS data is calculated by the CBOE Hybrid Trading System based on resting orders in the Book that remain from the prior business day and any orders and quotes submitted before the opening.[8] The EOP is the price at which the greatest number of orders and quotes in the Book are expected to trade.[9]

MDX also makes the FLEX BBO data available as a separate data feed at no charge to any Customer that wishes to subscribe to only that data. EOP/EOS data is not offered separate from the BBO Data Feed.

1. Statutory Basis

The Exchange believes the proposed rule change is consistent with the provisions of Section 6 of the Securities Exchange Act of 1934 (the ''Act'') [10] in general and with Section 6(b)(5) of the Act [11] in particular in that it is designed to prevent fraudulent and manipulative acts and practices, promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system and, in general, to protect investors and the public interest, and is not designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

In adopting Regulation NMS, the Commission granted self-regulatory organizations and broker-dealers increased authority and flexibility to offer new and unique market data to the public. It was believed that this authority would expand the amount of data available to consumers, and also spur innovation and competition for the provision of market data. The Exchange believes that the proposed rule change is in keeping with those principles by promoting increased transparency through the dissemination of more useful proprietary data and also by clarifying its availability to market participants.

Additionally, the Exchange believes the proposed rule change would not permit unfair discrimination because the BBO Data Feed, including FLEX BBO data and EOP/EOS data, and the separate FLEX BBO data feed are made equally available by MDX to any market participant that wishes to subscribe to them. The Exchange notes that other exchanges make information relating to the market opening available to members and non-members.[12]

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The Exchange believes the BBO Data Feed, including FLEX BBO data and EOP/EOS data, and the separate FLEX BBO data feed offered by MDX will help attract new users and new order flow to the Exchange, thereby improving the Exchange's ability to compete in the market for options order flow and executions.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

The Exchange neither solicited nor received comments on the proposed rule change.

[3] The BBO Data Feed and the fees charged by MDX for the BBO Data Feed were established in March 2011. *See* Securities Exchange Act Release No. 63997 (March 1, 2011), 76 FR 12388 (March 7, 2011).

[4] The BBO Data Feed includes the ''best bid and offer,'' or ''BBO'', consisting of all outstanding quotes and standing orders at the best available price level on each side of the market, with aggregate size (''BBO data,'' sometimes referred to as ''top of book data''). Data with respect to executed trades is referred to as ''last sale'' data.

[5] The Exchange notes that MDX makes available to ''Customers'' the BBO data and last sale data that is included in the BBO Data Feed no earlier than the time at which the Exchange sends that data to OPRA. A ''Customer'' is any entity that receives the BBO Data Feed directly from MDX's system and then distributes it either internally or externally to Subscribers. A ''Subscriber'' is a person (other than an employee of a Customer) that receives the BBO Data Feed from a Customer for its own internal use.

[6] An ''Authorized User'' is defined as an individual user (an individual human being) who is uniquely identified (by user ID and confidential password or other unambiguous method reasonably acceptable to MDX) and authorized by a Customer to access the BBO Data Feed supplied by the Customer. A ''Device'' is defined as any computer, workstation or other item of equipment, fixed or portable, that receives, accesses and/or displays data in visual, audible or other form.

[7] *See* Chapter 24.B of CBOE Rules.

[8] *See* CBOE Rule 6.2B(a)(ii) (''Hybrid Opening System''). The Exchange has filed a separate proposed rule change to amend CBOE Rule 6.2B(a)(ii) to provide that such pre-opening information will be disseminated to users that have elected to receive such information and to remove the existing reference to such pre-opening information being disseminated to market participants (as defined in CBOE Rules 6.45A and 6.45B). *See* SR–CBOE–2013–006.

[9] Id.

[10] 15 U.S.C. 78f(b).

[11] 15 U.S.C. 78f(b)(4) and (5). [sic]

[12] *See* e.g., Securities Exchange Act Release No. 66967 (May 11, 2012), 77 FR 29440 (May 17, 2012) (SR–PHLX–2012–60); and Securities Exchange Act Release No. 67720 (August 23, 2012), 77 FR 52769 (August 30, 2012) (SR–NYSEARCA–2012–89). In addition, the Nasdaq Options Market (''NOM'') disseminates certain pre-opening order imbalance information every five seconds for a period of time prior to the open and this information is made available via subscription. *See* NOM Chapter VI, Section 8(b)(1) and Chapter XV, Section 4(e); *see also http://www.nasdaqtrader.com/trader.aspx?id=openclose.*

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not:

A. Significantly affect the protection of investors or the public interest;

B. Impose any significant burden on competition; and

C. Become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A) of the Act [13] and Rule 19b–4(f)(6) [14] thereunder.

At any time within 60 days of the filing of this proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov*. Please include File Number SR–CBOE–2013–005 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–CBOE–2013–005. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filing also will be available for inspection and copying at the principal offices of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–CBOE–2013–005, and should be submitted on or before February 15, 2013.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[15]

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2013–01490 Filed 1–24–13; 8:45 am]

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[13] 15 U.S.C. 78s(b)(3)(A).

[14] 17 CFR 240.19b–4(f)(6).

[15] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–68694; File No. SR–NASDAQ–2012–129]

Self-Regulatory Organizations; The NASDAQ Stock Market LLC; Notice of Designation of a Longer Period for Commission Action on Proposed Rule Change To Establish the Retail Price Improvement Program on a Pilot Basis Until 12 Months From the Date of Implementation

January 18, 2013.

On November 19, 2012, The NASDAQ Stock Market LLC (''NASDAQ'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'') [1] and Rule 19b–4 thereunder,[2] a proposed rule change to establish a Retail Price Improvement Program to attract additional retail order flow to the Exchange while also providing the potential for price improvement to such order flow. The proposed rule change was published for comment in the **Federal Register** on December 7, 2012.[3] The Commission did not receive any comments on the proposed rule change.

In connection with the proposal, the Exchange requested exemptive relief from Rule 612 of Regulation NMS,[4] which, among other things, prohibits a national securities exchange from accepting or ranking orders priced greater than $1.00 per share in an increment smaller than $0.01.[5] On January 14, 2013, the Exchange submitted a letter requesting that the staff of the Division of Trading and Markets not recommend any enforcement action under Rule 602 of Regulation NMS (the ''Quote Rule'') based on the Exchange's and its Members' participation in the Program.[6]

Section 19(b)(2) of the Act [7] provides that within 45 days of the publication of notice of the filing of a proposed rule change, or within such longer period up to 90 days as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding or as to which the self-regulatory organization consents, the Commission shall either approve the proposed rule change, disapprove the proposed rule change, or institute proceedings to determine whether the proposed rule change should be disapproved. The 45th day for this filing is January 21, 2013.

The Commission is extending the 45-day time period for Commission action on the proposed rule change. The Commission finds that it is appropriate to designate a longer period to take action on the proposed rule change so that it has sufficient time to consider the Exchange's proposal, which would allow the Exchange to utilize non-displayed orders that offer price improvement to retail order flow potentially in sub-penny increments, as well as the Exchange's attendant requests for exemptive and no-action relief.

Accordingly, pursuant to Section 19(b)(2) of the Act,[8] the Commission designates March 7, 2013 as the date by which the Commission should either approve or disapprove, or institute proceedings to determine whether to

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 68336 (December 3, 2012), 77 FR 73097 (SR–NASDAQ–2012–129).

[4] 17 CFR 242.612 (the ''Sub-Penny Rule'').

[5] *See* Letter from Jeffrey Davis, Deputy General Counsel, The NASDAQ Stock Market LLC, to Elizabeth M. Murphy, Secretary, Commission, dated November 19, 2012).

[6] *See* Letter from Jeffrey Davis, Deputy General Counsel, The NASDAQ Stock Market LLC, to John Ramsay, Division of Trading and Markets, Commission, dated January 14, 2013.

[7] 15 U.S.C. 78s(b)(2).

[8] 15 U.S.C. 78s(b)(2).

disapprove, the proposed rule change (File Number SR–NASDAQ–2012–129).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority. [9]

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2013–01488 Filed 1–24–13; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–68698; File No. SR–Phlx–2013–04]

Self-Regulatory Organizations; NASDAQ OMX PHLX LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change Relating to Routing Fees

January 18, 2013.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'') [1], and Rule 19b–4 thereunder,[2] notice is hereby given that on January 8, 2013, 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 its Routing Fees at Section V of the Pricing Schedule. While changes to the Pricing Schedule pursuant to this proposal are effective upon filing, the Exchange has designated the proposed amendment to be operative on February 1, 2013. The text of the proposed rule change is available on the Exchange's Web site at *http://nasdaqomxphlx.cchwallstreet.com/,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant 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 this filing is to amend Routing Fees in Section V of the Pricing Schedule in order to recoup costs that the Exchange incurs for routing and executing orders in equity options to various away markets.

Today, the Exchange calculates Routing Fees by assessing certain Exchange costs related to routing orders to away markets plus the away market's transaction fee. The Exchange assesses a $0.04 per contract fixed Routing Fee when routing orders to the NASDAQ Options Market LLC (''NOM'') and NASDAQ OMX BX, Inc. (''BX Options) and a $0.10 per contract fixed Routing Fee to all other options exchanges in addition to the actual transaction fee or rebate paid by the away market.

The fixed Routing Fee is based on costs that are incurred by the Exchange when routing to an away market in addition to the away market's transaction fee. For example, the Exchange incurs a fee when it utilizes Nasdaq Options Services LLC (''NOS''), a member of the Exchange and the Exchange's exclusive order router,[3] to route orders in options listed and open for trading on the PHLX XL system to destination markets. Each time NOS routes to away markets NOS incurs a clearing-related cost [4] and, in the case of certain exchanges, a transaction fee is also charged in certain symbols, which fees are passed through to the Exchange. The Exchange also incurs administrative and technical costs associated with operating NOS, membership fees at away markets, Options Regulatory Fees (''ORFs'') and technical costs associated with routing options.

The Exchange proposes to amend its Routing Fees to increase the current fixed Routing Fee to BX Options and NOM from $0.04 to $0.05 [5] per contract and the fixed Routing Fee to all other options exchanges from $0.10 to $0.11 [6] per contract to capture the increased costs that the Exchange incurs when routing to away markets in addition to the transaction fee that is being assessed by the away market. Specifically, several exchanges have increased ORFs or adopted ORFs and the Exchange proposes to increase its Routing Fees to recoup those increased fees.[7]

Today, the transaction fee assessed by the Exchange is based on the away market's actual transaction fee or rebate for a particular market participant at the time that the order was entered into the Exchange's trading system. This transaction fee is calculated on an order-by-order basis, since different away markets charge different amounts.[8] In the event that there is no transaction fee

[9] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] In May 2009, the Exchange adopted Rule 1080(m)(iii)(A) to establish Nasdaq Options Services LLC (''NOS''), a member of the Exchange, as the Exchange's exclusive order router. *See* Securities Exchange Act Release No. 59995 (May 28, 2009), 74 FR 26750 (June 3, 2009) (SR–Phlx–2009–32). NOS is utilized by the Exchange's fully automated options trading system, PHLX XL.® ''PHLX XL'' is the Exchange's automated options trading system.

[4] The Options Clearing Corporation (''OCC'') assesses a clearing fee of $0.01 per contract side. *See* Securities Exchange Act Release No. 68025 (October 10, 2012), 77 FR 63398 (October 16, 2012) (SR–OCC–2012–18).

[5] In a previous rule filing, the Exchange discussed the manner in which it analyzed costs related to routing to BX Options and NOM and determined the costs are lower as compared to other away markets because NOS is utilized by all three exchanges to route orders. In that filing the Exchange noted that because Phlx, BX Options and NOM all utilize NOS, the cost to the Exchange is less as compared to routing to other away markets. In addition the fixed costs are reduced because NOS is owned and operated by NASDAQ OMX and the three exchanges and NOS share common technology and related operational functions. *See* Securities Exchange Act Release No. 68213 (November 13, 2012), 77 FR 69530 (November 19, 2012) (SR–Phlx–2012–129).

[6] The $0.11 per contract fixed fee would apply to all options exchanges other than BX Options and NOM, which are discussed separately in this proposal. The Exchange anticipates that if other options exchanges are approved by the Commission after the filing of this proposal, those exchanges would be assessed the $0.11 per contract fee applicable to ''all other options exchanges.''

[7] The Chicago Board Options Exchange, Incorporated (''CBOE'') recently increased its ORF from $.0065 to $.0085 per contract. *See* Securities Exchange Act Release No. 68480 (December 19, 2012), 77 FR 76119 (December 26, 2012) (SR–CBOE–2012–118). C2 Options Exchange, Incorporated (''C2'') recently increased its ORF from $.0015 to $.002 per contract. *See* Securities Exchange Act Release No. 68479 (December 19, 2012), 77 FR 76131 (December 26, 2012) (SR–C2–2012–040). NYSE MKT LLC (''NYSE Amex'') recently increased its ORF from $0.004 to $0.005 per contract. *See* Securities Exchange Act Release No. 68183 (November 8, 2012), 77 FR 68186 (November 15, 2012) (SR–NYSEMKT–2012–54). NYSE Arca, Inc. (''NYSE Arca'') recently increased its ORF from $0.004 to $0.005 per contract. *See* Securities Exchange Act Release No. 68174 (November 7, 2012), 77 FR 67845 (November 14, 2012) (SR–NYSEArca–2012–118). Miami International Securities Exchange, LLC (''MIAX'') recently adopted an ORF of $0.0040 per contract side. *See* SR–MIAX–2012–06 (not yet published).

[8] This is similar to the methodology utilized by ISE in assessing Routing Fees. *See* ISE's Fee Schedule.

or rebate assessed by the away market, the only fee assessed is the fixed Routing Fee. With respect to the rebate, the Exchange pays a market participant the rebate offered by an away market where there is such a rebate. Any rebate available is netted against a fee assessed by the Exchange.[9] The Exchange is not proposing to amend its calculation of the away market's transaction fee as described herein.

As with all fees, the Exchange may adjust these Routing Fees in response to competitive conditions by filing a new proposed rule change.

2. Statutory Basis

The Exchange believes that its proposal to amend its Pricing Schedule is consistent with Section 6(b) of the Act[10] in general, and furthers the objectives of Section 6(b)(4) of the Act[11] in particular, in that it is an equitable allocation of reasonable fees and other charges among Exchange members.

The Exchange believes that the proposed Routing Fees are reasonable because they seek to recoup costs that are incurred by the Exchange when routing Customer, Professional, Firm, Broker-Dealer, Specialist and Market Maker orders to away markets on behalf of members. Each destination market's transaction charge varies and there is a cost incurred by the Exchange when routing orders to away markets. The costs to the Exchange include clearing costs, administrative and technical costs associated with operating NOS, membership fees at away markets, ORFs and technical costs associated with routing options. The Exchange believes that the proposed Routing Fees would enable the Exchange to recover the costs it incurs to route orders to away markets in addition to transaction fees assessed to market participants for the execution of Customer, Professional, Firm, Broker-Dealer, Specialist and Market Maker orders by the away market. Specifically, other options exchanges have increased ORFs that are assessed per transaction.[12] The Exchange believes that it is reasonable to recoup these costs borne by the Exchange on each transaction.

Further, the Exchange believes that it is equitable and not unfairly discriminatory to increase the fixed Routing Fees from $0.04 to $0.05 per contract and from $0.10 to $0.11 per contract, depending on the away market, because the Exchange would uniformly assess these fees depending on the away market. Further, the Exchange believes that it is equitable and not unfairly discriminatory to assess a fixed cost of $0.05 per contract to route orders to NASDAQ OMX away markets (BX Options and NOM) because the cost, in terms of actual cash outlays, to the Exchange to route to those markets is lower. For example, costs related to routing to BX Options and NOM are lower as compared to other away markets because NOS is utilized by all three exchanges to route orders.[13] NOS and the three NASDAQ OMX options markets have a common data center and staff that are responsible for the day-to-day operations of NOS. Because the three exchanges are in a common data center, Routing Fees are reduced because costly expenses related to, for example, telecommunication lines to obtain connectivity are avoided when routing orders in this instance. The costs related to connectivity to route orders to other NASDAQ OMX exchanges are de minimis. When routing orders to non-NASDAQ OMX exchanges, the Exchange incurs costly connectivity charges related to telecommunication lines and other related costs when routing orders.

While the proposal increases the fixed fee for routing orders to all markets by $0.01 per contract, the Exchange is not proposing to amend the fee differential of $0.06 per contract that exists today when routing to a NASDAQ OMX exchange ($0.04 per contract) as compared to a non-NASDAQ OMX exchange ($0.10 per contract). The Exchange believes it is reasonable, equitable and not unfairly discriminatory to pass along savings realized by leveraging NASDAQ OMX's infrastructure and scale to market participants when those orders are routed to BX Options and NOM.[14] It is important to note with respect to routing to an away market that orders are routed based on price first. PHLX XL will route orders to away markets where the Exchange's disseminated bid or offer is inferior to the national best bid (best offer) (''NBBO'') price.[15] Market participants may submit orders to the Exchange as ineligible for routing or ''DNR'' to avoid incurring the Routing Fees proposed herein.[16]

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. The Exchange believes that the rule change would allow the Exchange to recoup its costs when routing orders designated as available for routing by the market participant. Members and member organizations may choose to mark the order as ineligible for routing to avoid incurring these fees.[17] Today, other options exchanges also assess similar fees to recoup costs incurred by the Exchange to route orders to away markets. With respect to routing to BX Options and NOM at a lower cost as compared to other away markets, the Exchange does not believe that the proposed amendments to increase those fees, while maintaining the same fee differential, imposes a burden because all market participants would be assessed the same fees depending on the away market and the fee increase is the same for all market participants. Also, the Exchange is proposing to recoup costs incurred only when members request the Exchange route their orders

[9] For example, if a Customer order is routed to BOX, and BOX offers a customer rebate of $0.20 per contract, the Exchange would assess a $0.10 per contract fixed fee which would net against the rebate ($0.20 per contract in this example). The market participant for whom the Customer contract was routed would receive a $0.10 per contract rebate. Today the market participant does not receive a rebate and only pays the current $0.11 per contract Routing Fee.

[10] 15 U.S.C. 78f(b).

[11] 15 U.S.C. 78f(b)(4).

[12] CBOE recently increased its ORF from $.0065 to $.0085 per contract. *See* Securities Exchange Act Release No. 68480 (December 19, 2012), 77 FR 76119 (December 26, 2012) (SR–CBOE–2012–118). C2 recently increased its ORF from $.0015 to $.002 per contract. *See* Securities Exchange Act Release No. 68479 (December 19, 2012), 77 FR 76131 (December 26, 2012) (SR–C2–2012–040). NYSE Amex recently increased its ORF from $0.004 to $0.005 per contract. *See* Securities Exchange Act Release No. 68183 (November 8, 2012), 77 FR 68186 (November 15, 2012) (SR–NYSEMKT–2012–54). NYSE Arca recently increased its ORF from $0.004 to $0.005 per contract. *See* Securities Exchange Act Release No. 68174 (November 7, 2012), 77 FR 67845 (November 14, 2012) (SR–NYSEArca–2012–118). MIAX recently adopted an ORF of $0.0040 per contract side. See SR–MIAX–2012–06 (not yet published).

[13] *See* Chapter VI, Section 11 of the BX Options and NOM Rules.

[14] Today, the Exchange assesses a $0.11 per contract fixed fee for routing orders to BX Options and NOM. That fee is proposed to be reduced to a $0.04 per contract fixed fee, which would be in addition to the actual transaction fee assessed by the away market.

[15] *See* Rule 1080(m). The Phlx XL II system will contemporaneously route an order marked as an Intermarket Sweep Order (''ISO'') to each away market disseminating prices better than the Exchange's price, for the lesser of: (a) The disseminated size of such away markets, or (b) the order size and, if order size remains after such routing, trade at the Exchange's disseminated bid or offer up to its disseminated size. If contracts still remain unexecuted after routing, they are posted on the book. Once on the book, should the order subsequently be locked or crossed by another market center, the Phlx XL II system will not route the order to the locking or crossing market center, with some exceptions noted in Rule 1080(m).

[16] *See* Rule 1066(h) (Certain Types of Orders Defined) and 1080(b)(i)(A) (PHLX XL and PHLX XL II).

[17] *Id.*

to an away market. The Exchange is passing along savings realized by leveraging NASDAQ OMX's infrastructure and scale to market participants when those orders are routed to BX Options and NOM and is providing those savings to all market participants. Finally, PHLX XL routes orders to away markets where the Exchange's disseminated bid or offer is inferior to the national best bid (best offer) (''NBBO'') price and based on price first.[18]

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A)(ii) of the Act.[19] 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 email to *rule-comments@sec.gov.* Please include File Number SR–Phlx–2013–04 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–2013–04. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml).* Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of 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–2013–04 and should be submitted on or before February 15, 2013.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[20]

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2013–01492 Filed 1–24–13; 8:45 am]

BILLING CODE 8011–01–P

[18] *See* Rule 1080(m). The Phlx XL II system will contemporaneously route an order marked as an Intermarket Sweep Order (''ISO'') to each away market disseminating prices better than the Exchange's price, for the lesser of: (a) The disseminated size of such away markets, or (b) the order size and, if order size remains after such routing, trade at the Exchange's disseminated bid or offer up to its disseminated size. If contracts still remain unexecuted after routing, they are posted on the book. Once on the book, should the order subsequently be locked or crossed by another market center, the Phlx XL II system will not route the order to the locking or crossing market center, with some exceptions noted in Rule 1080(m).

[19] 15 U.S.C. 78s(b)(3)(A)(ii).

[20] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–68701; File No. SR–FINRA–2013–006]

Self-Regulatory Organizations; Financial Industry Regulatory Authority, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change Relating to FINRA Rule 4530 (Reporting Requirements)

January 18, 2013.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'') [1] and Rule 19b–4 thereunder,[2] notice is hereby given that on January 14, 2013, Financial Industry Regulatory Authority, Inc. (''FINRA'') 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 FINRA. FINRA has designated the proposed rule change as constituting a ''non-controversial'' rule change under paragraph (f)(6) of Rule 19b–4 under the Act,[3] which renders the proposal effective upon receipt of this filing by the Commission. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

FINRA is proposing to amend FINRA Rule 4530 (Reporting Requirements) to: (1) Provide an exception from the rule for information disclosed on the Form U4 (Uniform Application for Securities Industry Registration or Transfer); (2) enable members to file required documents with FINRA online; and (3) provide an exception from the rule for findings and actions by FINRA.

The text of the proposed rule change is available on FINRA's Web site at *http://www.finra.org,* at the principal office of FINRA 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, FINRA 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. FINRA has prepared

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 17 CFR 240.19b–4(f)(6).

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

FINRA Rule 4530, which became effective on July 1, 2011,[4] requires members to report to FINRA specified events (*e.g.,* findings by a regulatory body) and quarterly statistical and summary information regarding written customer complaints.[5]

Exception for Information Disclosed on the Form U4

FINRA Rule 4530(e) currently provides that a firm is not required to report a specified event under the rule if it reports that event on the Form U5 (Uniform Termination Notice for Securities Industry Registration), consistent with the requirements of that form.[6] This provision is intended to eliminate duplicative reporting of information disclosed on the Form U5. FINRA proposes to provide a similar exception for certain specified events reported on the Form U4. The process applicable under the proposed Form U4 exception will, however, be slightly different, in part because of differences in the reporting criteria between Form U4 and FINRA Rule 4530 events.[7]

Under the Form U4 exception process, a member will be required to affirmatively request through functionality on the Central Registration Depository (CRD® system) that the data reported on a Form U4 Disclosure Reporting Page (DRP) also be applied to satisfy its corresponding FINRA Rule 4530 reporting obligation. Specifically, FINRA proposes to enable filers to designate through the use of checkboxes in the CRD system that the data reported on certain Form U4 DRPs also be applied to satisfy the corresponding requirement under FINRA Rule 4530(a)(1).[8] FINRA expects that this affirmative designation by the member will facilitate the staff's review process by allowing the staff to continue to identify, categorize and review Rule FINRA 4530 reportable events in a timely fashion and reduce the number of staff inquiries to the member to confirm or clarify the firm's intention. FINRA proposes to enable firms to designate that data on the following Form U4 DRPs be applied to satisfy the applicable FINRA Rule 4530(a)(1) events: (1) Criminal; (2) Regulatory Action; (3) Civil Judicial; and (4) Customer Complaint/Arbitration/Civil Litigation.

The proposed rule change will be effected through functionality in the CRD system; FINRA is not proposing changes to the Form U4. Moreover, firms can continue to report an event via the FINRA Rule 4530 application on the Firm Gateway. Finally, similar to the Form U5 exception, the proposed Form U4 exception will not extend to the reporting of quarterly statistical and summary customer complaint information pursuant to FINRA Rule 4530(d).

Availability of Online Filings

FINRA Rule 4530(f) requires firms to promptly file with FINRA copies of certain criminal actions, civil complaints and arbitration claims.[9] Firms have the option of filing the required documents either electronically (as a scanned email attachment or scanned and saved on a disk) or in paper form. Currently, firms do not have the option of filing these documents with FINRA online. FINRA proposes to amend FINRA Rule 4530 to give members the option of filing the required documents online via FINRA's Firm Gateway.[10] This will provide firms an online platform to satisfy both their reporting and filing obligations under FINRA Rule 4530. The documents will be automatically uploaded in an existing centralized FINRA database. This change has the potential to reduce the burden on those firms that prefer to file documents electronically while also providing firms and FINRA with a more efficient audit trail and saving FINRA staff time currently spent uploading documents to the centralized database.

However, firms that choose to file their documents electronically using the Firm Gateway will be required to provide limited summary information regarding the documents,[11] such as the name and telephone number of the contact person and the name of the complainant or plaintiff. The required summary information will also automatically populate the centralized database. This will allow FINRA staff to retrieve and analyze information contained in these submissions from a consolidated source. Further, because the summary information will automatically populate the centralized database, FINRA staff will not have to separately enter such information into the database, which will improve the efficiency of the review process.

In conjunction with the proposed rule change, FINRA proposes to create a new form, which will be available through the Firm Gateway.[12] Members that choose to file their documents online will be required to complete the mandatory fields on the new online form and attach to the form a scanned copy of the required documents, in a format such as Adobe PDF.

Firms will continue to have the option of filing the documents required under FINRA Rule 4530(f) via mail or email. In addition, the requirement to provide limited summary information regarding the documents only applies to firms that choose to file the documents with FINRA online using the new form; the requirement does not apply to firms that use other permissible electronic means (*e.g.,* email) to file the documents with FINRA.[13]

[4] FINRA Rule 4530 replaced NASD Rule 3070 (Reporting Requirements) and the corresponding provisions in Incorporated NYSE Rule 351 (Reporting Requirements). *See Regulatory Notice* 11–06 (February 2011).

[5] The specified events and customer complaint information must be electronically reported to FINRA via an application on FINRA's Firm Gateway. *See Regulatory Notice* 11–10 (March 2011).

[6] This exception does not extend to the reporting of quarterly statistical and summary customer complaint information under the rule.

[7] For example, a registered person's Form U4 must be amended to report pending arbitration claims initiated by a customer where the registered person is the subject of such a claim, the customer alleges sales practice violations, and the customer claims damages in the amount of $5,000 or more. A member must report such a matter promptly (in general, not later than 30 days after the member is served with the customer claim) and before the claim has a final disposition. In contrast, FINRA Rule 4530(a)(1)(G) requires the reporting of such matters only when there has been a final disposition that results in an award or a settlement for an amount exceeding $15,000.

[8] FINRA Rules 4530(a)(1)(A) through (H), which address the reporting of regulatory, criminal and civil actions, in general, correspond with information disclosed on the Form U4. There is no corresponding provision on the Form U4 for matters reportable under FINRA Rule 4530(a)(2) (disciplinary actions taken by a member against an associated person) or FINRA Rule 4530(b) (a member's internal conclusions of violations).

[9] FINRA Rule 4530 provides an exception for any arbitration claim that is originally filed in the FINRA Dispute Resolution forum and for those documents that have already been requested by FINRA's Registration and Disclosure (RAD) staff, provided that the firm produces those requested documents to RAD staff within 30 days after receipt of such request.

[10] *See* proposed FINRA Rule 4530(g).

[11] *See supra* note 10.

[12] A copy of the proposed online form, including explanations of certain fields on the form, is attached as Exhibit 3. The Commission notes that Exhibit 3 is attached to the filing, not to this Notice.

[13] FINRA is not proposing to require firms that use other permissible electronic means to file the documents with FINRA to provide the summary information, because the functionality to prepopulate the centralized database with such information is limited to online filings.

Exception for FINRA Findings and Actions

FINRA Rule 4530(a)(1)(A) requires a member to report external findings regarding the member or an associated person. FINRA Rules 4530(a)(1)(C) and (D) require a member to report regulatory actions against the member or an associated person. FINRA Rules 4530(a)(1)(A), (C) and (D) do not expressly exclude findings and actions by FINRA. However, since FINRA staff has access to such information through an enterprise-wide solution, FINRA proposes to add Supplementary Material .10 to FINRA Rule 4530 to provide that, for purposes of FINRA Rules 4530(a)(1)(A), (C) and (D) only, members are not required to report findings and actions by FINRA. This exception is, in general, consistent with the exception under FINRA Rule 4530(f) for arbitration claims filed in the FINRA Dispute Resolution forum.

FINRA has filed the proposed rule change for immediate effectiveness. FINRA will announce the implementation date of the proposed rule change in a *Regulatory Notice* to be published no later than 60 days following the date of filing. The implementation date will be no later than 180 days after the date of filing.

2. Statutory Basis

FINRA believes that the proposed rule change is consistent with the provisions of Section 15A(b)(6) of the Act,[14] which requires, among other things, that FINRA rules must be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, and, in general, to protect investors and the public interest. FINRA believes that the proposed rule change will further these purposes by eliminating unnecessary duplicative reporting of information to FINRA and providing firms with the option to file documents required under FINRA Rule 4530 online. FINRA believes that the proposed rule change will serve to reduce potential burdens imposed by the rule without compromising the regulatory information available to FINRA.

B. Self-Regulatory Organization's Statement on Burden on Competition

FINRA does not believe that the proposed rule change will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

The proposed amendment to FINRA Rule 4530(e) to provide an exception for information disclosed on the Form U4 will eliminate the burden on firms of having to report the same event twice. While firms will be required to affirmatively request that the data reported on a Form U4 be applied to satisfy a corresponding FINRA Rule 4530 reporting obligation, FINRA believes any resulting burden will be less than the current burden of separately reporting an event via the FINRA Rule 4530 application. In addition, as noted above, FINRA expects the affirmative designation requirement to facilitate the staff's review process and reduce the need for follow-up communications with firms.

The proposed change to FINRA Rule 4530(g) to provide firms the option of filing required documents online will not impact or burden firms that wish to continue filing the required documents via mail or email. With respect to those firms that choose to file the required documents online, FINRA believes that the burden on them will be negligible for the following reasons. All members have an existing obligation to have online access to FINRA, including a user ID and password, for purposes of other regulatory filings.[15] In addition, with respect to the requirement to attach to the online form a scanned copy of the required documents, FINRA believes that the requirement does not create an unreasonable burden for members given the widespread use of scanning technology, such as PDF. Further, the proposed rule change will require that they provide limited summary information regarding the documents. However, FINRA believes that any administrative burden imposed upon such members by this requirement would be outweighed by the benefit to FINRA's regulatory program in allowing the staff to retrieve and analyze information contained in these submissions from a consolidated source that is prepopulated by the firms' submissions.

Moreover, FINRA does not believe that the proposed change to FINRA Rule 4530(g) places members that cannot submit their documents electronically because they lack scanning technology at a disadvantage to those members that have the capability to do so. As noted above, members that cannot submit their documents electronically can continue to submit their documents via mail without any interruption to their existing processes. In addition, while such members will not have the benefit of tracking their submissions electronically, they can use non-electronic means, such a return receipt, for tracking purposes.

Finally, the addition of Supplementary Material .10 to FINRA Rule 4530 eliminates the burden on firms of having to report findings and actions by FINRA for purposes of FINRA Rules 4530(a)(1)(A), (C) and (D). FINRA staff will continue to have access to such information through an enterprise-wide solution.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A) of the Act[16] and Rule 19b–4(f)(6) thereunder.[17]

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 email to *rule-comments@sec.gov.* Please include File

[14] 15 U.S.C. 78*o*–3(b)(6).

[15] *See, e.g.,* FINRA Rule 1010 (Electronic Filing Requirements for Uniform Forms).

[16] 15 U.S.C. 78s(b)(3)(A).

[17] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. FINRA has satisfied this requirement.

Number SR–FINRA–2013–006 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–FINRA–2013–006. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filing also will be available for inspection and copying at the principal office of FINRA. 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–FINRA–2013–006 and should be submitted on or before February 15, 2013.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[18]

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2013–01495 Filed 1–24–13; 8:45 am]

BILLING CODE 8011–01–P

[18] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–68695; File No. SR–CBOE–2013–004]

Self-Regulatory Organizations; Chicago Board Options Exchange, Incorporated; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend the Fees Schedule

January 18, 2013.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the ''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on January 7, 2013, Chicago Board Options Exchange, Incorporated (the ''Exchange'' or ''CBOE'') filed with the Securities and Exchange Commission (the ''Commission'' or ''SEC'') 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 the Substance of the Proposed Rule Change

The Exchange proposes to amend its Fees Schedule. The text of the proposed rule change is available on the Exchange's Web site (*http://www.cboe.com/AboutCBOE/CBOELegalRegulatoryHome.aspx*), at the Exchange's Office of the Secretary, and at the Commission.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend its Fees Schedule. Specifically, the Exchange proposes to amend its Volume Incentive Program (''VIP''), through which the Exchange credits each Trading Permit Holder (''TPH'') the per contract amount resulting from each public customer (''C'' origin code) order transmitted by that TPH which is executed electronically on the Exchange in all multiply-listed option classes (excluding Qualified Contingent Cross (''QCC'') trades and executions related to contracts that are routed to one or more exchanges in connection with the Options Order Protection and Locked/Crossed Market Plan referenced in Rule 6.80), provided the Trading Permit Holder meets certain volume thresholds in a month. First, the Exchange proposes to change the different fee tier thresholds in the VIP from nominal customer contracts per day thresholds (i.e. contracts 250,001–375,000 customer contracts per day (''CPD'')) to a relative contracts per month threshold structure (i.e. 2.25%–3.50% of total national customer volume in multiply-listed options monthly). Going forward, qualification for the different fee rates at different tiers in the VIP will be based on a TPH's percentage of national customer volume in multiply-listed options monthly, and the heading for the different percentage tiers will be Percentage Thresholds of National Customer Volume in Multiply-Listed Options Classes (Monthly).[3] The purpose of the change to move away from basing the fee tiers on a TPH's nominal customer contracts per day to a TPH's relative contracts per month (as a percentage of total national customer volume in multiply-listed options) is to control and account for changes in national industry-wide customer multiply-listed options volume. Corresponding to this change, the Exchange also proposes to amend the section of the ''Notes'' on the VIP table to state that, in the event of a CBOE System outage or other interruption of electronic trading on CBOE, the Exchange will adjust the national customer volume in multiply-listed options for the duration of the outage.[4]

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] The Exchange uses contract sides, rather than contracts, to calculate the denominator for the percentage of national customer volume. *See* email from Jeff Dritz, Assistant Secretary, CBOE, to Richard Holley, Assistant Director, SEC Division of Trading and Markets, Office of Market Supervision, dated January 11, 2013.

[4] Currently, the relevant passage states that ''In the event of a CBOE System outage or other interruption of electronic trading on CBOE, the Exchange will take into account, on a pro rata basis, the length of time of the interruption for purposes of calculating the contracts per day.'' However, this accounting (which is currently relevant as CBOE is measuring qualification for the VIP on a nominal customer contracts per day basis) will no longer be relevant under the proposed relative contracts per month VIP qualification structure.

This means that, in the event of a CBOE System outage or other interruption of electronic trading on CBOE, any national customer trading in multiply-listed options during the outage will not be counted towards the establishment of a TPH's VIP threshold.

The Exchange also proposes to change the amounts of the credits in the second and fourth tiers of the VIP. The credit in the second tier will be increased from $0.05 per contract to $0.07 per contract, and the credit in the fourth tier will be decreased from $0.20 per contract to $0.18 per contract. Going forward, the relative (percentage) volume thresholds and credit amounts will be as follows:

Percentage thresholds of national customer volume in multiply-listed options classes (monthly)	Per contract credit
0%–0.75%	$0.00
Above 0.75%–2.25%	0.07
Above 2.25%–3.50%	0.12
Above 3.50%–5.00%	0.18
Above 5.00%	0.05

The purpose of increasing the credit in the second tier and decreasing the credit in the fourth tier by $0.02 each is to rationalize the opportunity to receive a credit under the VIP across a broader set of participants. Lowering the credit in the fourth tier allows the Exchange to make up for increasing the credit in the second tier.

The Exchange also proposes to add to the notes on the VIP table an additional credit of $0.10 per contract, on top of other VIP credits, at every tier, for the electronic execution of each leg of a customer complex order in multiply-listed options (the ''Customer Complex Credit''). The purpose of the proposed Customer Complex Credit is to respond to competitive pricing schedules of other exchanges that specifically attempt to attract customer complex order flow through increased rebates for electronic complex customer orders.[5]

The Exchange also proposes to assess an additional surcharge of $0.10 per contract, on top of regular transaction fees, for the electronic execution of each leg of a complex order in multiply-listed options that executes against a customer complex order (the ''Surcharge''). The Surcharge applies to all market participants except customers. This Surcharge will not be assessed to individual leg markets that execute against a customer complex order. The Surcharge will be described in proposed new footnote 30 to the Fees Schedule. The purpose of the Surcharge is to offset the additional payments that will be required by the Customer Complex Credit.

2. Statutory Basis

The Exchange believes the proposed rule change is consistent with the Act and the rules and regulations thereunder applicable to the Exchange and, in particular, the requirements of Section 6(b) of the Act.[6] Specifically, the Exchange believes the proposed rule change is consistent with Section 6(b)(4) of the Act,[7] which provides that Exchange rules may provide for the equitable allocation of reasonable dues, fees, and other charges among its Trading Permit Holders and other persons using its facilities. The Exchange believes that converting the qualification for the different fee tiers in the VIP from measuring by a TPH's nominal contracts per day to measuring by the TPH's relative contracts per month (based on the percentage of national customer volume in multiply-listed options that the TPH electronically executes) is reasonable because it allows the Exchange to control and account for changes in national industry-wide customer multiply-listed options volume. Further, it will still allow TPHs to receive a credit for electronically executing customer orders in multiply-listed options, just as prior to this change. The Exchange believes that the change is equitable and not unfairly discriminatory because it will be applied to all TPHs, who, like before, will be eligible to receive credits for electronically executing customer orders in multiply-listed options. The change merely switches out the measuring stick to use one that accounts for changes in industry-wide volume.

The Exchange believes that the proposed changes to increase the credit in the second tier of the VIP and decrease the credit in the fourth tier by $0.02 each are reasonable. In the case of the increase in the credit for the second tier, the change will allow TPHs who reach the percentage threshold in that tier to receive an increased credit for doing so. In the case of the decrease in the credit for the fourth tier, the change will still allow TPHs who reach the percentage threshold in that tier to receive a credit (the highest credit of any tier). These changes are equitable and not unfairly discriminatory because they will be applied to all TPHs. Moreover, the purpose of these proposed changes is to encourage the sending and electronic execution of customer multiply-listed options volume to the Exchange. This increased volume creates greater trading opportunities that benefit all market participants (including TPHs that do not reach the higher-credit tiers in the VIP). Further, the increased volume and improved trading opportunities will provide such TPHs with a better opportunity to reach the higher-credit tiers in the VIP.

The Exchange believes that the proposed Customer Complex Credit is reasonable because it will allow customers who electronically execute complex orders in multiply-listed options to receive an extra $0.10 credit for doing so. Limiting the Customer Complex Credit to customers is equitable and not unfairly discriminatory because other market participants generally prefer to execute their orders against customer orders, and the Customer Complex Credit is designed to encourage the sending and electronic execution of customer complex orders to the Exchange, which will provide other market participants with more opportunities to achieve these preferred executions. Further, while only customer order flow qualifies for the proposed Customer Complex Credit Program, an increase in customer order flow will bring greater volume and liquidity, which benefit all market participants by providing more trading opportunities and tighter spreads. Limiting the Customer Complex Credit to multiply-listed options is equitable and not unfairly discriminatory because the Exchange has devoted a lot of resources to develop its proprietary singly-listed options classes, and therefore needs to retain funds collected in order to recoup those expenditures.

The Exchange also proposes limiting the Customer Complex Credit to electronic orders because the vast majority of TPHs that transmit customer orders in multiply-listed options to the Exchange do so electronically. The Exchange believes that it is reasonable to offer a rebate only for order entered electronically in an attempt to attract greater electronic business and compete with other exchanges for such business. Moreover, the competitive pressures from other exchanges in electronic orders and different business model for electronic orders as opposed to open outcry orders leads the Exchange to offer a rebate in order to compete with other exchanges for electronic orders. The business models surrounding electronic orders and open outcry orders are different, and as such, the Exchange

[5] *See* Section II of the Schedule of Fees of the International Securities Exchange, LLC (''ISE''), which shows significant rebates for Priority Customers executing complex orders (compare with Section I, which shows non-complex order fees). The ISE is an all-electronic options exchange.

[6] 15 U.S.C. 78f(b).

[7] 15 U.S.C. 78f(b)(4).

offers different incentives to encourage the entry of electronic and open outcry orders. The Exchange also believes that paying a different credit for electronic orders than it does for open outcry orders is equitable and not unfairly discriminatory because other exchanges distinguish between delivery methods for certain market participants and pay different rebates depending on the method of delivery. This type of distinction is not novel and has long existed within the industry. Further, the Exchange believes that the offering of the Customer Complex Credit will cause an increase in volume. The Exchange has expended considerable resources to develop its electronic trading platforms and seeks to recoup the costs of such expenditures through the receipt of the fees associated with such increased volume.

The Exchange believes that the Surcharge is reasonable because it is necessary to offset the payments that will be made by the Exchange under the Customer Complex Credit. Further, other exchanges assess higher fees for complex orders than for non-complex ones.[8] Applying the Surcharge to all market participants except customers is equitable and not unfairly discriminatory because other market participants generally prefer to execute their orders against customer orders. By exempting customer orders, the Surcharge will not discourage the sending of customer orders, and therefore there should still be plenty of customer orders for other market participants to trade with. Further, the options industry has a long-standing practice of assessing preferable fee structures to customers. Moreover, assessing the Surcharge only to complex orders that execute against customer orders is equitable and not unfairly discriminatory because, as stated above, other market participants generally prefer to execute their orders against customer orders, and therefore it is justifiable for them to be assessed a premium for such preferable executions.

Limiting the Surcharge to multiply-listed options is equitable and not unfairly discriminatory because the Exchange has devoted a lot of resources to develop its proprietary singly-listed options classes, and therefore does not desire to risk discouraging the trading of such proprietary singly-listed options classes. The Exchange needs to retain funds collected from fees from proprietary singly-listed options transactions in order to recoup the expenditures associated with developing such products.

Limiting the Surcharge to orders entered electronically is equitable and not unfairly discriminatory because the competitive pressures from other exchanges in electronic orders and different business model for electronic orders as opposed to open outcry orders leads the Exchange to sometimes offer a different fee structure in order to compete with other exchanges for electronic orders. The business models surrounding electronic orders and open outcry orders are different, and as such, the Exchange offers different incentives to encourage the entry of electronic and open outcry orders. Other exchanges distinguish between delivery methods for certain market participants and pay different rebates depending on the method of delivery. This type of distinction is not novel and has long existed within the industry. The Exchange also believes that assessing different fees and rebates for electronic orders than it does for open outcry orders is equitable and not unfairly discriminatory because the Exchange has expended considerable resources to develop its electronic trading platforms and seeks to recoup the costs of such expenditures.

B. Self-Regulatory Organization's Statement on Burden on Competition

CBOE does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The Exchange does not believe that the proposed conversion of the VIP thresholds to relative (as opposed to nominal) thresholds and the changes to the per-contract credit amounts in the second and fourth tiers of the VIP will impose an unnecessary burden on intramarket competition because the changes will apply to all CBOE TPHs (as the VIP will still and did previously apply to all CBOE TPHs). The Exchange also does not believe that such changes will impose any burden on intermarket competition that is not necessary or appropriate in furtherance of the purposes of the Act. To the extent that some of the changes to the VIP may attract greater trading volume to CBOE (and away from other exchanges), the Exchange notes that market participants trading on other exchanges can always elect to become TPHs on CBOE. Further, the Exchange exists in a competitive marketplace, and to the extent that these proposed changes make other exchanges less competitive with CBOE, market participants trading on those other exchanges can elect to trade on CBOE.

CBOE does not believe that the adoption of the Customer Complex Credit will impose any burden on intramarket competition that is not necessary or appropriate in furtherance of the purposes of the Act. While the Customer Complex Credit only applies to customers, other market participants generally prefer to execute their orders against customer orders, and the Customer Complex Credit is designed to encourage the sending and electronic execution of customer complex orders to the Exchange, which will provide other market participants with more opportunities to achieve these preferred executions. Further, while only customer order flow qualifies for the proposed Customer Complex Credit Program, an increase in customer order flow will bring greater volume and liquidity, which benefit all market participants by providing more trading opportunities and tighter spreads. Therefore, any potential effects that the adoption of the Customer Complex Credit may have on intramarket competition are justifiable due to the reasons stated above. The Exchange does not believe that the adoption of the Customer Complex Credit will impose any burden on intermarket competition that is not necessary or appropriate in furtherance of the purposes of the Act. The Exchange believes that the Customer Complex Credit will increase competition with other exchanges, as the purpose of the proposed Customer Complex Credit is to respond to competitive pricing schedules of other exchanges that specifically attempt to attract customer complex order flow through increased rebates for electronic complex customer orders.[9] To the extent that the adoption of Customer Complex Credit may result in increased trading volume on CBOE and lessened volume on these other exchanges, the Exchange notes that market participants trading on other exchanges can always elect to become TPHs on CBOE. Further, the Exchange exists in a competitive marketplace, and to the extent that these proposed changes make other exchanges less competitive with CBOE, market participants trading on those other exchanges can elect to trade on CBOE.

The Exchange does not believe that the adoption of the Surcharge will impose any burden on intramarket

[8] *See* ISE Schedule of Fees, Section I (which lists regular Maker rebates and fees and Taker fees for Select Symbols) as compared to Section II (which lists complex order fees and rebates for Select Symbols). Market participants are assessed higher fees for executing complex orders, and specifically and especially for executions in complex orders that execute against Priority Customer orders.

[9] *See* Section II of the Schedule of Fees of the ISE, which shows significant rebates for Priority Customers executing complex orders (compare with Section I, which shows non-complex order fees). The ISE is an all-electronic options exchange.

competition that is not necessary or appropriate in furtherance of the purposes of the Act. While it does apply to all market participants except for customers, other market participants generally prefer to execute their orders against customer orders. By exempting customer orders, the Surcharge will not discourage the sending of customer orders, and therefore there should still be plenty of customer orders for other market participants to trade with. Therefore, any potential effects that the adoption of the Surcharge may have on intramarket competition are justifiable. Further, the options industry has a long-standing practice of assessing preferable fee structures to customers. The Exchange does not believe that the adoption of the Surcharge will impose any burden on intramarket [sic] competition that is not necessary or appropriate in furtherance of the purposes of the Act. The imposition of the Surcharge (which is important to offset the costs of the Customer Complex Credit) should not, by itself, attract trading volume from other exchanges (as it requires payment of a surcharge for an activity that did not previously require such payment). Further, other exchanges assess higher fees for complex orders than for non-complex ones.[10]

The Exchange also notes that it operates in a highly-competitive market in which market participants can readily direct order flow to competing venues if they deem fee levels at a particular venue to be excessive. The proposed rule change reflects a competitive pricing structure designed to incent market participants to direct their order flow to the Exchange, and the Exchange believes that such structure will help the Exchange remain competitive with those fees and rebates assessed by other venues.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange neither solicited nor received comments on the proposed rule change.

[10] *See* ISE Schedule of Fees, Section I (which lists regular Maker rebates and fees and Taker fees for Select Symbols) as compared to Section II (which lists complex order fees and rebates for Select Symbols). Market participants are assessed higher fees for executing complex orders, and specifically and especially for executions in complex orders that execute against Priority Customer orders.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A) of the Act [11] and paragraph (f) of Rule 19b–4 [12] thereunder. At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–CBOE–2013–004 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–CBOE–2013–004. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filing also will be available for inspection and copying at the principal 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–CBOE–2013–004, and should be submitted on or before February 15, 2013.

[11] 15 U.S.C. 78s(b)(3)(A).

[12] 17 CFR 240.19b–4(f).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[13]

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2013–01489 Filed 1–24–13; 8:45 am]

BILLING CODE 8011–01–P

[13] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–68699; File No. SR–CBOE–2013–003]

Self-Regulatory Organizations; Chicago Board Options Exchange, Incorporated; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend the Fees Schedule

January 18, 2013.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the ''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on January 7, 2013, Chicago Board Options Exchange, Incorporated (the ''Exchange'' or ''CBOE'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of the Substance of the Proposed Rule Change

The Exchange proposes to amend its Fees Schedule. The text of the proposed rule change is available on the Exchange's Web site (*http://www.cboe.com/AboutCBOE/CBOELegalRegulatoryHome.aspx*), at the Exchange's Office of the Secretary, and at the Commission.

[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, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend its Fees Schedule. Specifically, the Exchange proposes to adopt a new Clearing Trading Permit Holder Proprietary VIX Options Sliding Scale (the ''VIX Options Sliding Scale''). The VIX Options Sliding Scale allows VIX volatility index options (''VIX options'') transaction fees for Clearing Trading Permit Holder (including its Non-Trading Permit Holder affiliates) proprietary orders to be reduced provided a Clearing Trading Permit Holder (including its Non-Trading Permit Holder affiliates) reaches certain proprietary VIX options volume thresholds during a month. The proposed applicable transaction fees for the different volume tiers on the VIX Options Sliding Scale are as follows:

Tier	VIX Options contracts per month	Transaction fee per contract
1	Contracts 1–250,000	$0.25
2	Contracts 250,001–500,000	0.15
3	Contracts 500,001–750,000	0.10
4	Contracts 750,000+	0.05

The VIX Options Sliding Scale applies to orders bearing the origin codes ''F'' [3] and ''L'' [4]. The purpose of the VIX Options Sliding Scale is to encourage greater Clearing Trading Permit Holder proprietary trading of VIX options.

In conjunction with the adoption of the VIX Options Sliding Scale, the Exchange proposes to amend footnote 11 to its Fees Schedule. Footnote 11 provides the details regarding the Clearing Trading Permit Holder Fee Cap in all products except SPX, SRO, VIX or other volatility indexes, OEX or XEO and the CBOE Proprietary Products Sliding Scale for Clearing Trading Permit Holder Proprietary Orders, both of which apply to Clearing Trading Permit Holder proprietary orders. Because the VIX Options Sliding Scale also applies to Clearing Trading Permit Holder proprietary orders, and because many of the details regarding the Clearing Trading Permit Holder Fee Cap in all products except SPX, SRO, VIX or other volatility indexes, OEX or XEO and the CBOE Proprietary Products Sliding Scale for Clearing Trading Permit Holder Proprietary Orders will also apply to the VIX Options Sliding Scale, the Exchange proposes to add the details regarding the VIX Options Sliding Scale into footnote 11.

First, footnote 11 describes the Clearing Trading Permit Holder Fee Cap in all products except SPX, SRO, VIX or other volatility indexes, OEX or XEO as the ''fee cap'' and the CBOE Proprietary Products Sliding Scale for Clearing Trading Permit Holder Proprietary Orders as the ''sliding scale''. In order to avoid confusion that could arise due to the addition of the VIX Options Sliding Scale, the Exchange proposes to define the Clearing Trading Permit Holder Fee Cap in all products except SPX, SRO, VIX or other volatility indexes, OEX or XEO as the ''Fee Cap'' and the CBOE Proprietary Products Sliding Scale for Clearing Trading Permit Holder Proprietary Orders as the ''Sliding Scale''. Any references within footnote 11 to the ''fee cap'' will now be referred to as the ''Fee Cap'' and any references within footnote 11 to the ''sliding scale'' will now be referred to as the ''Sliding Scale''. The Clearing Trading Permit Holder Proprietary VIX Options Sliding Scale is also defined within footnote 11 as the ''VIX Options Sliding Scale'' and any references to the Clearing Trading Permit Holder Proprietary VIX Options Sliding Scale within footnote 11 are referred to as the ''VIX Options Sliding Scale.''

Like the Fee Cap and the Sliding Scale, the VIX Options Sliding Scale will apply to (i) Clearing Trading Permit Holder proprietary orders (''F'' origin code), and (ii) orders of Non-Trading Permit Holder Affiliates of a Clearing Trading Permit Holder. A ''Non-Trading Permit Holder Affiliate'' would be defined for the purposes of the VIX Options Sliding Scale the same way it is defined for the Fee Cap and Sliding Scale: A 100% wholly-owned affiliate or subsidiary of a Clearing Trading Permit Holder that is registered as a United States or foreign broker-dealer and that is not a CBOE Trading Permit Holder (''TPH''). As with the Fee Cap and the Sliding Scale, only proprietary orders of the Non-Trading Permit Holder Affiliate (currently, the Fees Schedule reads that such orders have a ''B'' origin code, but such orders actually have an ''L'' origin code, so the Exchange also proposes to correct this error) effected for purposes of hedging the proprietary over-the-counter trading of the Clearing Trading Permit Holder or its affiliates will be included in calculating the VIX Options Sliding Scale, and such orders must be marked with a code approved by the Exchange identifying the orders as eligible for the VIX Options Sliding Scale. As with the Fee Cap and the Sliding Scale, each Clearing Trading Permit Holder is responsible for notifying the TPH Department of all of its affiliations so that fees and contracts of the Clearing Trading Permit Holder and its affiliates may be aggregated for purposes of the VIX Options Sliding Scale and is required to certify the affiliate status of any Non-Trading Permit Holder Affiliate whose trading activity it seeks to aggregate. In addition, each Clearing Trading Permit Holder is required to inform the Exchange immediately of any event that causes an entity to cease to be an affiliate.

As with the Fee Cap and the Sliding Scale, the Exchange will aggregate the

[3] The ''F'' origin code is used for OCC clearing member firm proprietary account orders.

[4] The ''L'' origin code is used for orders for the account of Non-Trading Permit Holder Affiliates effected for the purpose of hedging the proprietary over-the-counter trading of the Clearing Trading Permit Holder or its affiliates to be aggregated with the trading activity of the Clearing Trading Permit Holder for purposes of the Multiply-Listed Options Fee Cap and CBOE Proprietary Products Sliding Scale for Clearing Trading permit Holder proprietary orders; a ''Non-Trading Permit Holder Affiliate'' is defined as a 100% wholly-owned affiliate or subsidiary of a Clearing Trading Permit Holder that is (i) registered as United States or foreign broker/dealer and (ii) is not itself a CBOE Trading Permit Holder.

fees and trading activity of separate Clearing Trading Permit Holders for the purposes of the VIX Options Sliding Scale if there is at least 75% common ownership between the Clearing Trading Permit Holders as reflected on each Clearing Trading Permit Holder's Form BD, Schedule A. As with the Fee Cap and the Sliding Scale, a Clearing Trading Permit Holder's fees and contracts executed pursuant to a CMTA agreement (i.e., executed by another clearing firm and then transferred to the Clearing Trading Permit Holder's account at the OCC) are aggregated with the Clearing Trading Permit Holder's non-CMTA fees and contracts for purposes of the VIX Options Sliding Scale.

For calculating a Clearing Trading Permit Holder's total proprietary product transaction fees, CBOE will use the following methodology: If using the VIX Options Sliding Scale plus the Sliding Scale (minus VIX options volume) results in lower total Clearing Trading Permit Holder proprietary transaction fees than just using the Sliding Scale, CBOE will apply the new VIX Options Sliding Scale plus the Sliding Scale, and deduct the VIX options volume from the Sliding Scale. If using the VIX options Sliding Scale plus the Sliding Scale (minus VIX options volume) results in higher total Clearing Trading Permit Holder proprietary transaction fees than just using the Sliding Scale, CBOE will apply only the Sliding Scale. The purpose of this methodology is to provide a Clearing Trading Permit Holder with the most beneficial fee arrangement (the lowest fees) without double-counting VIX options volume.

For example, consider a situation in which, in a month, a Clearing Trading Permit Holder has qualifying proprietary multiply-listed options volume of 450,000 contracts, qualifying proprietary VIX options volume of 850,000 contracts, and qualifying volume of other proprietary products of 500,000 contracts (totaling 1,350,000 contracts of proprietary products). Under the Sliding Scale, because the Clearing Trading Permit Holder has executed greater than (or equal to) 375,000 contracts of multiply-listed options volume but less than 1,500,000 such contracts, the Clearing Trading Permit Holder will be assessed an $0.18-per-contract fee on the first 750,000 proprietary products contracts (totaling $135,000), a $0.05-per-contract fee on the next 250,000 proprietary products contracts (totaling $12,500), and a $0.02-per-contract fee on the remaining 350,000 proprietary products (totaling $7,000). Therefore, under the Sliding Scale, the Clearing Trading Permit Holder's proprietary transaction fees would be $154,500 ($135,000 + $12,500 + $7,000).

We would then determine the Clearing Trading Permit Holder's fees using the VIX Options Sliding Scale plus the Sliding Scale (minus VIX options volume). Under the VIX Options Sliding Scale, because the Clearing Trading Permit Holder executed 850,000 VIX contracts, the Clearing Trading Permit Holder would be assessed a $0.25-per-contract fee for contracts 1–250,000 (totaling $62,500), a $0.15-per-contract fee for contracts 250,001–500,000 (totaling $37,500), a $0.10-per-contract fee for contracts 500,001–750,000 (totaling $25,000), and a $0.05-per-contract fee for contracts 750,001–850,000 ($5,000). Therefore, under the VIX Options Sliding Scale, the Clearing Trading Permit Holder's proprietary transaction fees are $130,000 ($62,500 + $37,500 + $25,000 + $5,000). To this we would add the Clearing Trading Permit Holder's proprietary fees using the Sliding Scale (subtracting out the VIX options volume). Under the Sliding Scale, because the Clearing Trading Permit Holder has executed greater than (or equal to) 375,000 contracts of multiply-listed options volume but less than 1,500,000 such contracts, the Clearing Trading Permit Holder will be assessed an $0.18-per-contract fee on the 500,000 non-VIX options proprietary product contracts, which comes out to $90,000. If we add the Clearing Trading Permit Holder's fees under the VIX Options Sliding Scale ($130,000) to fees using the Sliding Scale (minus VIX options volume) ($90,000), the Clearing Trading Permit Holder's total proprietary fees come out to $220,000. Because this amount is greater than the Clearing Trading Permit Holder's fees using just the Sliding Scale (including the VIX options volume) of $154,500, the Exchange would just apply the Sliding Scale to determine the Clearing Trading Permit Holder's proprietary fees, and assess the lower fee of $154,500.

2. Statutory Basis

The Exchange believes the proposed rule change is consistent with the Act and the rules and regulations thereunder applicable to the Exchange and, in particular, the requirements of Section 6(b) of the Act.[5] Specifically, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)[6] requirements that the rules of an exchange be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitation transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest. Additionally, the Exchange believes the proposed rule change is consistent with Section 6(b)(4) of the Act,[7] which provides that Exchange rules may provide for the equitable allocation of reasonable dues, fees, and other charges among its Trading Permit Holders and other persons using its facilities.

The adoption of the VIX Options Sliding Scale is reasonable because it will allow Clearing Trading Permit Holders who engage in VIX options trading the opportunity to pay lower fees for such transactions. Similarly, aggregating the fees and trading activity of separate Clearing Trading Permit Holders for the purposes of the VIX Options Sliding Scale if there is at least 75% common ownership between the Clearing Trading Permit Holders and aggregating a Clearing Trading Permit Holder's fees and contracts executed pursuant to a CMTA agreement with the Clearing Trading Permit Holder's non-CMTA fees and contracts for the purpose of the VIX Options Sliding Scale is reasonable because this will allow more Clearing Trading Permit Holders to qualify for the lowered fees at the higher volume tiers in the VIX Options Sliding Scale.

The proposed methodology to be used in calculating a Clearing Trading Permit Holder's total proprietary product transaction fees is reasonable because it provides Clearing Trading Permit Holders who engage in VIX options trading with a second way to maximize their ability to limit their proprietary products transaction fees. Subtracting VIX options volume from the Sliding Scale when taking into account the VIX Options Sliding Scale to calculate proprietary product transaction fees is reasonable because it would be illogical (and not financially viable) to count VIX options volume twice (once in the VIX Options Sliding Scale and once in the Sliding Scale) to allow a Clearing Trading Permit Holder to qualify for a lowered fee rate when the VIX options transactions (and volume such transactions created) only occurred once and fees were therefore only assessed on such transactions once.

[5] 15 U.S.C. 78f(b).

[6] 15 U.S.C. 78f(b)(5).

[7] 15 U.S.C. 78f(b)(4).

Applying the VIX Options Sliding Scale to Clearing Trading Permit Holder (and their affiliates, in the manner described above) proprietary orders only is equitable and not unfairly discriminatory because Clearing Trading Permit Holders take on a number of obligations and responsibilities (such as membership with the Options Clearing Corporation), significant regulatory burdens, and financial obligations that other market participants are not required to undertake. Further, the VIX Options Sliding Scale is designed to encourage increased Clearing Trading Permit Holder proprietary VIX options volume, which provides increased VIX options volume and greater trading opportunities for all market participants. Similarly, applying lower fee rates for Clearing Trading Permit Holders who hit the higher VIX options contract volume tiers on the VIX Options Sliding Scale is equitable and not unfairly discriminatory because this is designed to encourage increased Clearing Trading Permit Holder proprietary VIX options volume, which provides increased VIX options volume and greater trading opportunities for all Clearing Trading Permit Holders, including those who are not able to reach the higher-volume tiers. Indeed, this increased VIX options volume and greater trading opportunities may provide such Clearing Trading Permit Holders to reach the higher tiers (and pay the lower fees such tiers entail). Moreover, the Exchange already offers other fee-lowering programs (such as the Fee Cap and Sliding Scale) which entail lower fees for Clearing Trading Permit Holders (and their affiliates, in the manner described above) and are limited to Clearing Trading Permit Holders (and their affiliates, in the manner described above).

Applying the VIX Options Sliding Scale to VIX options and not to other products is equitable and not unfairly discriminatory because the Exchange has expended considerable time and resources in developing VIX options. The VIX Options Sliding Scale is designed to encourage greater VIX options trading, which, along with bringing greater VIX options trading opportunities to all market participants, will bring in more fees to the Exchange, and such fees can be used to recoup the Exchange's costs and expenditures from developing VIX options.

The Exchange proposes to define the Fee Cap, Sliding Scale, and VIX Options Sliding Scale in footnote 11 of the Fees Schedule in order to avoid any potential confusion by investors reading the Fees Schedule. Similarly, the Exchange proposes to correct, in footnote 11, the erroneous reference to the origin code for proprietary orders of the Non-Trading Permit Holder Affiliate effected for purposes of hedging the proprietary over-the-counter trading of the Clearing Trading Permit Holder or its affiliates (changing such reference from the origin code ''B'' to the correct origin code for such orders, ''L'') in order to avoid any potential confusion by investors reading the Fees Schedule. This avoidance of confusion removes impediments to and perfects the mechanism of a free and open market and a national market system, and, in general, protects investors and the public interest.

B. Self-Regulatory Organization's Statement on Burden on Competition

CBOE does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The Exchange believes that the adoption of the proposed VIX Options Sliding Scale will not impose any unnecessary burden on intramarket competition because, while it applies only to Clearing Trading Permit Holder proprietary orders, Clearing Trading Permit Holders take on a number of obligations and responsibilities (such as membership with the Options Clearing Corporation), significant regulatory burdens, and financial obligations that other market participants are not required to undertake. Further, the VIX Options Sliding Scale is designed to encourage increased Clearing Trading Permit Holder proprietary VIX options volume, which provides increased VIX options volume and greater trading opportunities for all market participants. Therefore, the Exchange believes that any potential effects on intramarket competition that the adoption of the proposed VIX Options Sliding Scale may cause are therefore justifiable. Moreover, the Exchange already offers other fee-lowering programs (such as the Fee Cap and Sliding Scale) which entail lower fees for Clearing Trading Permit Holders (and their affiliates, in the manner described above) and are limited to Clearing Trading Permit Holders (and their affiliates, in the manner described above). The Exchange does not believe that the adoption of the proposed VIX Options Sliding Scale will cause any unnecessary burden on intermarket competition because VIX options is a proprietary product that is traded solely on CBOE.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange neither solicited nor received comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A) of the Act [8] and paragraph (f) of Rule 19b–4 [9] thereunder. At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml);* or

- Send an email to *rule-comments@sec.gov.* Please include File Number SR–CBOE–2013–003 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.

All submissions should refer to File Number SR–CBOE–2013–003. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml).* Copies of the 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

[8] 15 U.S.C. 78s(b)(3)(A).

[9] 17 CFR 240.19b–4(f).

those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filing also will be available for inspection and copying at the principal 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–CBOE–2013–003 and should be submitted on or before February 15, 2013.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[10]

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2013–01493 Filed 1–24–13; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–68700; File No. SR–FINRA–2013–002]

Self-Regulatory Organizations; Financial Industry Regulatory Authority, Inc.; Notice of Filing of Proposed Rule Change To Amend FINRA Rule 2267 (Investor Education and Protection)

January 18, 2013.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'')[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on January 7, 2013, Financial Industry Regulatory Authority, Inc. (''FINRA'') 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 FINRA. 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

FINRA is proposing to amend FINRA Rule 2267 (Investor Education and Protection) to require that members include a prominent description of and link to FINRA BrokerCheck, as prescribed by FINRA, on their Web sites, social media pages and any comparable Internet presence and on Web sites, social media pages and any comparable Internet presence relating to a member's investment banking or securities business maintained by or on behalf of any person associated with a member.

The text of the proposed rule change is available on FINRA's Web site at *http://www.finra.org,* at the principal office of FINRA 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, FINRA 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. FINRA 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

FINRA established BrokerCheck in 1988 (then known as the Public Disclosure Program) to provide the public with information on the professional background, business practices, and conduct of FINRA-member firms and their associated persons. The information that FINRA releases to the public through BrokerCheck is derived from the Central Registration Depository (''CRD®''), the securities industry online registration and licensing database. FINRA-member firms, their associated persons and regulators report information to the CRD system via the uniform registration forms. By making most of this information publicly available, BrokerCheck, among other things, helps investors make informed choices about the individuals and firms with which they conduct business.

In January 2011, Commission staff released its *Study and Recommendations on Improved Investor Access to Registration Information About Investment Advisers and Broker-Dealers* (''Study''),[3] in furtherance of Section 919B of the Dodd-Frank Act. The Study contains four recommendations for improving investor access to registration information through BrokerCheck and the Commission's Investment Adviser Public Disclosure (''IAPD'') database. In May 2012, FINRA implemented the Study's three ''near-term'' recommendations.[4] FINRA is currently working on the Study's ''intermediate-term'' recommendation, which involves analyzing the feasibility and advisability of expanding the information available through BrokerCheck, as well as the method and format that BrokerCheck information is displayed.

In light of the Study's ''intermediate-term'' recommendation and FINRA's belief that regular evaluation of its BrokerCheck program is an important part of its statutory obligation to make information available to the public,[5] FINRA has initiated a thorough review of BrokerCheck. As part of this review, FINRA issued *Regulatory Notice* 12–10 requesting comment on ways to facilitate and increase investor use of BrokerCheck information. In addition, FINRA engaged a market research consultant that conducted focus groups and surveyed investors throughout the country to obtain their opinions on the BrokerCheck program.

Participants in the focus groups were asked questions about a variety of topics, including the financial markets, working with a broker or investment adviser, and the BrokerCheck program. Many of the participants stated that they had been unaware of the existence of BrokerCheck prior to their participation in the focus groups.[6] After learning about BrokerCheck, the consensus among focus group participants was that investors should use BrokerCheck when considering whether to work with a new investment professional or firm and that it therefore was important for BrokerCheck to be more widely known among investors. Based on the focus group results and the comments received in response to *Regulatory*

[10] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] The Study is available online at *http://www.sec.gov/news/studies/2011/919bstudy.pdf.*

[4] These recommendations are to unify search returns for BrokerCheck and IAPD, add the ability to search BrokerCheck by ZIP code, and increase the educational content on BrokerCheck.

[5] *See* Section 15A(i) of the Act. 15 U.S.C. 78*o*–3(i). Since establishing BrokerCheck, FINRA has regularly assessed the scope and utility of the information it provides to the public and, as a result, has made numerous changes to improve the program.

[6] This is consistent with a 2009 study that found that only 15 percent of respondents said that they had checked a financial advisor's background with a state or federal regulator. *See Financial Capability in the United States* (FINRA Investor Education Foundation, Dec. 1, 2009), available at *http://www.finrafoundation.org/web/groups/foundation/@foundation/documents/foundation/p120536.pdf.*

Notice 12–10, FINRA is proposing to amend Rule 2267.[7]

Subject to limited exceptions, FINRA Rule 2267(a) currently requires members to annually provide in writing to each of their customers the BrokerCheck hotline number, the FINRA Web site address, and a notification of the availability of an investor brochure that includes information describing BrokerCheck.[8] To further increase investor awareness and use of BrokerCheck, the proposed rule change would amend Rule 2267 to require all members to include a prominent description of and link to BrokerCheck, as prescribed by FINRA, on their Web sites, social media pages and any comparable Internet presence, as well as on the Web sites, social media pages and any comparable Internet presence relating to the firm's investment banking or securities business maintained by or on behalf of any person associated with a member.

To ensure consistency and help with the implementation of the proposed rule change, FINRA would provide members with the text description and web address format for the link to BrokerCheck. The web address provided by FINRA, which would include a firm's or individual's CRD number, would be specific to each member or associated person. The link would take the user to BrokerCheck's search results screen for the subject firm or individual, which displays basic information, such as CRD number, SEC number (for firms), registration status, and employing firm (for individuals). Once the investor completes the challenge-response test (used to make it more difficult for an automated application to collect BrokerCheck information) and agrees to BrokerCheck's terms and conditions, the investor will be able to obtain a detailed BrokerCheck report on the subject firm or individual.

FINRA believes that the proposed change will increase investor use of BrokerCheck because the link provided on a firm's or individual's Web site will take investors to that firm's or individual's specific BrokerCheck search results screen rather than the BrokerCheck homepage. Thus, investors will not be required to enter the name of the firm or individual they are searching for or to select the correct broker or firm from the search results.

To further help with implementation of the proposed rule change, FINRA will provide in the *Regulatory Notice* announcing the effective date of the proposed rule change guidance regarding the prominence and placement of the BrokerCheck description and link.

FINRA will announce the effective date of the proposed rule change in a *Regulatory Notice* to be published no later than 60 days following Commission approval. The effective date will be no later than 180 days following publication of the *Regulatory Notice* announcing Commission approval.

2. Statutory Basis

FINRA believes that the proposed rule change is consistent with the provisions of Section 15A(b)(6) of the Act,[9] which requires, among other things, that FINRA rules must be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, and, in general, to protect investors and the public interest. FINRA believes that the proposed rule change would increase investor awareness and use of BrokerCheck, thereby helping investors make informed choices about the individuals and firms with which they conduct business. Specifically, FINRA believes that the proposed description of BrokerCheck will alert investors to the existence of the program and the link to the subject firm or individual will make BrokerCheck even easier to use as a research tool.

B. Self-Regulatory Organization's Statement on Burden on Competition

FINRA does not believe that the proposed rule change will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

FINRA believes that the proposed rule change will enhance investor protection by increasing the public's awareness and use of BrokerCheck. FINRA expects that the inclusion of a prominent description of BrokerCheck on a firm's or associated person's Web site will increase the public's awareness of the program by alerting investors to the existence of BrokerCheck while they are researching a firm or broker. FINRA believes that the proposal will not result in a significant burden on members or associated persons. In this regard, although FINRA has not found any independent estimates relating to the cost of adding a link to a Web site, FINRA anticipates that the costs to comply with the proposed rule change to members and associated persons will be limited, particularly for those firms that will make the changes with a content management system,[10] and will not significantly burden small firms. In addition, FINRA will provide firms with the specific links (in a user-friendly URL format) to be added to their Web sites, thereby helping to contain the costs associated with the proposal.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The proposed rule change was published for comment by FINRA in *Regulatory Notice* 12–10 (February 2012). A copy of the *Regulatory Notice* is attached as Exhibit 2a.[11] The comment period expired on April 27, 2012. FINRA received 71 comment letters in response to the *Regulatory Notice.* A list of the comment letters received in response to the *Regulatory Notice* is attached as Exhibit 2b.[12] Eleven of the 71 comment letters received addressed proposed changes to Rule 2267.[13] Of these 11 comment letters, 10 were in favor of an increase in the communication by firms to their customers about the existence of BrokerCheck and one was opposed.

Several commenters expressed the view that firms should include a link to BrokerCheck on their Web sites to help increase investor awareness of the program.[14] Some of these commenters also suggested that firms be required to include the BrokerCheck Web site address in various other locations such as public communications, new account documents, and monthly statements.[15]

FINRA appreciates the commenters' suggestions on additional ways to increase investor awareness of

[7] FINRA continues to consider other comments regarding changes to BrokerCheck that were submitted in response to *Regulatory Notice* 12–10.

[8] Any member whose contact with customers is limited to introducing customer accounts to be held directly at an entity other than a FINRA member and thereafter does not carry customer accounts or hold customer funds and securities may furnish a customer with such information at or prior to the time of the customer's initial purchase, in lieu of once every calendar year. Any member that does not have customers or is a party to a carrying agreement where the carrying firm member furnishes a customer with such information is exempt from the requirements of FINRA Rule 2267(a).

[9] 15 U.S.C. 78*o*–3(b)(6).

[10] In general, a content management system is a software application that is used to manage text, images, audio and video content for a Web site. FINRA recognizes that some firms may not use a content management system and therefore may incur additional development costs depending on how their Web sites are configured.

[11] The Commission notes that Exhibit 2a is attached to the filing, not to this Notice.

[12] The Commission notes that Exhibit 2b is attached to the filing, not to this Notice. All references to the commenters under this Item are to the commenters as listed in Exhibit 2b.

[13] ARM, CFA, CFP, Davis, Dickenson, Dorsey, Foresters, Kelly, McCraken, PIRC, and Podolak.

[14] CFA, CFP, Davis, Foresters, Kelly, McCracken, and PIRC.

[15] ARM, CFA, CFP, PIRC, and Podolak.

BrokerCheck and will consider them in the future. When considering the commenters' suggestions, FINRA will examine, among other things, whether the inclusion of the BrokerCheck Web site address on materials such as public communications, new account documents, and monthly statements would materially increase investor awareness or use of BrokerCheck, as well as the potential additional costs that the suggested changes would impose on members and their associated persons.

One commenter suggested that no changes be made to Rule 2267.[16] As previously mentioned, FINRA believes that the proposed rule change will benefit investors by increasing the awareness and use of BrokerCheck.

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 (i) as the Commission may designate up to 90 days of such date if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the self-regulatory organization consents, the Commission will:

(A) By order approve or disapprove such proposed rule change, or

(B) Institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–FINRA–2013–002 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–FINRA–2013–002. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filing also will be available for inspection and copying at the principal office of FINRA. 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–FINRA–2013–002 and should be submitted on or before February 15, 2013.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[17]

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2013–01494 Filed 1–24–13; 8:45 am]

BILLING CODE 8011–01–P

[16] Dorsey.

[17] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–68691; File No. SR–CBOE–2013–008]

Self-Regulatory Organizations; Chicago Board Options Exchange, Incorporated; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend Its Rules Relating to Preferred Market-Makers' Continuous Quoting Obligation

January 18, 2013.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the ''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on January 11, 2013, Chicago Board Options Exchange, Incorporated (the ''Exchange'' or ''CBOE'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend its rules relating to Preferred Market-Makers' (''PMMs'') continuous quoting obligations. The text of the proposed rule change is provided below.[3]

(additions are italicized; deletions are [bracketed])

* * * * *

Chicago Board Options Exchange, Incorporated Rules

* * * * *

Rule 8.13. Preferred Market-Maker Program

(a) *Generally.* The Exchange may allow, on a class-by-class basis, for the receipt of marketable orders, through the Exchange's Order Routing System when the Exchange's disseminated quote is the NBBO, that carry a designation from the Trading Permit Holder transmitting the order that specifies a Market-Maker in that class as the ''Preferred Market-Maker'' for that order. A qualifying recipient of a

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] The Exchange recently proposed to, among other things, (a) reduce to 90% the percentage of time for which a PMM is required to provide electronic quotes in an appointed option class on a given trading day and (b) to increase to the lesser of 99% or 100% minus one call-put pair the percentage of series in each class in which a PMM must provide continuous electronic quotes in classes in which it receives PMM orders, which proposed rule change was immediately effective upon filing. Securities Exchange Act Release No. 34–67410 (July 11, 2012), 77 FR 42040 (July 17, 2012) (SR–CBOE–2012–064); *see also* Securities Exchange Act Release No. 34–67644 (August 13, 2012), 77 FR 49846 (August 17, 2012) (SR–CBOE–2012–077) (immediately effective rule change to delay the implementation date of the proposed rule change in rule filing SR–CBOE–2012–064 and to indicate that the Exchange will announce the new implementation date by Regulatory Circular); and Securities Exchange Act Release No. 34–68218 (November 13, 2012), 77 FR 69667 (November 20, 2012) (SR–CBOE–2012–106) (immediately effective rule change to further delay the implementation date of the proposed rule change in rule filing SR–CBOE–2012–064 and to indicate that the Exchange will announce the new implement date by Regulatory Circular). The rule text in this filing includes the effective (but not implemented) changes to the rule text made by rule filing SR–CBOE–2012–064. The Exchange expects to implement the effective rule changes to quoting obligations in filing SR–CBOE–2012–064 in conjunction with the implementation of the proposed rule change in this filing.

Preferred Market-Maker order shall be afforded a participation entitlement as set forth in subparagraph (c) below.

(b) *Eligibility.* No change.

(c) *Entitlement Rate.* No change.

(d) *Quoting Obligations:* The Preferred Market-Maker must comply with the quoting obligations applicable to its Market-Maker type under Exchange rules and must provide continuous electronic quotes (as defined in Rule 1.1(ccc)) in at least the lesser of 99% of the non-adjusted option series *that have a time to expiration of less than nine months* or 100% of the non-adjusted option series *that have a time to expiration of less than nine months* minus one call-put pair of each class for which it receives Preferred Market-Maker orders, with the term ''call-put pair'' referring to one call and one put that cover the same underlying instrument and have the same expiration date and exercise price.

* * * *Interpretations and Policies:*

.01 No change.

.02 Rule 8.13(d) does not require a Preferred Market-Maker to provide continuous electronic quotes in series that have a time to expiration of nine months or more in the classes for which it receives Preferred Market-Maker orders. However, a Preferred Market-Maker may still receive a participation entitlement in such series if it elects to quote in such series and otherwise satisfies the requirements set forth in Rule 8.13(b).

* * * * *

The text of the proposed rule change is also available on the Exchange's Web site (*http://www.cboe.com/AboutCBOE/CBOELegalRegulatoryHome.aspx*), at the Exchange's Office of the Secretary, and at the Commission.

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

Rule 8.13(d) currently requires that PMMs provide continuous electronic quotes when the Exchange is open for trading in at least 90% of the non-adjusted option series of each class for which it receives PMM orders.[4] Rule 1.1(ccc) currently provides that a PMM will be deemed to have provided ''continuous electronic quotes'' if the PMM provides electronic two-sided quotes for 99% of the time.[5]

The Exchange proposes to exclude series that have a time to expiration of nine months or more (*i.e.,* Long-Term Equity Options Series, or ''LEAPS'') from PMMs' continuous quoting obligation. As a result, PMMs' continuous quoting obligation will not apply to options series with a time to expiration of nine months or more.[6] Exchange Rule 8.7(d)(ii)(B) currently excludes series that have a time to expiration of nine months or more from the quoting obligations of Market-Makers.

The Exchange is proposing this rule change for competitive reasons. NASDAQ OMX PHLX LLC (''PHLX'') excludes, among other series, option series with a time to expiration of nine months or more from the quoting obligations of its streaming quote traders (''SQTs), remote SQTs (''RSQTs''), directed SQTs (''DSQTs'') and directed RSQTs (''DRSQTs''), the PHLX market participants generally equivalent to Market-Makers (SQTs and RSQTs) and PMMs (DSQTs and DRSQTs).[7] The Exchange believes this proposal changes the continuous quoting obligation of PMMs so that PMMs are required to quote in substantially similar types of series as equivalent market participants at another options exchange and is therefore essential for competitive purposes.[8] CBOE believes it is disadvantageous to PMMs if they are subject to stricter quoting requirements with respect to their continuous quoting obligations than equivalent market participants at a competing options exchange.

The Exchange also notes that this proposed rule change is consistent with the approach in current Rule 5.8, which states that strike price interval, bid/ask differential and continuity rules will not apply to equity LEAPS until the time to expiration is less than nine months.[9]

The Exchange believes the proposed rule change will continue to ensure that PMMs create a fair and orderly market in classes in which they receive PMM orders, as it does not absolve PMMs from providing continuous electronic quotes in a significant percentage of series of each class for a substantial portion of the trading day. PMMs must engage in activities that constitute a course of dealings reasonably calculated to contribute to the maintenance of a fair and orderly market, including (1) Competing with other Market-Makers to improve markets in all series of options classes comprising their appointments, (2) making markets that, absent changed market conditions, will be honored in accordance with firm quote rules, and (3) updating market quotations in

[4] *See supra* note 3 for a discussion regarding the implementation of a change to increase PMMs' continuous quoting obligations to require continuous electronic quotes in the lesser of 99% of the non-adjusted option series or 100% of the non-adjusted option series minus one put-class pair of each appointed class.

[5] *See* Rule 1.1(ccc), which provides that a Hybrid Market-Maker will be deemed to have provided ''continuous electronic quotes'' if the Hybrid Market-Maker provides electronic two-sided quotes for 99% of the time that the Hybrid Market-Maker is required to provide electronic quotes in an appointed option class on a given trading day. As discussed above, rule filing SR–CBOE–2012–064 reduced this percentage of time from 99% to 90% (which change is effective but not yet operative, and the Exchange expects to implement in conjunction with this proposed rule change). *See supra* note 3. The Rule also provides that if a technical failure or limitation of a system of the Exchange prevents the Hybrid Market-Maker from maintaining, or prevents the Hybrid Market-Maker from communicating to the Exchange, timely and accurate electronic quotes in a class, the duration of the failure will not be considered in determining whether the Hybrid Market-Maker has satisfied the 99% (and soon to be 90%) quoting standard with respect to that option class. The Exchange may consider other exceptions to this continuous electronic quote obligation based on demonstrated legal or regulatory requirements or other mitigating circumstances.

[6] As set forth in Rule 8.13(d), PMMs also have no quoting obligations in adjusted option series, which are option series for which, as a result of a corporate action by the issuer of the underlying security, one option contract in the series represents the delivery of other than 100 shares of underlying stock or Units.

[7] *See* PHLX Rule 1014(b)(ii)(D)(4). Additionally, while not specified in its rules, International Securities Exchange (''ISE'') Regulatory Information Circular 2009–248 similarly excludes these option series from the quoting obligations of competitive market-makers, including competitive market-makers that receive preferenced orders, the ISE market participants generally equivalent to PMMs. The Exchange notes that other exchanges exclude these long-term options from the quoting obligations of market participants that are equivalent to Lead Market-Makers (''LMMs'') or Designated Primary Market-Makers (''DPMs''), but not PMMs. *See, e.g.,* NYSE MKT Options Rule 925.1NY, Commentary .01; and NYSE Arca Options Rule 6.37B, Commentary .01.

[8] As noted below, PMMs will still be required to quote in quarterly options series, which DSQTs and DRSQTs are not.

[9] Similarly, Rule 24.9(b)(1)(A) states that strike price interval, bid/ask differential and continuity rules will not apply to index LEAPS until the time to expiration is less than twelve months.

response to changed market conditions in their appointed options classes and to assure that any market quote it causes to be disseminated is accurate.[10]

The relief proposed in this filing is mitigated by a PMM's other obligations. The proposed rule change would not excuse a PMM that is present on the trading floor from its obligation to provide a two-sided market complying with the bid/ask differential requirements in response to any request for quote by a floor broker, Trading Permit Holder or PAR Official.[11] The proposed rule change would also not excuse a PMM that is present on the trading floor from its obligation to provide an open outcry two-sided market complying with the bid/ask differential requirements in response to a request for a quote by a Trading Permit Holder or PAR Official directed at that Market-Maker or when, in response to a general request for a quote by a Trading Permit Holder or PAR Official, a market is not then being vocalized by a reasonable number of Market-Makers.[12] Further, the proposed rule change would not excuse a PMM from its obligation to submit a single quote or maintain continuous quotes in one or more series of a class to which the PMM is appointed when called upon by an Exchange official if, in the judgment of such official, it is necessary to do so in the interest of maintaining a fair and orderly market.[13]

The proposed rule change also adds Interpretation and Policy .02 to Rule 8.13 to clarify that while Rule 8.13(d) does not require a PMM to provide continuous electronic quotes in LEAPS in the classes for which it receives Preferred Market-Maker orders, a PMM may still receive a participation entitlement in a LEAPS series if it elects to quote in that series and otherwise satisfies the requirements set forth in Rule 8.13(b). If a PMM elects to quote in a LEAPS series in one of its preferred classes, in order to receive the participation entitlement in that series, the PMM must still be quoting at the best bid or offer on the Exchange and satisfying its other obligations set forth in Rule 8.13(b). PMMs already receive participation entitlements in series they are not required to quote. As discussed above, a PMM is currently required to provide continuous electronic quotes in at least 90% of the non-adjusted option series of each class for which it receives PMM orders.[14] If the PMM elects to quote in 100% of the non-adjusted series in the class, it will receive a participation entitlement in all of those series when quoting at the best price, including the 10% of the series in which it is not required to quote. Thus, under the proposed rule change, the market would continue to function as it does now. The Exchange believes this benefit is appropriate, as it incentivizes PMMs to quote in as many series as possible in the classes in which it receives PMM orders, even LEAPS, which Rule 8.13 does not require them to continuously quote.

The Exchange does not believe that the proposed rule change would adversely affect the quality of the Exchange's markets or lead to a material decrease in liquidity. Rather, the Exchange believes that its current market structure with its high rate of participation by Market-Makers permits the proposed rule change without fear of losing liquidity. This is especially true given that the quoting obligations of LMMs, DPMs, and electronic DPMs (''e-DPMs'') in Hybrid option classes set forth in Rules 8.15A, 8.85, and 8.93, respectively, will still apply to LEAPS, so the Exchange may still have a disseminated continuous two-sided market in LEAPS. Further, the Exchange believes that the current quoting obligation in LEAPS is a minor part of PMMs' overall obligations, so the burden of continuous quoting in these series by PMMs while DPMs and LMMs are also required to continuously quote in those series is counter to efforts to mitigate the number of quotes collected and disseminated. The Exchange also believes that market-making activity may increase as a result of adopting a provision that is already in place at another options exchange. Additionally, the Exchange believes that the proposed rule change to clarify that PMMs may still receive participation entitlements in LEAPS in the classes for which they received PMM orders in which they are quoting, even though Rule 8.13(d) does not require the PMMs to continuously quote in LEAPS, will incent PMMs to quote in LEAPS, which may increase liquidity in those classes.

The Exchange will announce the implementation date of the proposed rule change in a Regulatory Circular to be published no later than 90 days following the effective date. The implementation date will be no later than 150 days following the effective date.

2. Statutory Basis

The Exchange believes the proposed rule change is consistent with the Act and the rules and regulations thereunder applicable to the Exchange and, in particular, the requirements of Section 6(b) of the Act.[15] Specifically, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)[16] requirements that the rules of an exchange be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitation transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest. Additionally, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)[17] requirement that the rules of an exchange not be designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

In particular, the Exchange believes the proposed rule change promotes just and equitable principles of trade because it reduces burdens and unnecessary restrictiveness on PMMs. The quoting obligations of LMMs, DPMs, and e-DPMS will still apply to LEAPS, which the Exchange believes eliminates the risk of a material decrease in liquidity of LEAPS. The Exchange still imposes many obligations on PMMs to maintain a fair and orderly market in their appointed classes, including obligations to provide continuous electronic quotes for a significant part of the trading day in a substantial number of series of each appointed class. Further, the elimination of PMMs' continuous quoting obligations in LEAPS is a minor change and should not impact the quality of CBOE's market. Consequently, continuous quotes in these series by PMMs, in addition to DPMs and LMMs, increases quote traffic and burdens systems without a corresponding benefit. Thus, by not requiring PMMs to continuously quote in LEAPS, the Exchange's proposed rule change would further the Exchange's goal of measured quote mitigation. Additionally, PMMs will continue to be obligated to quote the series when requested by a floor broker, Trading Permit Holder, or PAR Official, or if the need otherwise arises.

[10] *See* Rule 8.7(a) and (b).

[11] *See* Rule 8.7(d)(i)(C) (relating to a request for quote by a floor broker) and (ii)(C) (relating to a request for a quote by a Trading Permit Holder or PAR Official).

[12] *See* Rule 8.7(d)(iv).

[13] *Id.*

[14] As discussed above, this obligation will change upon implementation of a recent rule change. *See supra* note 3.

[15] 15 U.S.C. 78f(b).

[16] 15 U.S.C. 78f(b)(5).

[17] *Id.*

Accordingly, the proposal supports the quality of CBOE's markets by helping to ensure that PMMs will continue to be obligated to quote in series when necessary. The Exchange believes these changes are reasonable and are offset by PMMs' continued responsibilities to provide significant liquidity to the market to the benefit of market participants. In addition, the proposed rule change removes impediments to and allows for a free and open market, while protecting investors, by promoting additional transparency regarding PMMs' obligations and benefits in the Exchange Rules. In addition, the Exchange believes that the proposed rule change is designed to not permit unfair discrimination, as the proposed rule change provides the proposed relief for all PMMs.

The proposed rule change to clarify that PMMs may still receive participation entitlements in LEAPS in the classes for which they received PMM orders in which they are quoting, even though Rule 8.13(d) does not require the PMMs to continuously quote in LEAPS, further supports the quality of the Exchange's trading markets because it encourages PMMs to quote in LEAPS, which ultimately benefits all investors. This benefit is offset by the PMMs' continued quoting obligations and the fact that they must still satisfy all of their other obligations in order to receive the entitlement in these ''non-required'' series. The Exchange also believes that this proposed change is consistent with its current practice, pursuant to which PMMs receive participation entitlements in additional series in which they elect to quote above the minimum percentage of series in which they are required to continuously quote under Rule 8.13.

The proposed rule change is also consistent with the rules of another options exchange.[18] The proposed rule change requires its PMMs to provide continuous quotes in the same types of series as equivalent market participants at a competing options exchange, which the Exchange believes could increase market-making activity on the Exchange.

For the foregoing reasons, the Exchange believes that the balance between the benefits provided to and the obligations imposed upon PMMs by the proposed rule change is appropriate.

B. Self-Regulatory Organization's Statement on Burden on Competition

CBOE does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The proposed rule change provides the same relief to a group of similarly situated market participants—PMMs. While other types of Market-Makers will still be required to continuously quote in LEAPS, the Exchange believes this is not unfairly discriminatory, as its Rules already impose different obligations on each type of Market-Maker based on the purposes and functions of, and benefits received by, that type of Market-Maker *(e.g.* Market-Makers are already not required to continuously quote in LEAPS, while LMMs, DPMs, and e-DPMs are, and will continue to be).

CBOE believes that the proposed rule change will in fact relieve any burden on, or otherwise promote, competition. The Exchange believes the proposed rule change is procompetitive because it would enable the Exchange to provide its PMMs with rules that are similar to those of another options exchange applicable to equivalent market participants at that exchange. The Exchange believes this will promote trading activity on the Exchange to the benefit of the Exchange, its Trading Permit Holders, and market participants.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange neither solicited nor received comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not:

A. Significantly affect the protection of investors or the public interest;

B. Impose any significant burden on competition; and

C. Become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A) of the Act[19] and Rule 19b–4(f)(6)[20] thereunder. At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–CBOE–2013–008 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–CBOE–2013–008. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filing also will be available for inspection and copying at the principal 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–CBOE–2013–008 and should be submitted on or before February 15, 2013.

[18] *See supra* note 7.

[19] 15 U.S.C. 78s(b)(3)(A).

[20] 17 CFR 240.19b–4(f)(6).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[21]

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2013–01485 Filed 1–24–13; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–68702; File No. SR–CBOE–2013–002]

Self-Regulatory Organizations; Chicago Board Options Exchange, Incorporated; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend the Fees Schedule

January 18, 2013.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the ''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on January 7, 2013, Chicago Board Options Exchange, Incorporated (the ''Exchange'' or ''CBOE'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of the Substance of the Proposed Rule Change

The Exchange proposes to amend its Fees Schedule. The text of the proposed rule change is available on the Exchange's Web site (*http://www.cboe.com/AboutCBOE/CBOELegalRegulatoryHome.aspx*), at the Exchange's Office of the Secretary, and at the Commission.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to make a number of amendments to its Fees Schedule. First, the Exchange proposes to amend the fees applicable to orders for a joint back office (''JBO'') account to be cleared into the Firm range at the Options Clearing Corporation (''JBO Orders''). Until November 1, such orders were marked with the ''F'' origin code and were included within the category of Clearing Trading Permit Holder Proprietary orders (and assessed fees as if they were Clearing Trading Permit Holder Proprietary orders). As of November 1, the Exchange assigned a new origin code (''J'') to JBO Orders,[3] but continued to assess the same fees for JBO Orders as if they were Clearing Trading Permit Holder Proprietary orders.[4]

The Exchange now proposes to increase the fees for JBO Orders to the same amounts as are assessed to Professional and Voluntary Professional orders (except for SPX trades).[5] This would involve increasing the following fees for JBO Orders (fee amounts are per-contract):

Product	Execution type	Previous fee	New fee
Equity, ETF, ETN, HOLDRs and Index Options[6]	Manual (Penny and Non-Penny Classes)	$0.20	$0.25
Equity, ETF, ETN, HOLDRs and Index Options[7]	Electronic (Penny and Non-Penny Classes)[8]	[9]0.20	0.30
Proprietary Index Options[10]	All	0.25	0.40
SPX Range Options (SRO)	All	0.50	0.80
Credit Default Options and Credit Default Basket Options.	All	0.20	0.85

The Exchange proposes assessing JBO Orders these increased fee amounts because JBOs do not have the obligations (such as membership with the Options Clearing Corporation), significant regulatory burdens, or financial obligations, that Clearing Trading Permit Holders must take on. Further, unlike Clearing Trading Permit Holders, JBOs do not need to be Exchange Trading Permit Holders. Instead, JBOs are able to effect transactions on the Exchange through a Clearing Trading Permit Holder. As such, JBOs operate more like Professional customers, in that they do not possess these obligations and are merely trading for themselves.

The acts of assigning JBO Orders their own origin code and assessing them different fee amounts from Clearing Trading Permit Holder Proprietary orders (and thereby listing JBO Orders separately from Clearing Trading Permit Holder Proprietary orders) necessitate a number of other changes to the Fees Schedule. First, footnote 11 of the Fees Schedule states that the Clearing Trading Permit Holder Fee Cap in all products except SPX, SRO, VIX or other volatility indexes, OEX or XEO (the ''Fee Cap'') and CBOE Proprietary Products Sliding Scale for Clearing Trading Permit Holder Proprietary Orders (the ''Sliding Scale'') applies to Clearing Trading Permit Holder

[21] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* CBOE Regulatory Circulars RG12–118 (August 27, 2012) and RG12–136 (October 5, 2012).

[4] *See* Securities Exchange Act Release No. 68163 (November 6, 2012), 77 FR 67701 (November 13, 2012) (SR–CBOE–2012–098).

[5] SPX is traded on the Exchange's Hybrid 3.0 system, which does not recognize Professional and Voluntary Professional orders. As such, Professional and Voluntary Professional orders in SPX are assessed the same fees as Customer SPX orders. The Exchange instead proposes to assess the same fees for JBO Orders in SPX that the Exchange proposes to assess for JBO Orders in other proprietary index options.

[6] Excluding SPX, SPXW, SRO, OEX, XEO, VIX and VOLATILITY INDEXES.

[7] Excluding SPX, SPXW, SRO, OEX, XEO, VIX and VOLATILITY INDEXES.

[8] Including CFLEX AIM executions (''AIM'' stands for the Exchange's Automated Improvement Mechanism).

[9] This proposed rule change filing also proposes to increase the fee for Clearing Trading Permit Holder Proprietary electronic executions (including CFLEX AIM executions) in equity, ETF, ETN, HOLDRs and index options (excluding SPX, SPXW, SRO, OEX, XEO, VIX and VOLATILITY INDEXES) from $0.20 to $0.25 per contract. As such, the fee for JBO Orders for such executions would only be $0.05 more per contract than for similar Clearing Trading Permit Holder Proprietary executions.

[10] SPX, SPXW, SRO, OEX, XEO, VIX and VOLATILITY INDEXES.

Proprietary orders (''F'' origin code), except for orders of joint back-office (''JBO'') participants. Footnote 12 of the Fees Schedule also states that the Clearing Trading Permit Holder Proprietary Transaction Fee shall be waived for Clearing Trading Permit Holders, except JBO participants, executing facilitation orders in multiply-listed FLEX Options classes. Because JBO Orders are no longer included in or listed with Clearing Trading Permit Holder Proprietary orders on the Fees Schedule, there is no reason for them to be excepted out in this manner (and indeed, it would be confusing to do so). Therefore, the Exchange proposes to remove these references to JBOs from footnotes 11 and 12.

Similarly, footnote 13 caps transaction fees for a number of market participants (including Clearing Trading Permit Holders) at $1,000 for all (i) merger strategies and (ii) short stock interest strategies executed on the same trading day in the same options class. Footnote 13 also caps transaction fees for a number of market participants (including initiating Clearing Trading Permit Holders) at $25,000 per month for all merger strategies, short stock interest strategies, reversals, conversions and jelly roll strategies (together, the ''Strategy Caps''). As both of these Strategy Caps apply to Clearing Trading Permit Holders, they also applied to JBO Orders. The Exchange wishes to continue to apply such Strategy Caps to JBO Orders. As such, the Exchange proposes to explicitly state that these Strategy Caps apply to JBO participants.

Footnote 14 states that the Surcharge Fees apply to all non-public customer transactions (*i.e.* CBOE and non-Trading Permit Holder market-maker, Clearing Trading Permit Holder and broker-dealer), including voluntary professionals, and professionals. Because JBOs are not currently stated explicitly in footnote 14 (as they were included within the category of Clearing Trading Permit Holder), the Exchange now proposes to add a reference in this footnote in order to clarify that the Surcharge Fees apply to JBO Orders.

Footnote 19 applies the AIM Agency/Primary Fee to a variety of market participants (including Professionals and Voluntary Professionals) for orders in all products, except volatility indexes, executed in AIM, SAM (the Exchange's Solicitation Auction Mechanism), FLEX AIM and FLEX SAM auctions, that were initially entered as an Agency/Primary Order. Because JBO Orders could be entered on the Agency/Primary side of AIM, SAM, FLEX AIM and FLEX SAM auctions, the Exchange proposes to add a reference to JBO participant orders to footnote 19 to state that such orders will be subject to the AIM Agency/Primary Fee.

The Exchange also proposes to amend its fees for customer transactions in VIX volatility index options (''VIX options''). Currently, all customer VIX options transactions incur a fee of $0.40 per contract. The Exchange proposes to lower the fee for customer transactions in VIX options whose premium is less than $1.00 to $0.25 per contract, and raise the fee for customer transactions in VIX options whose premium is greater than or equal to $1.00 to $0.45 per contract. The purpose of these proposed changes is to provide greater incentives for customers to trade VIX options. Most of the VIX options currently trading are below a premium of $1.00 (due to the low price of the underlying index), so the lowered fee will encourage more trading of such options. The increase of the fee for customer transactions in VIX options whose premium is greater than or equal to $1.00 is being utilized in order to achieve some level of revenue balance in connection with the lowered fee for customer transactions in VIX options whose premium is less than $1.00. On the whole, the Exchange expects the per-contract fee for all customer VIX options transactions to decrease due to these two changes.

The Exchange proposes to increase the SPX (including SPXW) Index License Surcharge Fee (the ''SPX Surcharge'') from $0.10 per contract to $0.13 per contract (and from $0.20 per contract to $0.26 per contract for SPX Range Options).[11] The Exchange licenses from Standard & Poor's the right to offer an index option product based on the S&P 500 index (that product being SPX and other SPX-based index option products). In order to recoup the costs of the SPX license, the Exchange assesses the SPX Surcharge. However, the cost of that license works out to more than the current SPX Surcharge amount of $0.10 per SPX contract traded (or even the proposed SPX Surcharge amount of $0.13 per contract), so the Exchange ends up subsidizing that SPX license cost. The Exchange therefore proposes to increase the SPX Surcharge from $0.10 per contract to $0.13 per contract in order to recoup more of the costs associated with the SPX license. The Exchange will still be subsidizing the costs of the SPX license.

The Exchange also proposes increasing the fee assessed to Clearing Trading Permit Holder Proprietary orders for electronic executions (including CFLEX AIM and FLEX Options) in equity, ETF, ETN HOLDRs and index options[12] from $0.20 per contract to $0.25 per contract. This change is proposed due to competitive reasons and to better reflect the costs associated with supporting a larger number of option classes, option series, and overall transaction volumes that have grown over time. Further, this increased amount is within the range of fees assessed for similar transactions on other exchanges.[13]

The Exchange also proposes to amend its Liquidity Provider Sliding Scale, which applies to Liquidity Provider (CBOE Market-Maker, DPM, e-DPM and LMM) transaction fees in all products except SPX, SRO, VIX or other volatility indexes, OEX or XEO. A Liquidity Provider's standard per-contract transaction fee shall be reduced to the fees shown on the Liquidity Provider Sliding Scale as the Liquidity Provider reaches the contract volume thresholds shown on the Liquidity Provider Sliding Scale in a month. The Exchange proposes to amend the tier volume thresholds and fees for each tier as follows:

Tier	Current volume threshold (contracts per month)	Proposed volume threshold (contracts per month)	Current fee (per contract)	Proposed fee (per contract)
1	1–51,000	1–100,000	$0.20	$0.25
2	51,001–810,000	100,001–2,000,000	0.18	0.17

[11] The exposure provided by Range Options is equivalent to four option positions. As such, the Exchange determined to assess an SPX Range Options Surcharge Fee of twice the amount of the SPX Surcharge (*See* Securities Exchange Act Release No. 67777 (September 4, 2012), 77 FR 55515 (September 10, 2012) (SR–CBOE–2012–084)). As the Exchange hereby proposes to increase the amount of the SPX Surcharge, the Exchange correspondingly proposes to increase the SPX Range Options Surcharge Fee by the same proportion.

[12] Excluding SPX, SPXW, SRO, OEX, XEO, VIX and VOLATILITY INDEXES.

[13] The International Securities Exchange, LLC (''ISE'') assesses a Taker fee of $0.33 per contract for firm proprietary orders in select symbol (*see* ISE Schedule of Fees, Section 1). The NASDAQ OMX PHLX LLC (''PHLX'') assesses a Taker fee of $0.45 per contract for firm orders (*see* PHLX Pricing Schedule, Section 1A).

Tier	Current volume threshold (contracts per month)	Proposed volume threshold (contracts per month)	Current fee (per contract)	Proposed fee (per contract)
3	810,001–2,055,000	2,000,001–4,000,000	0.15	0.10
4	2,055,001–3,285,000	4,000,001–6,000,000	0.10	0.05
5	3,285,001–6,300,000	6,000,001+	0.03	0.03
6	6,300,001+	Tier 6 eliminated	0.01	Not applicable

The purpose of amending the tier volume thresholds and fees for such tiers is to adjust for current volume trends and demographics across the Liquidity Provider population and to rationalize fees across that population.

The Exchange also proposes to amend some of the language in footnote 10 of the Fees Schedule regarding prepayment for the Liquidity Provider Sliding Scale. First, the Exchange proposes to delete the prepayment amounts listed in footnote 10, as they will not be relevant due to the proposed changes to the tier volume thresholds and fees for each tier that are discussed above. Those prepayment amounts listed functionally required prepayment of annual fees for the first two tiers of the Liquidity Provider Sliding Scale in order to qualify for tiers 3 and above of the Liquidity Provider Sliding Scale. The Exchange proposes to delete the listed prepayment amounts and instead just list the tier numbers themselves. The Exchange also proposes to remove the requirement that a prepayment for the entire year be made for the first two tiers of the Liquidity Provider Sliding Scale in order for a Liquidity Provider to be eligible for the fees applicable to tiers 3–5 of the Liquidity Provider Sliding Scale. This means that a Liquidity Provider will no longer be prohibited from being eligible for the fees applicable to tiers 3–5 if the Liquidity Provider did not prepay for the first two tiers for the entire year. Instead, a prepayment can be made for the first two tiers of the Liquidity Provider Sliding Scale at any time during the year to be eligible for the fees applicable to tiers 3–5 for the remainder of the year. The amended statement will read that ''A Liquidity Provider can elect to prepay to be eligible for the fees applicable to tiers 3–5 of the sliding scale for the remainder of the year at any time during the year, but such prepayment (and eligibility) will only be applied prospectively for the remainder of the year.'' The purpose of this proposed change is to make it easier for Liquidity Providers to qualify for the lower fees in tiers 3–5 without having to pre-commit to the entire year. The Exchange also proposes to delete the statement that ''If a Liquidity Provider prepays annual fees for the first four tiers of the sliding scale, the Liquidity Provider will receive a $410,960 prepayment discount (total amount of the prepayment will be $5,067,840)''. The Exchange proposes deleting this prepayment discount for economic reasons and to allow the Exchange to retain fees in order to manage Exchange administrative and regulatory expenses.

The Exchange proposes to amend any references in the Fees Schedule to CBOE*direct* to refer to CBOE Command, as the manner through which Trading Permit Holders (''TPHs'') connect to the CBOE System is now called CBOE Command. Such references can be found in the title of the table describing Connectivity Charges, in the notes to the Volume Incentive Plan table, and in footnote 27. All will be updated to refer to CBOE Command instead of CBOE*direct.*

The Exchange also proposes to amend its connectivity fees. In order to connect to CBOE Command, which allows a TPH to trade on the CBOE System, a TPH must connect via either a CMI or FIX interface (depending on the configuration of the TPH's own systems). For TPHs that connect via a CMI interface, they must use CMI CAS Servers. The Exchange proposes to state that, for every 15 Trading Permits that a TPH that accesses CBOE Command via CMI holds, that TPH receives one CAS Server (plus one total backup CAS Server regardless of the number of Trading Permits that the TPH holds). If a TPH elects to connect via an extra CMI CAS Server (in order to segregate TPH users for business or availability purposes) beyond the TPH's allotted number of CMI CAS Servers (based on the number of Trading Permits the TPH holds), that TPH will be assessed a fee of $10,000 per month for each extra CMI CAS Server. The Exchange will aggregate the Trading Permits from affiliated TPHs (TPHs with at least 75% common ownership between the firms as reflected on each firm's Form BD, Schedule A) for purposes of determining the number of Trading Permits a TPH holds. The purpose of this proposed change is to manage the allotment of CMI CAS Servers in a fair manner and to prevent the Exchange from being required to expend large amounts of resources (the provision and management of the CMI CAS Servers can be costly) in order to provide TPHs with an unlimited amount of CMI CAS Servers. The purpose of the fee for extra CMI CAS Servers is to cover the costs related to the provision, management and upkeep of such CMI CAS Servers.

The Exchange also proposes to amend its Non-Standard Booth Rental Fees for booths on the trading floor as follows:

Length of lease	1 year (current)	1 year (proposed)	2 years (current)	2 years (proposed)	3 years (current)	3 years (proposed)
Booth Size	Per Sq. Ft.					
Extra-Large (1000 sq. ft. or greater)	$5.50	2.83	5.34	2.75	5.23	2.69
Large (800–999 sq. ft.)	8.00	4.12	7.76	4.00	7.60	3.91
Medium (401–799 sq. ft.)	9.50	4.89	9.22	4.74	9.03	4.65
Small (400 sq. ft. or less)	15.00	7.72	14.55	7.49	14.25	7.33

As previously [sic], the fees for committing to a longer lease are lower than those for committing to a one-year lease (the fee for a two-year lease is 97% of the fee for a one-year lease, and the fee for a three-year lease is 95% of the fee for a one-year lease; the proportions remain the same for the lowered proposed fees). The Exchange proposes lowering the Non-Standard Booth Rental fees in order to encourage rental of booth space on and around the Exchange trading floor.

The Exchange also proposes to amend the WebCRD℠ fees listed on its Fees

Schedule. Such fees are collected and retained by the Financial Industry Regulatory Authority, Inc. (''FINRA'') via the WebCRD[SM] registration system for the registration of associated persons of Exchange TPHs and TPH organizations that are not also FINRA members. The Exchange merely lists such fees on its Fees Schedule. FINRA recently filed a proposed rule change to increase a number of these fees (the ''FINRA Fee Change'').[14] The FINRA Fee Change increases the FINRA Non-Member Processing Fee from $85 to $100, the FINRA Annual System Processing Fee Assessed only during Renewals from $30 to $45, and the FINRA Disclosure Processing Fee from $95 to $110. The FINRA Fee Change also applies the FINRA Disclosure Processing Fee (which already applied to Form U–4 and U–5 filings and their amendments) to Form BD filings and corresponding amendments.

The FINRA Fee Change also amended FINRA's Fingerprint Processing Fees. In 2012, FINRA only offered one set of fees ($27.50 for the initial submission, $13.00 for the second submission, and $27.50 for the third submission). For 2013, FINRA is offering two sets of fees. For fingerprints submitted on paper card, the fees will be $44.50 per initial submission, $30.00 per second submission, and $44.50 per third submission. For fingerprints submitted electronically, the fees will be $29.50 per initial submission, $15.00 per second submission, and $29.50 per third submission. The FINRA Fee Change also increases from $13.00 to $30.00 the fingerprint processing fee for those submitted by TPHs or TPH organizations on behalf of their associated persons who had had their prints processed through a self-regulatory organization other than FINRA.

2. Statutory Basis

The Exchange believes the proposed rule change is consistent with the Act and the rules and regulations thereunder applicable to the Exchange and, in particular, the requirements of Section 6(b) of the Act.[15] Specifically, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)[16] requirements that the rules of an exchange be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitation transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest. The Exchange also believes the proposed rule change is consistent with Section 6(b)(4) of the Act,[17] which provides that Exchange rules may provide for the equitable allocation of reasonable dues, fees, and other charges among its Trading Permit Holders and other persons using its facilities.

Increasing the fee amounts for JBO Orders, as described in Item 3(a) above, is reasonable because the amounts of all such fees are within the range of fees assessed to other market participants for the same types of transactions. Specifically, the proposed amounts of the increased fees are equivalent to the amounts of such fees assessed to Professionals and Voluntary Professionals (except for SPX trades). Assessing JBO Orders the increased fee amounts (the same amounts as Professionals and Voluntary Professionals) is equitable and not unfairly discriminatory because JBOs do not have the obligations (such as membership with the Options Clearing Corporation), significant regulatory burdens, or financial obligations, that Clearing Trading Permit Holders must take on. Further, unlike Clearing Trading Permit Holders, JBOs do not need to be Exchange Trading Permit Holders. Instead, JBOs are able to effect transactions on the Exchange through a Clearing Trading Permit Holder. As such, JBOs operate more like Professional customers, in that they do not possess these obligations and are merely trading for themselves.

Removing references in footnotes 11 and 12 of the Fees Schedule that except JBO Orders out of Clearing Trading Permit Holder Proprietary orders for the sake of the Fee Cap and the Sliding Scale eliminates potential investor confusion, since JBO Orders no longer are marked with the ''F'' origin code, included within the category of Clearing Trading Permit Holder Proprietary orders, or assessed fees as if they were Clearing Trading Permit Holder Proprietary orders. This elimination of investor confusion removes impediments to and perfects the mechanism of a free and open market and a national market system, and, in general, protects investors and the public interest. Similarly, explicitly stating that JBO Orders (which, because they were marked with the ''F'' origin code and assessed fees as if they were Clearing Trading Permit Holder Proprietary orders, have been subject to the Strategy Caps and Surcharge Fees) will still be subject to the Strategy Caps and Surcharge Fees also prevents investor confusion, thereby removing impediments to and perfecting the mechanism of a free and open market and a national market system, and, in general, protecting investors and the public interest.

Applying the AIM Agency/Primary Fee to the orders of JBO participants (JBO Orders) is reasonable because the amount of the AIM Agency/Primary Fee will be the same for JBO Orders as it is for the orders of other market participants to whom the AIM Agency/Primary Fee applies. Applying the AIM Agency/Primary Fee to the orders of JBO participants is equitable and not unfairly discriminatory because the AIM Agency/Primary Fee applies to other market participants who reasonably could be foreseen as entering an order on the Agency/Primary side of AIM, SAM, FLEX AIM and FLEX SAM auctions.

The proposed changes to the customer VIX options transaction fees are reasonable because the amounts of the new fees are within the range of fees assessed for customer transactions in other CBOE proprietary products. Indeed, the fee for customer transactions in SPX options whose premium is less than $1.00 is $0.35 per contract, and the fee for customer transactions in SPX options whose premium is greater than or equal to $1.00 is $0.44 per contract. The proposed changes to the customer VIX options transaction fees are equitable and not unfairly discriminatory because they are designed to attract greater customer order flow to the Exchange. This would bring greater liquidity to the market, which benefits all market participants. Customer fees for VIX options will still be below than those assessed to broker-dealers and non-Trading Permit Holder Market-Makers (among other market participants) because customers are not assessed a Surcharge Fee for VIX options transactions.

Assessing a higher fee for customer transactions in VIX options whose premium is greater than or equal to $1.00 than for customer transactions in VIX options whose premium is less than

[14] *See* Securities Exchange Act Release No. 67247 (June 25, 2012) 77 FR 38866 (June 29, 2012) (SR–FINRA–2012–030). These new fees and fee amounts are discussed in FINRA Regulatory Notice 12–32, available at *http://www.finra.org/Industry/Regulation/Notices/2012/P127240,* and are listed in the listing of FINRA's 2013 Regulatory Fees, available on the FINRA Web site at *http://www.finra.org/Industry/Compliance/Registration/CRD/FilingGuidance/P197266.*

[15] 15 U.S.C. 78f(b).

[16] 15 U.S.C. 78f(b)(5).

[17] 15 U.S.C. 78f(b)(4).

$1.00 is equitable and not unfairly discriminatory because the Exchange expects the per-contract fee for all customer VIX options transactions to decrease due to these two changes. Most VIX options have a premium below $1.00, so the lowered fee will encourage more trading of such options. The increase of the fee for customer transactions in VIX options whose premium is greater than or equal to $1.00 is being utilized in order to achieve some level of revenue balance in connection with the lowered fee for customer transactions in VIX options whose premium is less than $1.00. Further, the Exchange currently offers different fees depending on the premium for customer transactions in SPX options (as described in the previous paragraph).

Increasing the SPX Surcharge (and SPX Range Options Surcharge Fee) is reasonable because the Exchange still pays more for the SPX license than the amount of the proposed SPX Surcharge (meaning that the Exchange is, and will still be, subsidizing the costs of the SPX license). This increase is equitable and not unfairly discriminatory because the increased amount will be assessed to all market participants to whom the SPX Surcharge applies. Also, in proposing to increase the SPX Surcharge by 30%, the Exchange merely also proposes to increase the SPX Range Options Surcharge Fee in the same proportion.

The proposed increase in the fee assessed to Clearing Trading Permit Holder Proprietary orders for electronic executions (including CFLEX AIM and FLEX Options) in equity, ETF, ETN HOLDRs and index options [18] is reasonable because the increased amount ($0.25 per contract) is within the range of fees assessed to other market participants for the same type of transactions (for example, broker-dealers are assessed a fee of as much as $0.60 per contract for such transactions, and Professionals are assessed a fee of $0.30 per contract for such transactions). This proposed increase is equitable and not unfairly discriminatory because it will be applied to all Clearing Trading Permit Holder Proprietary orders. The amount of the fee will still be lower than that assessed to all other CBOE market participants (except customers), as Clearing Trading Permit Holders have a number of obligations (such as membership with the Options Clearing Corporation), significant regulatory burdens, and financial obligations, that those other market participants do not need to take on. Finally, the proposed increased fee amount is within the range of fee amounts assessed by other exchanges for similar transactions by similar market participants.[19] Assessing a different fee amount for electronic executions than for manual executions is equitable and not unfairly discriminatory because the Exchange has expended considerable resources to develop its electronic trading platforms and seeks to recoup the costs of such expenditures. Moreover, the business models surrounding electronic orders and open outcry orders are different, and as such, the Exchange offers different incentives to encourage the entry of electronic and open outcry orders. Further, in assessing what fee amounts to assess, the Exchange experiences different competitive pressures from other exchanges with respect to electronic orders than it does with respect to open outcry orders. The Exchange also believes that assessing a different fee for electronic orders than it does for open outcry orders is equitable and not unfairly discriminatory because other exchanges distinguish between delivery methods for certain market participants and pay different rebates depending on the method of delivery. This type of distinction is not novel and has long existed within the industry.

The amendments to the tier volume thresholds and corresponding fees for the Liquidity Provider Sliding Scale are reasonable because even the amount of the highest fee (assessed at the lowest tier) is within the range of fees assessed to other CBOE market participants [20] and because, as a Liquidity Provider executes more contracts in a month, that Liquidity Provider will pay lower fees for such executions. Assessing lower fees for executing more contracts is equitable and not unfairly discriminatory because it provides Liquidity Providers with an incentive to execute more contracts on the Exchange. This brings greater liquidity and trading opportunity, which benefits all market participants (including those Liquidity Providers only reaching the lower tiers of the Liquidity Provider Sliding Scale). Offering lower fees for Liquidity Providers than for other CBOE market participants (such as Broker-Dealers, Professionals, Voluntary Professionals, and Non-Trading Permit Holder Market-Makers) is equitable and not unfairly discriminatory because, as CBOE Market-Makers, Liquidity Providers take on certain obligations, such as quoting obligations, that these other market participants do not.

Eliminating the prepayment discount from the Liquidity Provider Sliding Scale is reasonable because it merely eliminates a discount and will require Liquidity Providers to pay the fee amounts they normally would. Indeed, they will still be able to pay lowered fee amounts by executing more contracts, per the Liquidity Provider Sliding Scale; they just will not be able to receive a discount for committing to do so beforehand. This is equitable and not unfairly discriminatory because the elimination of the prepayment discount will apply to all Liquidity Providers, and therefore no Liquidity Providers will be able to receive the prepayment discount. Eliminating the requirement that a Liquidity Provider must prepay the annual fees for the first two tiers of the Liquidity Provider Sliding Scale in order to be eligible for the fees applicable to tiers 3–5, and instead allowing a Liquidity Provider to elect to prepay to be eligible for the fees applicable to tiers 3—5 of the sliding scale for the remainder of the year at any time during the year is reasonable because it will make it easier for a Liquidity Provider to be eligible for the lower fees applicable to tiers 3–5. This change is equitable and not unfairly discriminatory because it will be applied equally to all Liquidity Providers. Further, prepayment allows CBOE to more safely conceptualize Exchange finances for the future. This allows the Exchange to offer the lower fees related to prepayment, and such lower fees incentivize greater trading and liquidity provision by Liquidity Providers, which benefits all market participants (including Liquidity Providers who do not prepay).

The change of the reference from ''CBOE*direct*'' to ''CBOE Command'' eliminates confusion, thereby removing impediments to and perfecting the mechanism of a free and open market and a national market system, and, in general, protecting investors and the public interest.

The proposed allotment of one CMI CAS Server for every 15 Trading Permits that a TPH holds (plus one total backup CAS Server regardless of the number of Trading Permits that a TPH holds) is reasonable because one CMI CAS Server should be capable of handling the bandwidth needs of at least 15 Trading Permits. This proposed allotment is equitable and not unfairly discriminatory because it will be applied to all TPHs accessing CBOE Command via a CMI connection. The proposed fee of $10,000 for each extra

[18] Excluding SPX, SPXW, SRO, OEX, XEO, VIX and VOLATILITY INDEXES.

[19] ISE assesses a Taker fee of $0.33 per contract for firm proprietary orders in select symbol (*see* ISE Schedule of Fees, Section 1). PHLX assesses a Taker fee of $0.45 per contract for firm orders (*see* PHLX Pricing Schedule, Section 1A).

[20] *See* CBOE Fees Schedule, page 1.

CMI CAS Server that a TPH requests is reasonable because it is necessary to recoup the costs related to the provision, maintenance and upkeep of such Servers, and is equitable and not unfairly discriminatory because it the fee will be applied to all TPHs that request an extra CMI CAS Server.

The proposed lower Non-Standard Booth Rental Fees are reasonable because they will allow any market participants paying the Non-Standard Booth Rental Fee to pay less than such market participants are currently paying. These changes are equitable and not unfairly discriminatory because they will apply to all market participants who rent Non-Standard Booths. The lowered fees for committing to a longer lease are equitable and not unfairly discriminatory because they encourage greater commitment to booth rental and trading from the floor and on the Exchange, which benefits all market participants. Moreover, the Exchange currently offers lower fees for committing to a longer lease, and merely proposes to decrease these fees in the same proportion as they currently exist.

The proposed changes to the listings of the FINRA WebCRD℠ fees are reasonable from the Exchange's position because the amounts are those provided by FINRA, and the Exchange does not collect or retain these fees. The proposed fee changes are equitable and not unfairly discriminatory from the Exchange's position because the Exchange will not be collecting or retaining these fees, and therefore will not be in a position to apply them in an inequitable or unfairly discriminatory manner.

B. Self-Regulatory Organization's Statement on Burden on Competition

CBOE does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The Exchange believes that the proposal to increase fees for JBO Orders will not cause an unnecessary burden on intramarket competition because the amounts of all such fees are within the range of fees assessed to other market participants for the same types of transactions. Specifically, the proposed amounts of the increased fees are equivalent to the amounts of such fees assessed to Professionals and Voluntary Professionals (except for SPX trades). Assessing JBO Orders the increased fee amounts (the same amounts as Professionals and Voluntary Professionals) does not cause an unnecessary burden on intramarket competition because JBOs do not have the obligations (such as membership with the Options Clearing Corporation), significant regulatory burdens, or financial obligations, that Clearing Trading Permit Holders must take on. Further, unlike Clearing Trading Permit Holders, JBOs do not need to be Exchange Trading Permit Holders. Instead, JBOs are able to effect transactions on the Exchange through a Clearing Trading Permit Holder. As such, JBOs operate more like Professional customers, in that they do not possess these obligations and are merely trading for themselves. Therefore, the Exchange does not believe that the proposal to increase fees for JBO Orders will not impose any burden on intramarket competition, but to the extent that such increase may result in any change in intramarket competition, it is justifiable for the reasons stated above. The Exchange believes that the proposal to increase fees for JBO Orders will not cause an unnecessary burden on intermarket competition because the Exchange was not motivated by intermarket competition in proposing such changes and because many other exchanges do not list out separate fees for JBO Orders and therefore it is difficult to even determine the amounts of fees for JBO Orders on other exchanges.

The Exchange does not believe that the proposed changes to customer VIX options transaction fees will cause any unnecessary burden on intramarket competition because, while customers are assessed differently, and often lower, fee rates than other market participants, this is a common practice within the options marketplace, and customers often do not have the sophisticated trading algorithms and systems that other market participants often possess. Further, to the extent that any change in intramarket competition may result from the proposed changes to customer VIX options transaction fees, such possible change is justifiable and offset because the changes to such fees are designed to attract greater customer order flow to the Exchange. This would bring greater liquidity to the market, which benefits all market participants. The Exchange does not believe that the proposed changes to customer VIX options transaction fees will cause any unnecessary burden on intermarket competition because VIX options is a proprietary product that is traded solely on CBOE.

The Exchange does not believe that the increase of the SPX Surcharge will cause any unnecessary burden on intramarket competition because the increased amount will be assessed to all market participants to whom the SPX Surcharge applies. The Exchange does not believe that the increase of the SPX Surcharge will cause any unnecessary burden on intermarket competition because SPX is a proprietary product that is traded solely on CBOE.

The Exchange does not believe that the proposed increase in the fee assessed to Clearing Trading Permit Holder Proprietary orders for electronic executions (including CFLEX AIM and FLEX Options) in equity, ETF, ETN HOLDRs and index options [21] will cause any unnecessary burden on intramarket competition because the amount of the fee will still be lower than that assessed to all other CBOE market participants (except customers), as Clearing Trading Permit Holders have a number of obligations (such as membership with the Options Clearing Corporation), significant regulatory burdens, and financial obligations, that those other market participants do not need to take on. As such, to the extent that the proposed increase could cause any change in intramarket competition, it is justifiable for these reasons. The Exchange does not believe that the proposed increase will cause any unnecessary burden on intermarket competition because the proposed increased fee amount is within the range of fee amounts assessed by other exchanges for similar transactions by similar market participants.[22]

The Exchange does not believe that the proposed changes to the Liquidity Provider Sliding Scale will cause an unnecessary burden on intramarket competition because, while offering lower fees for Liquidity Providers than for other CBOE market participants (such as Broker-Dealers, Professionals, Voluntary Professionals, and Non-Trading Permit Holder Market-Makers) may affect such competition, this impact is justified by the fact that as CBOE Market-Makers, Liquidity Providers take on certain obligations, such as quoting obligations, that these other market participants do not. Further, assessing lower fees for executing more contracts will provide Liquidity Providers with an incentive to execute more contracts on the Exchange. This brings greater liquidity and trading opportunity, which benefits all market participants (including those Liquidity Providers only reaching the lower tiers of the Liquidity Provider Sliding Scale). The Exchange does not believe that the

[21] Excluding SPX, SPXW, SRO, OEX, XEO, VIX and VOLATILITY INDEXES.

[22] ISE assesses a Taker fee of $0.33 per contract for firm proprietary orders in select symbol (*see* ISE Schedule of Fees, Section 1). PHLX assesses a Taker fee of $0.45 per contract for firm orders (*see* PHLX Pricing Schedule, Section 1A).

proposed changes to the Liquidity Provider Sliding Scale will cause an unnecessary burden on intermarket competition because, while the proposed changes are designed to attract greater liquidity and trading volume, market participants trading on other exchanges can always elect to become TPHs on CBOE. Further, the Exchange exists in a competitive marketplace, and to the extent that these proposed changes make other exchanges less competitive with CBOE, market participants trading on those other exchanges can elect to trade on CBOE.

The Exchange does not believe that the proposed allotment of one CMI CAS Server for every 15 Trading Permits that a TPH holds (plus one total backup CAS Server regardless of the number of Trading Permits that a TPH holds) and the proposed fee of $10,000 for each extra CMI CAS Server that a TPH requests will cause an unnecessary burden on intramarket competition because such allotment and fee will be applied to all TPHs accessing CBOE Command via a CMI connection. The Exchange does not believe such proposed allotment and fee will cause an unnecessary burden on intermarket competition because different exchanges have different systemic setups for connection to such exchanges and are likely not comparable or competitive.

It is not within the Exchange's position to determine whether the proposed changes to the listings of the FINRA WebCRD SM will cause any unnecessary burden on competition, as the Exchange does not establish, assess or collect such fees (FINRA does). The Exchange merely lists such fees on its Fees Schedule. That said, such increased fees will apply to all market participants (as they did before), and, to the Exchange's knowledge, apply to all other exchanges as well.

The Exchange does not believe that the proposed lower Non-Standard Booth Rental Fees will cause an unnecessary burden on intramarket competition because they will apply to all market participants who rent Non-Standard Booths. The Exchange does not believe that such fees will cause an unnecessary burden on intermarket competition because, while they are designed to encourage booth rental on and around the Exchange trading floor, which could encourage market participants to rent booths on CBOE's trading floor instead of that of other exchanges, each exchange has a different setup for its trading floor (some exchanges do not have trading floors at all), which makes a competitive comparison difficult. Further, market participants on such other exchanges can always elect to trade on CBOE and rent such space here at CBOE.

The Exchange also notes that it operates in a highly-competitive market in which market participants can readily direct order flow to competing venues if they deem fee levels at a particular venue to be excessive. The proposed rule change reflects a competitive pricing structure designed to incent market participants to direct their order flow to the Exchange, and the Exchange believes that such structure will help the Exchange remain competitive with those fees and rebates assessed by other venues.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange neither solicited nor received comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A) of the Act [23] and paragraph (f) of Rule 19b–4 [24] thereunder. At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–CBOE–2013–002 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–CBOE–2013–002. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filing also will be available for inspection and copying at the principal offices of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–CBOE–2013–002, and should be submitted on or before February 15, 2013.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[25]

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2013–01496 Filed 1–24–13; 8:45 am]

BILLING CODE 8011–01–P

[23] 15 U.S.C. 78s(b)(3)(A).

[24] 17 CFR 240.19b–4(f).

[25] 17 CFR 200.30–3(a)(12).

SMALL BUSINESS ADMINISTRATION

Data Collection Available for Public Comments and Recommendations

ACTION: 60 Day Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, this notice announces the Small Business Administration's intentions to request approval on a new and/or currently approved information collection.

DATES: Submit comments on or before March 26, 2013.

ADDRESSES: Send all comments regarding whether this information

collection is necessary for the proper performance of the function of the agency, whether the burden estimates are accurate, and if there are ways to minimize the estimated burden and enhance the quality of the collections, to Gina, Supervisory Administrative Specialist, Office of Disaster, Small Business Administration, 409 3rd Street, 8th Floor, Washington, DC 20416.

FOR FURTHER INFORMATION CONTACT: Gina Beyer, Supervisor Administrative Specialist, 202–205–6458 *gina.beyer@sba.gov* Curtis B. Rich, Management Analyst, 202–205–7030 *curtis.rich@sba.gov.*

SUPPLEMENTARY INFORMATION: Disaster loans are authorized upon terms and conditions to (1) assure proper use of proceeds, (2) comply with established recordkeeping requirements, and (3) assure sound credit position. Recordkeeping requirements provide a basis to assure proper use of proceeds and satisfy loan conditions. Respondents are borrowers who must provide necessary certifications of the use of loan proceeds.

Title: ''Borrower's Progress Certification''.

Description of Respondents: Recipients of Disaster Loans.

Form Number: 1366.

Annual Responses: 66,959.

Annual Burden: 33,479.

Curtis Rich,

Management Analyst.

[FR Doc. 2013–01582 Filed 1–24–13; 8:45 am]

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SMALL BUSINESS ADMINISTRATION

Reporting and Recordkeeping Requirements Under OMB Review

AGENCY: Small Business Administration.

ACTION: Notice of Reporting Requirements Submitted for OMB Review.

SUMMARY: Under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35), agencies are required to submit proposed reporting and recordkeeping requirements to OMB for review and approval, and to publish a notice in the **Federal Register** notifying the public that the agency has made such a submission.

DATES: Submit comments on or before February 25, 2013. If you intend to comment but cannot prepare comments promptly, please advise the OMB Reviewer and the Agency Clearance Officer before the deadline.

Copies: Request for clearance (OMB 83–1), supporting statement, and other documents submitted to OMB for review may be obtained from the Agency Clearance Officer.

ADDRESSES: Address all comments concerning this notice to: *Agency Clearance Officer,* Curtis Rich, Small Business Administration, 409 3rd Street SW., 5th Floor, Washington, DC 20416; and *OMB Reviewer,* Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Curtis Rich, Agency Clearance Officer, *curtis.rich@sba.gov* (202) 205–7030.

SUPPLEMENTARY INFORMATION:

Title: ''Disaster Assistance Customer Satisfaction Survey''.

Frequency: On Occasion.

SBA Form Number: 2313.

Description of Respondents: Recipients of Disaster Loans.

Responses: 2,400.

Annual Burden: 199.

Curtis Rich,

Management Analyst.

[FR Doc. 2013–01580 Filed 1–24–13; 8:45 am]

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SMALL BUSINESS ADMINISTRATION

Military Reservist Economic Injury Disaster Loans; Interest Rate for Second Quarter FY 2013

In accordance with the Code of Federal Regulations 13—Business Credit and Assistance § 123.512, the following interest rate is effective for Military Reservist Economic Injury Disaster Loans approved on or after January 18, 2013.

Military Reservist Loan Program—4.000%

Dated: January 18, 2013.

James E. Rivera,

Associate Administrator for Disaster Assistance.

[FR Doc. 2013–01576 Filed 1–24–13; 8:45 am]

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DEPARTMENT OF STATE

[Public Notice 8161]

Culturally Significant Object Imported for Exhibition Determinations: ''Piero della Francesca in America''

SUMMARY: Notice is hereby given of the following determinations: Pursuant to the authority vested in me by the Act of October 19, 1965 (79 Stat. 985; 22 U.S.C. 2459), Executive Order 12047 of March 27, 1978, the Foreign Affairs Reform and Restructuring Act of 1998 (112 Stat. 2681, *et seq.;* 22 U.S.C. 6501 note, *et seq.*), Delegation of Authority No. 234 of October 1, 1999, Delegation of Authority No. 236–3 of August 28, 2000 (and, as appropriate, Delegation of Authority No. 257 of April 15, 2003), I hereby determine that the object to be included in the exhibition ''Piero della Francesca in America'' imported from abroad for temporary exhibition within the United States, is of cultural significance. The object is imported pursuant to a loan agreement with the foreign owner or custodian. I also determine that the exhibition or display of the exhibit object at The Frick Collection, New York, NY, from on or about February 12, 2013, until on or about May 19, 2013, and at possible additional exhibitions or venues yet to be determined, is in the national interest. I have ordered that Public Notice of these Determinations be published in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: For further information, including the art object list, contact Julie Simpson, Attorney-Adviser, Office of the Legal Adviser, U.S. Department of State (telephone: 202–632–6467). The mailing address is U.S. Department of State, SA–5, L/PD, Fifth Floor (Suite 5H03), Washington, DC 20522–0505.

Dated: January 17, 2013.

J. Adam Ereli,

Principal Deputy Assistant Secretary, Bureau of Educational and Cultural Affairs, Department of State.

[FR Doc. 2013–01551 Filed 1–24–13; 8:45 am]

BILLING CODE 4710–05–P

DEPARTMENT OF STATE

[Public Notice 8162]

Culturally Significant Objects Imported for Exhibition Determinations: ''SHANGAA, Art of Tanzania''

SUMMARY: Notice is hereby given of the following determinations: Pursuant to the authority vested in me by the Act of October 19, 1965 (79 Stat. 985; 22 U.S.C. 2459), Executive Order 12047 of March 27, 1978, the Foreign Affairs Reform and Restructuring Act of 1998 (112 Stat. 2681, *et seq.;* 22 U.S.C. 6501 note, *et seq.*), Delegation of Authority No. 234 of October 1, 1999, Delegation of Authority No. 236–3 of August 28, 2000 (and, as appropriate, Delegation of Authority No. 257 of April 15, 2003), I hereby determine that the objects to be included in the exhibition ''SHANGAA, Art of Tanzania,'' imported from abroad for temporary exhibition within the United States, are of cultural significance. The objects are imported

pursuant to loan agreements with the foreign owners or custodians. I also determine that the exhibition or display of the exhibit objects at QCC Art Gallery, Queensborough Community College, Bayside, NY, from on or about February 22, 2013, until on or about May 17, 2013; the Portland Museum of Art, Portland, Maine, from on or about June 8, 2013, until on or about August 25, 2013, and at possible additional exhibitions or venues yet to be determined, is in the national interest. I have ordered that Public Notice of these Determinations be published in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: For further information, including a list of the exhibit objects, contact Julie Simpson, Attorney-Adviser, Office of the Legal Adviser, U.S. Department of State (telephone: 202–632–6467). The mailing address is U.S. Department of State, SA–5, L/PD, Fifth Floor (Suite 5H03), Washington, DC 20522–0505.

Dated: January 17, 2013.

J. Adam Ereli,

Principal Deputy Assistant Secretary, Bureau of Educational and Cultural Affairs, Department of State.

[FR Doc. 2013–01546 Filed 1–24–13; 8:45 am]

BILLING CODE 4710–05–P

DEPARTMENT OF STATE

[Public Notice 8160]

Culturally Significant Objects Imported for Exhibition Determinations: ''Frida & Diego: Passion, Politics and Painting''

SUMMARY: Notice is hereby given of the following determinations: Pursuant to the authority vested in me by the Act of October 19, 1965 (79 Stat. 985; 22 U.S.C. 2459), Executive Order 12047 of March 27, 1978, the Foreign Affairs Reform and Restructuring Act of 1998 (112 Stat. 2681, *et seq.;* 22 U.S.C. 6501 note, *et seq.*), Delegation of Authority No. 2'34 of October 1, 1999, and Delegation of Authority No. 236–3 of August 28, 2000 (and, as appropriate, Delegation of Authority No. 257 of April 15, 2003), I hereby determine that the objects to be included in the exhibition ''Frida & Diego: Passion, Politics and Painting,'' imported from abroad for temporary exhibition within the United States, are of cultural significance. The objects are imported pursuant to loan agreements with the foreign owners or custodians. I also determine that the exhibition or display of the exhibit objects at The High Museum of Art in Atlanta, Georgia from on or about February 14, 2013, until on or about May 12, 2013, and at possible additional exhibitions or venues yet to be determined, is in the national interest. I have ordered that Public Notice of these Determinations be published in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: For further information, including a list of the exhibit objects, contact Ona M. Hahs, Attorney-Adviser, Office of the Legal Adviser, U.S. Department of State (telephone: 202–632–6473). The mailing address is U.S. Department of State, SA–5, L/PD, Fifth Floor (Suite 5H03), Washington, DC 20522–0505.

Dated: January 17, 2013.

J. Adam Ereli,

Principal Deputy Assistant Secretary, Bureau of Educational and Cultural Affairs, Department of State.

[FR Doc. 2013–01549 Filed 1–24–13; 8:45 am]

BILLING CODE 4710–05–P

SUSQUEHANNA RIVER BASIN COMMISSION

Public Hearing

AGENCY: Susquehanna River Basin Commission.

ACTION: Notice.

SUMMARY: The Susquehanna River Basin Commission will hold a public hearing on February 14, 2013, in Harrisburg, Pennsylvania. At this public hearing, the Commission will hear testimony on the projects listed in the Supplementary Information section of this notice. Such projects are intended to be scheduled for Commission action at its next business meeting, tentatively scheduled for March 21, 2013, which will be noticed separately. The public should take note that this public hearing will be the only opportunity to offer oral comment to the Commission for the listed projects. The deadline for the submission of written comments is February 25, 2013.

DATES: The public hearing will convene on February 14, 2013, at 1:00 p.m. The public hearing will end at 2:45 p.m. or at the conclusion of public testimony, whichever is sooner. The deadline for the submission of written comments is February 25, 2013.

ADDRESSES: The public hearing will be conducted at the Pennsylvania State Capitol, Room 8E–B, East Wing, Commonwealth Avenue, Harrisburg, Pa.

FOR FURTHER INFORMATION CONTACT: Richard A. Cairo, General Counsel, telephone: (717) 238–0423, ext. 306; fax: (717) 238–2436.

Information concerning the applications for these projects is available at the SRBC Water Resource Portal at *www.srbc.net/wrp.* Materials and supporting documents are available to inspect and copy in accordance with the Commission's Access to Records Policy at *www.srbc.net/pubinfo/docs/2009-02%20Access%20to%20Records%20Policy%209-10-09.PDF.*

Opportunity To Appear and Comment: Interested parties may appear at the hearing to offer comments to the Commission on any project listed below. The presiding officer reserves the right to limit oral statements in the interest of time and to otherwise control the course of the hearing. Ground rules will be posted on the Commission's web site, *www.srbc.net,* prior to the hearing for review. The presiding officer reserves the right to modify or supplement such rules at the hearing. Written comments on any project listed below may also be mailed to Mr. Richard Cairo, General Counsel, Susquehanna River Basin Commission, 1721 North Front Street, Harrisburg, Pa. 17102–2391, or submitted electronically through *http://www.srbc.net/pubinfo/publicparticipation.htm.* Comments mailed or electronically submitted must be received by the Commission on or before February 25, 2013, to be considered.

SUPPLEMENTARY INFORMATION: The public hearing will cover the following projects:

Projects Scheduled for Rescission Action

1. Project Sponsor: AES Westover, LLC. Project Facility: AES Westover Generating Station, Town of Union and Village of Johnson City, Broome County, N.Y. (Docket No. 20070902).
2. Project Sponsor and Facility: Clark Trucking, LLC Northeast Division (Lycoming Creek), Lewis Township, Lycoming County, Pa. (Docket No. 20111207).
3. Project Sponsor and Facility: Southwestern Energy Production Company (Tuscarora Creek), Tuscarora Township, Bradford County, Pa. (Docket No. 20110313).
4. Project Sponsor and Facility: EQT Production Company (Frano Freshwater Impoundment), Washington Township, Jefferson County, Pa. (Docket No. 20110913).

Projects Scheduled for Action

1. Project Sponsor and Facility: Anadarko E&P Company LP (West Branch Susquehanna River), Nippenose Township, Lycoming County, Pa. Application for renewal of surface water withdrawal of up to 0.720 mgd (peak day) (Docket No. 20090307).
2. Project Sponsor and Facility: Black Bear Waters, LLC (Lycoming Creek),

Lewis Township, Lycoming County, Pa. Modification to increase surface water withdrawal by an additional 0.500 mgd (peak day), for a total of 0.900 mgd (peak day) (Docket No. 20120303).

3. Project Sponsor and Facility: Caernarvon Township Authority, Caernarvon Township, Berks County, Pa. Application for renewal of groundwater withdrawal of up to 0.080 mgd (30-day average) from Well 6 (Docket No. 19820912).

4. Project Sponsor and Facility: Chesapeake Appalachia, LLC (Susquehanna River), Athens Township, Bradford County, Pa. Application for renewal of surface water withdrawal of up to 1.440 mgd (peak day) (Docket No. 20080906).

5. Project Sponsor and Facility: Chesapeake Appalachia, LLC (Susquehanna River), Mehoopany Township, Wyoming County, Pa. Application for renewal of surface water withdrawal of up to 0.999 mgd (peak day) (Docket No. 20080923).

6. Project Sponsor and Facility: Chesapeake Appalachia, LLC (Susquehanna River), Wysox Township, Bradford County, Pa. Application for renewal of surface water withdrawal of up to 0.999 mgd (peak day) (Docket No. 20080914).

7. Project Sponsor and Facility: Citrus Energy (Susquehanna River), Washington Township, Wyoming County, Pa. Application for renewal of surface water withdrawal of up to 1.994 mgd (peak day) (Docket No. 20081205).

8. Project Sponsor and Facility: Equipment Transport, LLC (Pine Creek), Gaines Township, Tioga County, Pa. Application for surface water withdrawal of up to 0.467 mgd (peak day).

9. Project Sponsor and Facility: Galeton Borough Water Authority, Galeton Borough, Potter County, Pa. Application for groundwater withdrawal of up to 0.288 mgd (30-day average) from the Germania Street Well.

10. Project Sponsor and Facility: Houtzdale Municipal Authority (Beccaria Springs), Gulich Township, Clearfield County, Pa. Application for surface water withdrawal of up to 5.000 mgd (peak day).

11. Project Sponsor and Facility: Hydro Recovery-Antrim LP, Duncan Township, Tioga County, Pa. Application for consumptive water use of up to 1.872 mgd (peak day).

12. Project Sponsor and Facility: Mark Manglaviti & Scott Kresge (Tunkhannock Creek), Tunkhannock Township, Wyoming County, Pa. Application for surface water withdrawal of up to 0.999 mgd (peak day).

13. Project Sponsor and Facility: Mountain Energy Services, Inc. (Tunkhannock Creek), Tunkhannock Township, Wyoming County, Pa. Modification to increase surface water withdrawal by an additional 0.499 mgd (peak day), for a total of 1.498 mgd (peak day) (Docket No. 20100309).

14. Project Sponsor: Perdue Grain and Oilseed, LLC. Project Facility: Perdue Soybean Crush Plant, Conoy Township, Lancaster County, Pa. Application for consumptive water use of up to 0.300 mgd (peak day).

15. Project Sponsor: Perdue Grain and Oilseed, LLC. Project Facility: Perdue Soybean Crush Plant, Conoy Township, Lancaster County, Pa. Application for groundwater withdrawal of up to 0.028 mgd (30-day average) from Well AP–2.

16. Project Sponsor: R.R. Donnelley & Sons Company. Project Facility: West Plant, City of Lancaster, Lancaster County, Pa. Modification to increase consumptive water use by an additional 0.019 mgd (peak day), for a total of 0.099 mgd (peak day) (Docket No. 19910702).

17. Project Sponsor and Facility: Talisman Energy USA Inc. (Sugar Creek), West Burlington Township, Bradford County, Pa. Application for renewal of surface water withdrawal of up to 2.000 mgd (peak day) (Docket No. 20090327).

18. Project Sponsor and Facility: Talisman Energy USA Inc. (Towanda Creek—Franklin Township Volunteer Fire Department), Franklin Township, Bradford County, Pa. Application for renewal of surface water withdrawal of up to 2.000 mgd (peak day) (Docket No. 20081210).

19. Project Sponsor and Facility: Titanium Metals Corporation (TIMET), Caernarvon Township, Berks County, Pa. Modification to increase consumptive water use by an additional 0.044 mgd (peak day), for a total of 0.177 mgd (peak day) (Docket No. 20080616).

20. Project Sponsor and Facility: Ultra Resources, Inc. (Cowanesque River), Deerfield Township, Tioga County, Pa. Application for renewal of surface water withdrawal of up to 0.217 mgd (peak day) (Docket No. 20081229).

21. Project Sponsor and Facility: Ultra Resources, Inc. (Pine Creek), Pike Township, Potter County, Pa. Application for renewal of surface water withdrawal of up to 0.936 mgd (peak day) (Docket No. 20090332).

22. Project Sponsor and Facility: WPX Energy Appalachia, LLC (Susquehanna River), Great Bend Township, Susquehanna County, Pa. Application for renewal of surface water withdrawal of up to 1.000 mgd (peak day) (Docket No. 20090303).

Authority: Pub. L. 91–575, 84 Stat. 1509 *et seq.,* 18 CFR parts 806–808.

Dated: January 11, 2013.

Thomas W. Beauduy,

Deputy Executive Director.

[FR Doc. 2013–01499 Filed 1–24–13; 8:45 am]

BILLING CODE 7040–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Twenty-First Meeting: RTCA Special Committee 213, Enhanced Flight Vision Systems/Synthetic Vision Systems (EFVS/SVS)

AGENCY: Federal Aviation Administration (FAA), U.S. Department of Transportation (DOT).

ACTION: Meeting Notice of RTCA Special Committee 213, Enhanced Flight Vision Systems/Synthetic Vision Systems (EFVS/SVS).

SUMMARY: The FAA is issuing this notice to advise the public of the twenty-first meeting of the RTCA Special Committee 213, Enhanced Flight Vision Systems/Synthetic Vision Systems (EFVS/SVS).

DATES: The meeting will be held February 5–7, 2013 from 9:00 a.m.–5:00 p.m. on the first two days and from 9:00 a.m.–3:00 p.m. on the last day.

ADDRESSES: The meeting will be held in the Oak Ballroom of the Radisson Suite Hotel Oceanfront, 3101 North Highway A1A, Melbourne, FL, 32903, telephone (321) 773–9260.

FOR FURTHER INFORMATION CONTACT: The RTCA Secretariat, 1150 18th Street NW., Suite 910, Washington, DC 20036, or telephone at (202) 833–9339, fax at (202) 833–9434, or Web site at *http://www.rtca.org.* Alternately, contact Jennifer Iversen of RTCA at (202) 330–0662, email *jiversen@rtca.org,* Tim Etherington at (319) 295–5233, email *tjetheri@rockwellcollins.com,* or Patrick Krohn at (425) 602–1375, email *pkrohn@uasc.com.*

SUPPLEMENTARY INFORMATION: Pursuant to section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463, 5 U.S.C., App.), notice is hereby given for a meeting of Special Committee 213. The agenda will include the following:

Tuesday, February 5, 2013

Plenary Discussion

- Introductions and administrative items
- Review and approve minutes from last full plenary meeting

- Review of terms of reference
- Status of DO–341A and DO–315C
- DO–315C and DO–341A review

Wednesday, February 6, 2013

Plenary Discussion

- WG–1 DO–315C review
- WG–2 DO–341A review

Thursday, February 7, 2013

Plenary Discussion

- WG–1 DO–315C review
- WG–2 DO–341A review
- Administrative items
- Adjourn

Attendance is open to the interested public but limited to space availability. With the approval of the chairman, members of the public may present oral statements at the meeting. Persons wishing to present statements or obtain information should contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section. Members of the public may present a written statement to the committee at any time.

Issued in Washington, DC, on January 10, 2013.

Richard F. Gonzalez

Management Analyst, Business Operations Group, ANG–A12, NAS Business Solutions, NextGen Office.

[FR Doc. 2013–01380 Filed 1–24–13; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket No. FMCSA–2008–0362]

Medical Review Board Public Meeting

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), DOT.

ACTION: Notice of Medical Review Board (MRB) public meeting.

SUMMARY: FMCSA announces that the Medical Review Board (MRB) will meet on February 13, 2013. The MRB will review an evidence report about fatigue-related research concerning bus and motorcoach drivers to identify relevant scientific and medical studies the Agency could rely upon in making any future decisions about the HOS requirements applicable to such drivers. The meeting is open to the public and there will be a public comment period at the end of the day.

Times and Dates: The meeting will be held on Wednesday, February 13, 2013, from 9 a.m. to 5 p.m., Eastern Standard Time (E.S.T.). The meeting will be held at the Hilton Alexandria Old Town, 1767 King Street, Alexandria, VA 22314 in Salon BC on the main floor. The Hilton Alexandria Old Town is located across the street from the King Street Metro station.

An agenda for the meeting will be made available in advance of the meeting at *http://mrb.fmcsa.dot.gov.*

FOR FURTHER INFORMATION CONTACT: Angela Ward, R.N., Nurse Consultant, Medical Programs Division, Federal Motor Carrier Safety Administration, 1200 New Jersey Avenue SE., Washington, DC 20590, (202) 366–4001, *fmcsamedical@dot.gov.*

Services for Individuals With Disabilities

For information on facilities or services for individuals with disabilities or to request special assistance at the meeting, contact Angela Ward at (202) 366–4001 or at *fmcsamedical@dot.gov* by Tuesday, February 5, 2013.

SUPPLEMENTARY INFORMATION:

I. Background

MRB

The Medical Review Board (MRB) is comprised of five medical experts who serve staggered, 2-year terms. The U.S. Secretary of Transportation announced those currently serving on the MRB on November 2, 2010, and June 13, 2012. Section 4116 of the Safe, Accountable, Flexible, Efficient Transportation Equity Act: A Legacy for Users (SAFETEA–LU), [Pub. L. 109–59, 119 Stat. 1144, Aug. 10, 2005] requires the Secretary of Transportation, with the advice of the MRB and the chief medical examiner, to establish, review, and revise ''medical standards for operators of commercial motor vehicles that will ensure that the physical condition of operators of commercial motor vehicles is adequate to enable them to operate the vehicles safely.''

The MRB operates in accordance with the Federal Advisory Committee Act (FACA) as announced in the **Federal Register** (70 FR 57642, October 3, 2005). The MRB is charged initially with the review of all current FMCSA medical standards (49 CFR 391.41), as well as proposing new science-based standards and guidelines to ensure that drivers operating commercial motor vehicles (CMVs) in interstate commerce, as defined in 49 CFR 390.5, are physically capable of doing so.

II. Meeting Participation

The entire meeting of the MRB is open to the public. Oral comments on the topic from the public will be heard during the last hour (3:45 p.m. to 4:45 p.m.) of the meeting. Oral comments may be limited and will be accepted on a first come, first serve basis as requestors register at the meeting. Should all public comments be exhausted prior to the end of the specified period, the comment period will close. Members of the public may submit written comments to the Federal Docket Management System (FDMS) on this topic by Tuesday, February 5, 2013. You may submit written comments bearing the Federal Docket Management System (FDMS) Docket ID FMCSA–2008–0362 using any of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov.* Follow the on-line instructions for submitting comments.
- *Mail*: Docket Management Facility; U.S. Department of Transportation, 1200 New Jersey Avenue SE., West Building, Room W12–140, Washington, DC 20003–3302.
- *Hand Delivery:* West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m. ET., Monday through Friday, except Federal holidays.
- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov.* Follow the online instructions for submitting comments.
- *Fax:* 1–202–493–2251.

Instructions: Each submission must include the Agency name and FDMS Docket ID for this Notice. Note that DOT posts all comments without change to *http://www.regulations.gov,* including any personal information included in a comment. Please see the Privacy Act heading below for further information.

Docket: For access to the docket to read background documents or comments received, go to *http://www.regulations.gov* at any time or Room W12–140 on the ground level of the West Building, 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m. ET, Monday through Friday, except Federal holidays. The FDMS is available 24 hours each day, 365 days each year. If you want acknowledgment that we received your comments, please include a self-addressed, stamped envelope or postcard or print the acknowledgement page that appears after submitting comments on-line.

Privacy Act: Anyone may search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or of the person signing the comment, if submitted on behalf of an association, business, labor union, etc.).

You may review the DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000

(65 FR 19477). This information is also available at *http://www.regulations.gov.*

Issued on: January 18, 2013.

Larry W. Minor,

Associate Administrator of Policy.

[FR Doc. 2013–01510 Filed 1–24–13; 8:45 am]

BILLING CODE 4910–EX–P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[FMCSA Docket No. FMCSA–2012–0348]

Qualification of Drivers; Exemption Applications; Diabetes Mellitus

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), DOT

ACTION: Notice of final disposition.

SUMMARY: FMCSA announces its decision to exempt 26 individuals from its rule prohibiting persons with insulin-treated diabetes mellitus (ITDM) from operating commercial motor vehicles (CMVs) in interstate commerce. The exemptions will enable these individuals to operate CMVs in interstate commerce.

DATES: The exemptions are effective January 25, 2013. The exemptions expire on January 26, 2015.

FOR FURTHER INFORMATION CONTACT: Elaine M. Papp, Chief, Medical Programs Division, (202) 366–4001, *fmcsamedical@dot.gov,* FMCSA, Room W64–224, Department of Transportation, 1200 New Jersey Avenue SE., Washington, DC 20590–0001. Office hours are from 8:30 a.m. to 5 p.m., Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION:

Electronic Access

You may see all the comments online through the Federal Document Management System (FDMS) at: *http://www.regulations.gov.*

Docket: For access to the docket to read background documents or comments, go to *http://www.regulations.gov* and/or Room W12–140 on the ground level of the West Building, 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

Privacy Act: Anyone may search the electronic form of all comments received into any of DOT's dockets by the name of the individual submitting the comment (or of the person signing the comment, if submitted on behalf of an association, business, labor union, or other entity). You may review DOT's Privacy Act Statement for the Federal Docket Management System (FDMS) published in the **Federal Register** on December 29, 2010 (75 FR 82132), or you may visit *http://www.gpo.gov/fdsys/pkg/FR–2010–12–29/pdf/2010–32876.pdf.*

Background

On November 26, 2012, FMCSA published a notice of receipt of Federal diabetes exemption applications from 26 individuals and requested comments from the public (77 FR 70530). The public comment period closed on December 26, 2012, and no comments were received.

FMCSA has evaluated the eligibility of the 26 applicants and determined that granting the exemptions to these individuals would achieve a level of safety equivalent to or greater than the level that would be achieved by complying with the current regulation 49 CFR 391.41(b)(3).

Diabetes Mellitus and Driving Experience of the Applicants

The Agency established the current requirement for diabetes in 1970 because several risk studies indicated that drivers with diabetes had a higher rate of crash involvement than the general population. The diabetes rule provides that ''A person is physically qualified to drive a commercial motor vehicle if that person has no established medical history or clinical diagnosis of diabetes mellitus currently requiring insulin for control'' (49 CFR 391.41(b)(3)).

FMCSA established its diabetes exemption program, based on the Agency's July 2000 study entitled ''A Report to Congress on the Feasibility of a Program to Qualify Individuals with Insulin-Treated Diabetes Mellitus to Operate in Interstate Commerce as Directed by the Transportation Act for the 21st Century.'' The report concluded that a safe and practicable protocol to allow some drivers with ITDM to operate CMVs is feasible. The September 3, 2003 (68 FR 52441), **Federal Register** notice in conjunction with the November 8, 2005 (70 FR 67777), **Federal Register** notice provides the current protocol for allowing such drivers to operate CMVs in interstate commerce.

These 26 applicants have had ITDM over a range of 1 to 24 years. These applicants report no severe hypoglycemic reactions resulting in loss of consciousness or seizure, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning symptoms, in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the past 5 years. In each case, an endocrinologist verified that the driver has demonstrated a willingness to properly monitor and manage his/her diabetes mellitus, received education related to diabetes management, and is on a stable insulin regimen. These drivers report no other disqualifying conditions, including diabetes-related complications. Each meets the vision requirement at 49 CFR 391.41(b)(10).

The qualifications and medical condition of each applicant were stated and discussed in detail in the November 26, 2012, **Federal Register** notice and they will not be repeated in this notice.

Discussion of Comments

FMCSA received no comments in this proceeding.

Basis for Exemption Determination

Under 49 U.S.C. 31136(e) and 31315, FMCSA may grant an exemption from the diabetes requirement in 49 CFR 391.41(b)(3) if the exemption is likely to achieve an equivalent or greater level of safety than would be achieved without the exemption. The exemption allows the applicants to operate CMVs in interstate commerce.

To evaluate the effect of these exemptions on safety, FMCSA considered medical reports about the applicants' ITDM and vision, and reviewed the treating endocrinologists' medical opinion related to the ability of the driver to safely operate a CMV while using insulin.

Consequently, FMCSA finds that in each case exempting these applicants from the diabetes requirement in 49 CFR 391.41(b)(3) is likely to achieve a level of safety equal to that existing without the exemption.

Conditions and Requirements

The terms and conditions of the exemption will be provided to the applicants in the exemption document and they include the following: (1) That each individual submit a quarterly monitoring checklist completed by the treating endocrinologist as well as an annual checklist with a comprehensive medical evaluation; (2) that each individual reports within 2 business days of occurrence, all episodes of severe hypoglycemia, significant complications, or inability to manage diabetes; also, any involvement in an accident or any other adverse event in a CMV or personal vehicle, whether or not it is related to an episode of hypoglycemia; (3) that each individual provide a copy of the ophthalmologist's or optometrist's report to the medical

examiner at the time of the annual medical examination; and (4) that each individual provide a copy of the annual medical certification to the employer for retention in the driver's qualification file, or keep a copy in his/her driver's qualification file if he/she is self-employed. The driver must also have a copy of the certification when driving, for presentation to a duly authorized Federal, State, or local enforcement official.

Conclusion

Based upon its evaluation of the 26 exemption applications, FMCSA exempts Kenneth R. Anderson (AL), Randle A. Badertscher (WY), Gerald R. Bryson (MT), Matthew J. Burris (MN), Samuel F. Dyer (NV), Jerol G. Fox (DE), Michael S. Freeman (OR), Harold D. Grimes (MI), Daniel L. Helton (IL), Douglas W. Hunderman (MI), Robert L. Johnson (VA), Kevin R. Martin (MO), George R. Miller, III (PA), Ronald G. Monroe (IN), Ronald D. Norton (WI), Lawrence E. Olson (WA), Israel Ramos (NY), Jed Ramsey (ID), Raymond E. Richardson (MD), Craig W. Schafer (DE), Stephen L. Schug (FL), Shawn M. Seeley (CT), Mark S. Shepherd (MA), L. Everett Stamper (IN), Vernon F. Walters (ID), and Christopher M. Young (OK) from the ITDM requirement in 49 CFR 391.41(b)(3), subject to the conditions listed under ''Conditions and Requirements'' above.

In accordance with 49 U.S.C. 31136(e) and 31315 each exemption will be valid for two years unless revoked earlier by FMCSA. The exemption will be revoked if the following occurs: (1) The person fails to comply with the terms and conditions of the 1/exemption; (2) the exemption has resulted in a lower level of safety than was maintained before it was granted; or (3) continuation of the exemption would not be consistent with the goals and objectives of 49 U.S.C. 31136(e) and 31315. If the exemption is still effective at the end of the 2-year period, the person may apply to FMCSA for a renewal under procedures in effect at that time.

Issued on: January 18, 2013.

Larry W. Minor,

Associate Administrator for Policy.

[FR Doc. 2013–01512 Filed 1–24–13; 8:45 am]

BILLING CODE 4910–EX–P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

[Docket No. NHTSA–2012–0110; Notice 1]

Ford Motor Company, Receipt of Petition for Decision of Inconsequential Noncompliance

AGENCY: National Highway Traffic Safety Administration, DOT.

ACTION: Receipt of Petition.

SUMMARY: Ford Motor Company [1] (Ford) has determined that certain model year 2009–2012 Ford F–650 and F–750 trucks manufactured between June 26, 2008 and May 8, 2012, do not fully comply with paragraph S5.3.2(a) of Federal Motor Vehicle Safety Standard (FMVSS) No. 105, *Hydraulic and Electric Brake Systems.* Ford has filed an appropriate report pursuant to 49 CFR part 573, *Defect and Noncompliance Responsibility and Reports* (dated July 2, 2012).

Pursuant to 49 U.S.C. 30118(d) and 30120(h) (see implementing rule at 49 CFR part 556), Ford has petitioned for an exemption from the notification and remedy requirements of 49 U.S.C. Chapter 301 on the basis that this noncompliance is inconsequential to motor vehicle safety.

This notice of receipt of Ford's petition is published under 49 U.S.C. 30118 and 30120 and does not represent any agency decision or other exercise of judgment concerning the merits of the petition.

Vehicles Involved: Affected are approximately 19,756 model year 2009–2012 Ford F–650 and F–750 trucks that were manufactured between June 26, 2008 and May 8, 2012.

NHTSA notes that the statutory provisions (49 U.S.C. 30118(d) and 30120(h)) that permit manufacturers to file petitions for a determination of inconsequentiality allow NHTSA to exempt manufacturers only from the duties found in sections 30118 and 30120, respectively, to notify owners, purchasers, and dealers of a defect or noncompliance and to remedy the defect or noncompliance. Therefore, these provisions only apply to the 19,756 [2] model year 2009–2012 Ford F–650 and F–750 passenger vehicles that Ford no longer controlled at the time it determined that the noncompliance existed.

Noncompliance: Ford explains that the noncompliance is that the subject vehicles do not illuminate the parking brake telltale lamp when the ignition switch is in the ''on'' or ''start'' positions as required by FMVSS No. 105.

Rule Text

Paragraph S5.3.2(a) of FMVSS No. 105 requires:

S5.3.2(a) Except as provided in paragraph (b) of this section, all indicator lamps shall be activated as a check of lamp function either when the ignition (start) switch is turned to the ''on'' (run) position when the engine is not running, or when the ignition (start) switch is in a position between ''on'' (run) and ''start'' that is designated by the manufacturer as a check position.

Summary of Ford's Analysis and Arguments

Ford stated its belief that although the affected vehicles do not illuminate the parking brake telltale lamp when the ignition start switch is in the ''on'' or ''start'' positions that the condition is inconsequential to motor vehicle safety for the following reasons:

(1) The parking brake telltale lamp functions as intended. Only the telltale bulb check at start-up is not illuminated.

(2) Unlike most other telltales, the park brake telltale will simultaneously illuminate when the customer applies the handbrake—essentially functioning as a bulb check. And, if the lamp does not illuminate when the handbrake is applied, the customer is able to identify the condition.

(3) If customers inadvertently operate the vehicle with the parking brake applied, the service brakes will not be affected because the design of the subject vehicles utilizes a separate, dedicated parking brake mounted on the driveshaft. Additionally, inadvertent application of the parking brake will result in poor vehicle acceleration and ''drag'' providing further indications that the parking brake is engaged.

(4) Instrument panel telltale bulbs are highly reliable. Engineering has reported no parking telltale bulb warranty claims for the subject vehicles.

(5) The physical position of the parking brake handle provides a readily apparent indication when the parking brake is applied. Partial park brake applications are not a concern because

[1] Ford Motor Company is a manufacturer of motor vehicles and is registered under the laws of the State of Delaware.

[2] Ford's petition, which was filed under 49 CFR Part 556, requests an agency decision to exempt Ford as a vehicle manufacturer from the notification and recall responsibilities of 49 CFR Part 573 for 19,756 of the affected vehicles. However, a decision on this petition cannot relieve vehicle distributors and dealers of the prohibitions on the sale, offer for sale, introduction or delivery for introduction into interstate commerce of the noncompliant vehicles under their control after Ford notified them that the subject noncompliance existed.

the handle mechanism utilizes an over-cam locking design, which assures the parking brake is either fully applied or fully released. This design precludes a parking brake from being partially applied.

(6) The subject vehicles incorporate a warning chime which activates (in addition to the parking brake telltale) when the parking brake is applied and the vehicle is driven over 4 miles-per-hour.

(7) Ford is unaware of any field or owner complaints or injuries regarding the subject noncompliance.

In summation, Ford believes that the described noncompliance of its vehicles is inconsequential to motor vehicle safety, and that its petition, to exempt it from providing recall notification of noncompliance as required by 49 U.S.C. 30118 and remedying the recall noncompliance as required by 49 U.S.C. 30120 should be granted.

Comments: Interested persons are invited to submit written data, views, and arguments on this petition. Comments must refer to the docket and notice number cited at the beginning of this notice and be submitted by any of the following methods:

a. *By mail addressed to:* U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590.

b. By hand delivery to U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590. The Docket Section is open on weekdays from 10 a.m. to 5 p.m. except Federal Holidays.

c. *Electronically:* By logging onto the Federal Docket Management System (FDMS) Web site at *http://www.regulations.gov/*. Follow the online instructions for submitting comments. Comments may also be faxed to 1–202–493–2251.

Comments must be written in the English language, and be no greater than 15 pages in length, although there is no limit to the length of necessary attachments to the comments. If comments are submitted in hard copy form, please ensure that two copies are provided. If you wish to receive confirmation that your comments were received, please enclose a stamped, self-addressed postcard with the comments. Note that all comments received will be posted without change to *http://www.regulations.gov,* including any personal information provided.

Documents submitted to a docket may be viewed by anyone at the address and times given above. The documents may also be viewed on the Internet at *http://www.regulations.gov* by following the online instructions for accessing the dockets. DOT's complete Privacy Act Statement is available for review in the **Federal Register** published on April 11, 2000, (65 FR 19477–78).

The petition, supporting materials, and all comments received before the close of business on the closing date indicated below will be filed and will be considered. All comments and supporting materials received after the closing date will also be filed and will be considered to the extent possible. When the petition is granted or denied, notice of the decision will be published in the **Federal Register** pursuant to the authority indicated below.

DATES: Comment closing date: February 25, 2013.

Authority: 49 U.S.C. 30118, 30120: Delegations of authority at CFR 1.95 and 501.8.

Claude H. Harris,

Director, Office of Vehicle Safety Compliance.

[FR Doc. 2013–01578 Filed 1–24–13; 8:45 am]

BILLING CODE 4910–59–P

DEPARTMENT OF THE TREASURY

Proposed Collection; Comment Request; Office of the Fiscal Assistant Secretary

AGENCY: Departmental Offices, Department of Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3506(c)(2)(A)). Currently, the Office of the Fiscal Assistant Secretary (OFAS), within the Department of the Treasury, is soliciting comments concerning the Annual Performance Report and Certification for Section 1603.

DATES: Written comments must be received on or before March 26, 2013 to be assured of consideration.

ADDRESSES: Direct all written comments to the Department of the Treasury, Departmental Offices, OFAS, ATTN: Jean Whaley, 1500 Pennsylvania Avenue NW., Rm. 1050–S, Washington, DC 20220, (202) 622–0637; *www.1603questions@treasury.gov.*

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the form(s) and instructions should be directed to the Department of the Treasury, Departmental Offices, OFAS, ATTN: Jean Whaley, 1500 Pennsylvania Avenue NW., Rm. 1050–S, Washington, DC 20220, (202) 622–0637; *www.1603questions@treasury.gov.*

SUPPLEMENTARY INFORMATION:

Title: Annual Performance Report and Certification for Section 1603: Payments for Specified Renewable Energy Property in Lieu of Tax Credits.

OMB Number: 1505–0221.

Abstract: Authorized under the American Recovery and Reinvestment Act (ARRA), of 2009 (Pub. L. 111–5), the Department of the Treasury is implementing several provisions of the Act, more specifically Division B—Tax, Unemployment, Health, State Fiscal Relief, and Other Provisions. Among these components is a program which requires Treasury, in lieu of a tax credit, to reimburse persons who place in service certain specified energy properties. The collection of information is necessary to properly monitor compliance with program requirements. Applicants for Section 1603 payments commit in the Terms and Conditions that are part of the application to submitting an annual report for five years from the date the energy property is placed in service. The information will be used to (1) determine whether payment recipients remain eligible, (2) determine that the amount of the 1603 payment remains allowable under applicable laws, (3) assess compliance with applicable laws, and (4) report on the effectiveness of the program.

Type of Review: Revision of a currently approved collection.

Affected Public: State, Local, and Tribal Governments.

Estimated Number of Annual Respondents: 150,000.

Estimated Hours per Response: 0.25.

Estimated Total Annual Burden Hours: 37,500.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the

information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Dated: January 22, 2013.

Dawn D. Wolfgang,

Treasury PRA Clearance Officer.

[FR Doc. 2013–01569 Filed 1–24–13; 8:45 am]

BILLING CODE 4810–25–P

DEPARTMENT OF THE TREASURY

Office of Foreign Assets Control

Additional Designations, Foreign Narcotics Kingpin Designation Act

AGENCY: Office of Foreign Assets Control, Treasury.

ACTION: Notice.

SUMMARY: The U.S. Department of the Treasury 's Office of Foreign Assets Control (''OFAC'') is publishing the names of eight individuals and four entities whose property and interests in property have been blocked pursuant to the Foreign Narcotics Kingpin Designation Act (''Kingpin Act'') (21 U.S.C. 1901–1908, 8 U.S.C. 1182).

DATES: The designation by the Director of OFAC of the eight individuals and four entities identified in this notice pursuant to section 805(b) of the Kingpin Act is effective on January 17, 2013.

FOR FURTHER INFORMATION CONTACT: Assistant Director, Sanctions Compliance & Evaluation, Office of Foreign Assets Control, U.S. Department of the Treasury, Washington, DC 20220, Tel: (202) 622–2490.

SUPPLEMENTARY INFORMATION:

Electronic and Facsimile Availability

This document and additional information concerning OFAC are available on OFAC's Web site at *http://www.treasury.gov/ofac* or via facsimile through a 24-hour fax-on-demand service at (202) 622–0077.

Background

The Kingpin Act became law on December 3, 1999. The Kingpin Act establishes a program targeting the activities of significant foreign narcotics traffickers and their organizations on a worldwide basis. It provides a statutory framework for the imposition of sanctions against significant foreign narcotics traffickers and their organizations on a worldwide basis, with the objective of denying their businesses and agents access to the U.S. financial system and the benefits of trade and transactions involving U.S. companies and individuals.

The Kingpin Act blocks all property and interests in property, subject to U.S. jurisdiction, owned or controlled by significant foreign narcotics traffickers as identified by the President. In addition, the Secretary of the Treasury, in consultation with the Attorney General, the Director of the Central Intelligence Agency, the Director of the Federal Bureau of Investigation, the Administrator of the Drug Enforcement Administration, the Secretary of Defense, the Secretary of State, and the Secretary of Homeland Security may designate and block the property and interests in property, subject to U.S. jurisdiction, of persons who are found to be: (1) Materially assisting in, or providing financial or technological support for or to, or providing goods or services in support of, the international narcotics trafficking activities of a person designated pursuant to the Kingpin Act; (2) owned, controlled, or directed by, or acting for or on behalf of, a person designated pursuant to the Kingpin Act; or (3) playing a significant role in international narcotics trafficking.

On January 17, 2013, the Director of OFAC designated the following eight individuals and four entities whose property and interests in property are blocked pursuant to section 805(b) of the Kingpin Act.

Individuals

1. CHAN INZUNA, Araceli; DOB 08 Feb 1985; POB Mazatlan, Sinaloa, Mexico; nationality Mexico; Passport 03040074084 (Mexico) (individual) [SDNTK].
2. FLORES APODACA, Augustin (a.k.a. ''EL BARBON''; a.k.a. ''EL INGENIERO''; a.k.a. ''EL NINO''), Calle Sierra Madre Occidental No. 1280, Colonia Canadas, Culiacan, Sinaloa 8000, Mexico; DOB 09 Jun 1964; POB Sinaloa, Mexico; Passport 040070827 (Mexico) (individual) [SDNTK].
3. FLORES APODACA, Angelina; DOB 21 Jul 1958; POB Guasave, Sinaloa, Mexico; Passport 040068785 (Mexico) (individual) [SDNTK].
4. FLORES APODACA, Panfilo; DOB 01 Jun 1969; POB Guasave, Sinaloa, Mexico; Passport G00527961 (Mexico) (individual) [SDNTK].
5. MEZA FLORES, Fausto Isidro (a.k.a. ''ISIDRO, Chapito''; a.k.a. ''ISIDRO, Chapo''); DOB 19 Jun 1982; POB Navojoa, Sinaloa, Mexico; nationality Mexico; Passport 07040028724 (Mexico) (individual) [SDNTK] (Linked To: AUTOTRANSPORTES TERRESTRES S.A. DE C.V.; Linked To: AUTO SERVICIO JATZIRY S.A. DE C.V.; Linked To: CONSTRUCTORA JATZIRY DE GUASAVE S.A. DE C.V.).
6. MEZA FLORES, Salome (a.k.a. ''FINO''; a.k.a. ''PELON''); DOB 23 Oct 1962; POB Guasave, Sinaloa, Mexico; nationality Mexico; Passport 07040059504 (Mexico) (individual) [SDNTK].
7. MEZA ANGULO, Fausto Isidro; DOB 19 Jun 1982; Passport 07040028724 (individual) [SDNTK].
8. MEZA FLORES, Flor Angely; DOB 20 Sep 1989; POB Guasave, Sinaloa, Mexico; nationality Mexico; Passport 040068790 (Mexico) (individual) [SDNTK].

Entities

1. AUTO SERVICIO JATZIRY S.A. DE C.V., Callejon Tercero SN, Col. Centro, Guasave, Sinaloa, Mexico; Registration ID 12577 (Mexico) [SDNTK] (Linked To: MEZA FLORES, Fausto Isidro).
2. AUTOTRANSPORTES TERRESTRES S.A. DE C.V., Callejon Tercero SN, Col. Centro, Guasave, Sinaloa, Mexico [SDNTK] (Linked To: MEZA FLORES, Fausto Isidro).
3. CONSTRUCTORA JATZIRY DE GUASAVE S.A. DE C.V., Callejon Tercero SN, Col. Centro, Guasave, Sinaloa, Mexico; Registration ID 13554 [SDNTK] (Linked To: MEZA FLORES, Fausto Isidro).
4. MEZA FLORES DRUG TRAFFICKING ORGANIZATION, Mexico [SDNTK].

Dated: January 17, 2013.

Adam J. Szubin,

Director, Office of Foreign Assets Control.

[FR Doc. 2013–01538 Filed 1–24–13; 8:45 am]

BILLING CODE 4810–AL–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for Form 8872

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed

and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3506(c)(2)(A)). Currently, the IRS is soliciting comments concerning Form 8872, Political Organization Report of Contributions and Expenditures.

DATES: Written comments should be received on or before March 26, 2013 to be assured of consideration.

ADDRESSES: Direct all written comments to Yvette Lawrence, Internal Revenue Service, Room 6129, 1111 Constitution Avenue NW., Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the form and instructions should be directed to Martha R. Brinson at Internal Revenue Service, Room 6129, 1111 Constitution Avenue NW., Washington, DC 20224, (202)–622–3869, or through the Internet at *Martha.R.Brinson@irs.gov.*

SUPPLEMENTARY INFORMATION:

Title: Political Organization Report of Contributions and Expenditures.

OMB Number: 1545–1696.

Form Number: 8872.

Abstract: Internal Revenue Code section 527(j) requires certain political organizations to report contributions received and expenditures made after July 1, 2000. Every section 527 political organization that accepts a contribution or makes an expenditure for an exempt function during the calendar year must file Form 8872 except for: A political organization that is not required to file Form 8871, or a state or local committee of a political party or political committee of a state or local candidate.

Current Actions: There are no changes being made to the form at this time.

Type of Review: Extension of a currently approved collection.

Affected Public: Not-for-profit institutions.

Estimated Number of Respondents: 40,000.

Estimated Time per Response: 10 hours, 47 minutes.

Estimated Total Annual Burden Hours: 431,200.

The following paragraph applies to all of the collections of information covered by this notice:

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: January 17, 2013.

Yvette Lawrence,

IRS Reports Clearance Officer.

[FR Doc. 2013–01524 Filed 1–24–13; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF VETERANS AFFAIRS

Privacy Act of 1974; Report of Matching Program

AGENCY: Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: The Department of Veterans Affairs (VA) provides notice that it intends to conduct a recurring computer-matching program matching Social Security Administration (SSA) income data from the Earnings Recording and Self-Employment Income System (also referred to as the Master Earnings File (MEF)) with VA pension, compensation, and parents' dependency and indemnity compensation records. The purpose of this match is to identify applicants and beneficiaries who have applied for or who are receiving VA benefits and received earned income, and to adjust or terminate VA benefits, if appropriate.

DATES: The match will start no sooner than 30 days after publication of this notice in the **Federal Register** or 40 days after copies of this notice and the agreement of the parties are submitted to Congress and the Office of Management and Budget, whichever is later, and end not more than 18 months after the agreement is properly implemented by the parties. The involved agencies' Data Integrity Boards (DIB) may extend this match for 12 months provided the agencies certify to their DIBs, within 3 months of the ending date of the original match, that the matching program will be conducted without change and that the matching program has been conducted in compliance with the original matching program.

ADDRESSES: Written comments may be submitted through *www.Regulations.gov;* by mail or hand-delivery to the Director, Regulations Management (02REG), Department of Veterans Affairs, 810 Vermont Ave. NW., Room 1068, Washington, DC 20420; or by fax to (202) 273–9026. Copies of comments received will be available for public inspection in the Office of Regulation Policy and Management, Room 1063B, between the hours of 8:00 a.m. and 4:30 p.m., Monday through Friday (except holidays). Please call (202) 461–4902 for an appointment. In addition, during the comment period, comments may be viewed online through the Federal Docket Management System (FDMS) at *www.Regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Sharon Nicely, Pension Analyst, Pension and Fiduciary Service (21PF), Department of Veterans Affairs, 810 Vermont Ave. NW., Washington, DC 20420, (202) 632–8863.

SUPPLEMENTARY INFORMATION: VA plans to match records of applicants and beneficiaries, including veterans and survivors, and their eligible dependent(s), who have applied for or who are receiving needs-based VA benefits, with earned income information maintained by SSA. VA will also match records of veterans, who have applied for or who are receiving disability compensation at the 100 percent rate based on unemployability, with SSA earned income information. VA will use this information to verify income information submitted by beneficiaries and adjust VA benefit payments as prescribed by law. The proposed matching program will enable VA to ensure accurate reporting of income and employment status.

The legal authority to conduct this match is 38 U.S.C. 5106, which requires any Federal department or agency to provide VA such information as VA requests for the purposes of determining eligibility for benefits or verifying other information concerning the payment of benefits. In addition, 26 U.S.C. 6103(l)(7) authorizes the disclosure of tax return information to VA.

VA records involved in the match are in ''Compensation, Pension, Education, and Vocational Rehabilitation and

Employment Records—VA (58VA21/22/28),'' a system of records which was first published at 41 FR 9294 (March 3, 1976), amended and republished in its entirety at 77 FR 42593 (July 19, 2012). The SSA records are from the system of records identified as the Earnings Recording and Self-Employment Income System (MEF), 60–0059, published at 71 FR 1819 (January 11, 2006).

In accordance with the Privacy Act, 5 U.S.C. 552a(o)(2) and (r), copies of the agreement are being sent to both Houses of Congress and to OMB. This notice is provided in accordance with provisions of the Privacy Act of 1974 as amended by Public Law 100–503.

Approved: January 8, 2013.

John R. Gingrich,

Chief of Staff, Department of Veterans Affairs.

[FR Doc. 2013–01531 Filed 1–24–13; 8:45 am]

BILLING CODE 8320–01–P

FEDERAL REGISTER

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Part II

Department of Health and Human Services

Office of the Secretary

45 CFR Parts 160 and 164

Modifications to the HIPAA Privacy, Security, Enforcement, and Breach Notification Rules Under the Health Information Technology for Economic and Clinical Health Act and the Genetic Information Nondiscrimination Act; Other Modifications to the HIPAA Rules; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

45 CFR Parts 160 and 164

RIN 0945–AA03

Modifications to the HIPAA Privacy, Security, Enforcement, and Breach Notification Rules Under the Health Information Technology for Economic and Clinical Health Act and the Genetic Information Nondiscrimination Act; Other Modifications to the HIPAA Rules

AGENCY: Office for Civil Rights, Department of Health and Human Services.

ACTION: Final rule.

SUMMARY: The Department of Health and Human Services (HHS or ''the Department'') is issuing this final rule to: Modify the Health Insurance Portability and Accountability Act (HIPAA) Privacy, Security, and Enforcement Rules to implement statutory amendments under the Health Information Technology for Economic and Clinical Health Act (''the HITECH Act'' or ''the Act'') to strengthen the privacy and security protection for individuals' health information; modify the rule for Breach Notification for Unsecured Protected Health Information (Breach Notification Rule) under the HITECH Act to address public comment received on the interim final rule; modify the HIPAA Privacy Rule to strengthen the privacy protections for genetic information by implementing section 105 of Title I of the Genetic Information Nondiscrimination Act of 2008 (GINA); and make certain other modifications to the HIPAA Privacy, Security, Breach Notification, and Enforcement Rules (the HIPAA Rules) to improve their workability and effectiveness and to increase flexibility for and decrease burden on the regulated entities.

DATES: *Effective date:* This final rule is effective on March 26, 2013.

Compliance date: Covered entities and business associates must comply with the applicable requirements of this final rule by September 23, 2013.

FOR FURTHER INFORMATION CONTACT: Andra Wicks 202–205–2292.

SUPPLEMENTARY INFORMATION:

I. Executive Summary and Background

A. Executive Summary

i. Purpose of the Regulatory Action

Need for the Regulatory Action

This final rule is needed to strengthen the privacy and security protections established under the Health Insurance Portability and Accountability of 1996 Act (HIPAA) for individual's health information maintained in electronic health records and other formats. This final rule also makes changes to the HIPAA rules that are designed to increase flexibility for and decrease burden on the regulated entities, as well as to harmonize certain requirements with those under the Department's Human Subjects Protections regulations. These changes are consistent with, and arise in part from, the Department's obligations under Executive Order 13563 to conduct a retrospective review of our existing regulations for the purpose of identifying ways to reduce costs and increase flexibilities under the HIPAA Rules. We discuss our specific burden reduction efforts more fully in the Regulatory Impact Analysis.

This final rule is comprised of four final rules, which have been combined to reduce the impact and number of times certain compliance activities need to be undertaken by the regulated entities.

Legal Authority for the Regulatory Action

The final rule implements changes to the HIPAA Rules under a number of authorities. First, the final rule modifies the Privacy, Security, and Enforcement Rules to strengthen privacy and security protections for health information and to improve enforcement as provided for by the Health Information Technology for Economic and Clinical Health (HITECH) Act, enacted as part of the American Recovery and Reinvestment Act of 2009 (ARRA). The rule also includes final modifications to the Breach Notification Rule, which will replace an interim final rule originally published in 2009 as required by the HITECH Act. Second, the final rule revises the HIPAA Privacy Rule to increase privacy protections for genetic information as required by the Genetic Information Nondiscrimination Act of 2008 (GINA). Finally, the Department uses its general authority under HIPAA to make a number of changes to the Rules that are intended to increase workability and flexibility, decrease burden, and better harmonize the requirements with those under other Departmental regulations.

ii. Summary of Major Provisions

This omnibus final rule is comprised of the following four final rules:

1. Final modifications to the HIPAA Privacy, Security, and Enforcement Rules mandated by the Health Information Technology for Economic and Clinical Health (HITECH) Act, and certain other modifications to improve the Rules, which were issued as a proposed rule on July 14, 2010. These modifications:

- Make business associates of covered entities directly liable for compliance with certain of the HIPAA Privacy and Security Rules' requirements.
- Strengthen the limitations on the use and disclosure of protected health information for marketing and fundraising purposes, and prohibit the sale of protected health information without individual authorization.
- Expand individuals' rights to receive electronic copies of their health information and to restrict disclosures to a health plan concerning treatment for which the individual has paid out of pocket in full.
- Require modifications to, and redistribution of, a covered entity's notice of privacy practices.
- Modify the individual authorization and other requirements to facilitate research and disclosure of child immunization proof to schools, and to enable access to decedent information by family members or others.
- Adopt the additional HITECH Act enhancements to the Enforcement Rule not previously adopted in the October 30, 2009, interim final rule (referenced immediately below), such as the provisions addressing enforcement of noncompliance with the HIPAA Rules due to willful neglect.

2. Final rule adopting changes to the HIPAA Enforcement Rule to incorporate the increased and tiered civil money penalty structure provided by the HITECH Act, originally published as an interim final rule on October 30, 2009.

3. Final rule on Breach Notification for Unsecured Protected Health Information under the HITECH Act, which replaces the breach notification rule's ''harm'' threshold with a more objective standard and supplants an interim final rule published on August 24, 2009.

4. Final rule modifying the HIPAA Privacy Rule as required by the Genetic Information Nondiscrimination Act (GINA) to prohibit most health plans from using or disclosing genetic information for underwriting purposes, which was published as a proposed rule on October 7, 2009.

iii. Costs and Benefits

This final rule is anticipated to have an annual effect on the economy of $100 million or more, making it an economically significant rule under Executive Order 12866. Accordingly, we have prepared a Regulatory Impact Analysis that presents the estimated costs and benefits of the proposed rule. The total cost of compliance with the rule's provisions is estimated to be between $114 million and $225.4 million in the first year of implementation and approximately $14.5 million annually thereafter. Costs associated with the rule include: (i) Costs to HIPAA covered entities of revising and distributing new notices of privacy practices to inform individuals of their rights and how their information is protected; (ii) costs to covered entities related to compliance with breach notification requirements; (iii) costs to a portion of business associates to bring their subcontracts into compliance with business associate agreement requirements; and (iv) costs to a portion of business associates to achieve full compliance with the Security Rule. We summarize these costs in Table 1 below and explain the components and distribution of costs in detail in the Regulatory Impact Analysis.

We are not able to quantify the benefits of the rule due to lack of data and the impossibility of monetizing the value of individuals' privacy and dignity, which we believe will be enhanced by the strengthened privacy and security protections, expanded individual rights, and improved enforcement enabled by the rule. We also believe that some entities affected by the rule will realize cost savings as a result of provisions that simplify and streamline certain requirements, and increase flexibility, under the HIPAA Rules. However, we are unable to quantify such cost savings due to a lack of data. We describe such benefits in the Regulatory Impact Analysis.

TABLE 1—ESTIMATED COSTS OF THE FINAL RULE

Cost element	Approximate number of affected entities	Total cost
Notices of Privacy Practices	700,000 covered entities	$55.9 million.
Breach Notification Requirements	19,000 covered entities	14.5 million.[1]
Business Associate Agreements	250,000–500,000 business associates of covered entities	21 million–42 million.
Security Rule Compliance by Business Associates.	200,000–400,000 business associates of covered entities	22.6 million–113 million.
Total		114 million–225.4 million.

B. Statutory and Regulatory Background

i. HIPAA and the Privacy, Security, and Enforcement Rules

The HIPAA Privacy, Security, and Enforcement Rules implement certain of the Administrative Simplification provisions of title II, subtitle F, of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) (Pub. L. 104–191), which added a new part C to title XI of the Social Security Act (sections 1171–1179 of the Social Security Act, 42 U.S.C. 1320d–1320d–8). The HIPAA Administrative Simplification provisions provided for the establishment of national standards for the electronic transmission of certain health information, such as standards for certain health care transactions conducted electronically and code sets and unique identifiers for health care providers and employers. The HIPAA Administrative Simplification provisions also required the establishment of national standards to protect the privacy and security of personal health information and established civil money penalties for violations of the Administrative Simplification provisions. The Administrative Simplification provisions of HIPAA apply to three types of entities, which are known as ''covered entities'': health care providers who conduct covered health care transactions electronically, health plans, and health care clearinghouses.

The HIPAA Privacy Rule, 45 CFR Part 160 and Subparts A and E of Part 164, requires covered entities to have safeguards in place to ensure the privacy of protected health information, sets forth the circumstances under which covered entities may use or disclose an individual's protected health information, and gives individuals rights with respect to their protected health information, including rights to examine and obtain a copy of their health records and to request corrections. Covered entities that engage business associates to work on their behalf must have contracts or other arrangements in place with their business associates to ensure that the business associates safeguard protected health information, and use and disclose the information only as permitted or required by the Privacy Rule.

The HIPAA Security Rule, 45 CFR Part 160 and Subparts A and C of Part 164, applies only to protected health information in electronic form and requires covered entities to implement certain administrative, physical, and technical safeguards to protect this electronic information. Like the Privacy Rule, covered entities must have contracts or other arrangements in place with their business associates that provide satisfactory assurances that the business associates will appropriately safeguard the electronic protected health information they create, receive, maintain, or transmit on behalf of the covered entities.

The HIPAA Enforcement Rule, 45 CFR Part 160, Subparts C–E, establishes rules governing the compliance responsibilities of covered entities with respect to the enforcement process, including the rules governing investigations by the Department, rules governing the process and grounds for establishing the amount of a civil money penalty where a violation of a HIPAA Rule has been found, and rules governing the procedures for hearings and appeals where the covered entity challenges a violation determination.

Since the promulgation of the HIPAA Rules, legislation has been enacted requiring modifications to the Rules. In particular, the Health Information Technology for Economic and Clinical Health (HITECH) Act, which was enacted on February 17, 2009, as title XIII of division A and title IV of division B of the American Recovery and Reinvestment Act of 2009 (ARRA), Public Law 111–5, modifies certain provisions of the Social Security Act pertaining to the HIPAA Rules, as well as requires certain modifications to the Rules themselves, to strengthen HIPAA privacy, security, and enforcement. The

[1] The costs associated with breach notification will be incurred on an annual basis. All other costs are expected in the first year of implementation.

Act also provides new requirements for notification of breaches of unsecured protected health information by covered entities and business associates. In addition, the Genetic Information Nondiscrimination Act of 2008 (GINA) calls for changes to the HIPAA Privacy Rule to strengthen privacy protections for genetic information. This final rule implements the modifications required by GINA, as well as most of the privacy, security, and enforcement provisions of the HITECH Act. This final rule also includes certain other modifications to the HIPAA Rules to improve their workability and effectiveness.

ii. The Health Information Technology for Economic and Clinical Health Act

The HITECH Act is designed to promote the widespread adoption and interoperability of health information technology. Subtitle D of title XIII, entitled ''Privacy,'' supports this goal by adopting amendments designed to strengthen the privacy and security protections for health information established by HIPAA. These provisions include extending the applicability of certain of the Privacy and Security Rules' requirements to the business associates of covered entities; requiring that Health Information Exchange Organizations and similar organizations, as well as personal health record vendors that provide services to covered entities, shall be treated as business associates; requiring HIPAA covered entities and business associates to provide for notification of breaches of ''unsecured protected health information''; establishing new limitations on the use and disclosure of protected health information for marketing and fundraising purposes; prohibiting the sale of protected health information; and expanding individuals' rights to access their protected health information, and to obtain restrictions on certain disclosures of protected health information to health plans. In addition, subtitle D adopts provisions designed to strengthen and expand HIPAA's enforcement provisions.

We discuss these statutory provisions in more detail below where we describe section-by-section how this final rule implements the provisions. We do not address in this rulemaking the accounting for disclosures requirement in section 13405 of the Act, which is the subject of a separate proposed rule published on May 31, 2011, at 76 FR 31426, or the penalty distribution methodology requirement in section 13410(c) of the Act, which will be the subject of a future rulemaking.

Since enactment of the HITECH Act a number of steps have been taken to implement the strengthened privacy, security, and enforcement provisions through rulemakings and related actions. On August 24, 2009, the Department published interim final regulations to implement the breach notification provisions at section 13402 of the HITECH Act (74 FR 42740), which were effective September 23, 2009. Similarly, the Federal Trade Commission (FTC) published final regulations implementing the breach notification provisions at section 13407 for personal health record vendors and their third party service providers on August 25, 2009 (74 FR 42962), effective September 24, 2009. For purposes of determining to what information the HHS and FTC breach notification regulations apply, the Department also issued, first on April 17, 2009 (published on April 27, 2009, 74 FR 19006), and then later with its interim final rule, the guidance required by the HITECH Act under 13402(h) specifying the technologies and methodologies that render protected health information unusable, unreadable, or indecipherable to unauthorized individuals. Additionally, to conform the provisions of the Enforcement Rule to the HITECH Act's tiered and increased civil money penalty structure, which became effective on February 18, 2009, the Department published an interim final rule on October 30, 2009 (74 FR 56123), effective November 30, 2009.

The Department published a notice of proposed rulemaking (NPRM) on July 14, 2010, (75 FR 40868) to implement many of the remaining privacy, security, and enforcement provisions of the HITECH Act. The public was invited to comment on the proposed rule for 60 days following publication. The comment period closed on September 13, 2010. The Department received about 300 comments on the NPRM.

The NPRM proposed to extend the applicability of certain of the Privacy and Security Rules' requirements to the business associates of covered entities, making business associates directly liable for violations of these requirements. Additionally, the NPRM proposed to define a subcontractor as a business associate to ensure any protected health information the subcontractor creates or receives on behalf of the business associate is appropriately safeguarded. The NPRM proposed to establish new limitations on the use and disclosure of protected health information for marketing and fundraising purposes and to prohibit the sale of protected health information without an authorization. The NPRM also proposed to expand an individual's right to obtain an electronic copy of an individual's protected health information, and the right to restrict certain disclosures of protected health information to a health plan for payment or health care operations purposes. In addition, the NPRM proposed to further modify the Enforcement Rule to implement more of the HITECH Act's changes to HIPAA enforcement.

In addition to the proposed modifications to implement the HITECH Act, the NPRM also proposed certain other modifications to the HIPAA Rules. The NPRM proposed to permit the use of compound authorizations for conditioned and unconditioned research activities and requested comment regarding permitting authorizations for future research. Additionally, the NPRM proposed to modify the Privacy Rule's application to the individually identifiable health information of decedents and to permit covered entities that obtain the agreement of a parent to provide proof of immunization without written authorization to schools that are required to have such information.

iii. The Genetic Information Nondiscrimination Act

The Genetic Information Nondiscrimination Act of 2008 (''GINA''), Pub. L. 110–233, 122 Stat. 881, prohibits discrimination based on an individual's genetic information in both the health coverage (Title I) and employment (Title II) contexts. In addition to the nondiscrimination provisions, section 105 of Title I of GINA contains new privacy protections for genetic information, which require the Secretary of HHS to revise the Privacy Rule to clarify that genetic information is health information and to prohibit group health plans, health insurance issuers (including HMOs), and issuers of Medicare supplemental policies from using or disclosing genetic information for underwriting purposes.

On October 7, 2009, the Department published a proposed rule to strengthen the privacy protections for genetic information under the HIPAA Privacy Rule by implementing the protections for genetic information required by GINA and making related changes to the Rule. The 60-day public comment period for the proposed rule closed on December 7, 2009. The Department received about 25 comments on the proposed rule.

II. Overview of the Final Rule

In this final rule the Department finalizes the modifications to the HIPAA Privacy, Security, and Enforcement Rules to implement many of the

privacy, security, and enforcement provisions of the HITECH Act and make other changes to the Rules; modifies the Breach Notification Rule; finalizes the modifications to the HIPAA Privacy Rule to strengthen privacy protections for genetic information; and responds to the public comments received on the proposed and interim final rules. Section III below describes the effective and compliance dates of the final rule. Section IV describes the changes to the HIPAA Privacy, Security, and Enforcement Rules under the HITECH Act and other modifications that were proposed in July 2010, as well as the modifications to the Enforcement Rule under the HITECH Act that were addressed in the interim final rule published in October 2009. Section V describes the changes to the Breach Notification Rule. Section VI discusses the changes to the HIPAA Privacy Rule to strengthen privacy protections for genetic information.

III. Effective and Compliance Dates

With respect to the HITECH Act requirements, section 13423 of the Act provides that the provisions in subtitle D took effect one year after enactment, i.e., on February 18, 2010, except as specified otherwise. However, there are a number of exceptions to this general rule. For example, the tiered and increased civil money penalty provisions of section 13410(d) were effective for violations occurring after the date of enactment, and sections 13402 and 13407 of the Act regarding breach notification required interim final rules within 180 days of enactment, with effective dates 30 days after the publication of such rules. Other provisions of the Act have later effective dates. For example, the provision at section 13410(a)(1) of the Act providing that the Secretary's authority to impose a civil money penalty will only be barred to the extent a criminal penalty has been imposed, rather than in cases in which the offense in question merely constitutes an offense that is criminally punishable, became effective for violations occurring on or after February 18, 2011. The discussion below generally pertains to the statutory provisions that became effective on February 18, 2010, or, in a few cases, on a later date.

Proposed Rule

We proposed that covered entities and business associates would have 180 days beyond the effective date of the final rule to come into compliance with most of the rule's provisions. We believed that a 180-day compliance period would suffice for future modifications to the HIPAA Rules, and we proposed to add a provision at § 160.105 to address the compliance date generally for implementation of new or modified standards in the HIPAA Rules. We proposed that § 160.105 would provide that with respect to new standards or implementation specifications or modifications to standards or implementation specifications in the HIPAA Rules, except as otherwise provided, covered entities and business associates would be required to comply with the applicable new or modified standards or implementation specifications no later than 180 days from the effective date of any such change. For future modifications to the HIPAA Rules necessitating a longer compliance period, we would specify a longer period in the regulatory text. Finally, we proposed to retain the compliance date provisions at §§ 164.534 and 164.318, which provide the compliance dates of April 14, 2003, and April 20, 2005, for initial implementation of the HIPAA Privacy and Security Rules, respectively, for historical purposes only.

Overview of Public Comments

Most of the comments addressing the proposed compliance periods as outlined above fell into three categories. First, several commenters supported the proposed compliance timelines and agreed that 180 days is sufficient time for covered entities, business associates, and subcontractors of all sizes to come into compliance with the final rule. Second, a few commenters supported the proposed 180-day compliance period, but expressed concern that the Department may wish to extend the 180-day compliance period in the future, if it issues modifications or new provisions that require a longer compliance period. Third, several commenters requested that the Department extend the 180-day compliance period both with regard to the modifications contained in this final rule and with regard to the more general proposed compliance deadline, as they believe 180 days is an insufficient amount of time for covered entities, business associates, and subcontractors to come into compliance with the modified rules, particularly with regard to changes in technology.

Final Rule

The final rule is effective on March 26, 2013. Covered entities and business associates of all sizes will have 180 days beyond the effective date of the final rule to come into compliance with most of the final rule's provisions, including the modifications to the Breach Notification Rule and the changes to the HIPAA Privacy Rule under GINA. We understand that some covered entities, business associates, and subcontractors remain concerned that a 180-day period does not provide sufficient time to come into compliance with the modifications. However, we believe not only that providing a 180-day compliance period best comports with section 1175(b)(2) of the Social Security Act, 42 U.S.C. 1320d–4, and our implementing provision at § 160.104(c)(1), which require the Secretary to provide at least a 180-day period for covered entities to comply with modifications to standards and implementation specifications in the HIPAA Rules, but also that providing a 180-day compliance period best protects the privacy and security of patient information, in accordance with the goals of the HITECH Act.

In addition, to make clear to the industry our expectation that going forward we will provide a 180-day compliance date for future modifications to the HIPAA Rules, we adopt the provision we proposed at § 160.105, which provides that with respect to new or modified standards or implementation specifications in the HIPAA Rules, except as otherwise provided, covered entities and business associates must comply with the applicable new or modified standards or implementation specifications no later than 180 days from the effective date of any such change. In cases where a future modification necessitates a longer compliance period, the Department will expressly provide for one, as it has done in this rulemaking with respect to the time permitted for business associate agreements to be modified.

For the reasons proposed, the final rule also retains the compliance date provisions at §§ 164.534 and 164.318, which provide the compliance dates of April 14, 2003, and April 20, 2005, for initial implementation of the HIPAA Privacy and Security Rules, respectively. We note that § 160.105 regarding the compliance date of new or modified standards or implementation specifications does not apply to modifications to the provisions of the HIPAA Enforcement Rule, because such provisions are not standards or implementation specifications (as the terms are defined at § 160.103). Such provisions are in effect and apply at the time the final rule becomes effective or as otherwise specifically provided. In addition, as explained above, our general rule for a 180-day compliance period for new or modified standards would not apply where we expressly provide a different compliance period in

the regulation for one or more provisions. For purposes of this rule, the 180-day compliance period would not govern the time period required to modify those business associate agreements that qualify for the longer transition period in § 164.532, as we discuss further below.

Finally, the provisions of section 13402(j) of the HITECH Act apply to breaches of unsecured protected health information discovered on or after September 23, 2009, the date of the publication of the interim final rule. Thus, during the 180 day period before compliance with this final rule is required, covered entities and business associates are still required to comply with the breach notification requirements under the HITECH Act and must continue to comply with the requirements of the interim final rule. We believe that this transition period provides covered entities and business associates with adequate time to come into compliance with the revisions in this final rule and at the same time to continue to fulfill their breach notification obligations under the HITECH Act.

IV. Modifications to the HIPAA Privacy, Security, and Enforcement Rules Under the HITECH Act; Other Modifications to the HIPAA Rules

The discussion below provides a section-by-section description of the final rule, as well as responds to public comments where substantive comments were received regarding particular provisions.

A. Subparts A and B of Part 160: Statutory Basis and Purpose, Applicability, Definitions, and Preemption of State Law

Subpart A of Part 160 of the HIPAA Rules contains general provisions that apply to all of the HIPAA Rules. Subpart B of Part 160 contains the regulatory provisions implementing HIPAA's preemption provisions. We proposed to amend a number of these provisions. Some of the proposed, and now final, changes are necessitated by the statutory changes made by the HITECH Act and GINA, while others are of a technical or conforming nature.

1. Subpart A—General Provisions, Section 160.101—Statutory Basis and Purpose

This section sets out the statutory basis and purpose of the HIPAA Rules. We proposed and include in this final rule a technical change to include references to the provisions of GINA and the HITECH Act upon which most of the regulatory changes below are based.

2. Subpart A—General Provisions, Section 160.102—Applicability

This section sets out to whom the HIPAA Rules apply. We proposed to add and include in this final rule a new paragraph (b) to make clear, consistent with the HITECH Act, that certain of the standards, requirements, and implementation specifications of the subchapter apply to business associates.

3. Subpart A—General Provisions, Section 160.103—Definitions

Section 160.103 contains definitions of terms that appear throughout the HIPAA Rules. The final rule modifies a number of these definitions to implement the HITECH Act and make other needed changes.

a. Definition of ''Business Associate''

The HIPAA Privacy and Security Rules permit a covered entity to disclose protected health information to a business associate, and allow a business associate to create, receive, maintain, or transmit protected health information on its behalf, provided the covered entity obtains satisfactory assurances in the form of a contract or other arrangement that the business associate will appropriately safeguard the information. The HIPAA Rules define ''business associate'' generally to mean a person who performs functions or activities on behalf of, or certain services for, a covered entity that involve the use or disclosure of protected health information. We proposed a number of modifications to the definition of ''business associate'' to implement the HITECH Act, to conform the term to the statutory provisions of the Patient Safety and Quality Improvement Act of 2005 (PSQIA), 42 U.S.C. 299b–21, et seq., and to make other changes to the definition.

i. Inclusion of Patient Safety Organizations

Proposed Rule

We proposed to add patient safety activities to the list of functions and activities a person may undertake on behalf of a covered entity that give rise to a business associate relationship. PSQIA, at 42 U.S.C. 299b–22(i)(1), provides that Patient Safety Organizations (PSOs) must be treated as business associates when applying the Privacy Rule. PSQIA provides for the establishment of PSOs to receive reports of patient safety events or concerns from providers and provide analyses of events to reporting providers. A reporting provider may be a HIPAA covered entity and, thus, information reported to a PSO may include protected health information that the PSO may analyze on behalf of the covered provider. The analysis of such information is a patient safety activity for purposes of PSQIA and the Patient Safety Rule, 42 CFR 3.10, et seq. While the HIPAA Rules as written would treat a PSO as a business associate when the PSO was performing quality analyses and other activities on behalf of a covered health care provider, we proposed this change to the definition of ''business associate'' to more clearly align the HIPAA and Patient Safety Rules.

Overview of Public Comment

Commenters on this topic supported the express inclusion of patient safety activities within the definition of ''business associate.''

Final Rule

The final rule adopts the proposed modification.

ii. Inclusion of Health Information Organizations (HIO), E-Prescribing Gateways, and Other Persons That Facilitate Data Transmission; as Well as Vendors of Personal Health Records

Proposed Rule

Section 13408 of the HITECH Act provides that an organization, such as a Health Information Exchange Organization, E-prescribing Gateway, or Regional Health Information Organization, that provides data transmission of protected health information to a covered entity (or its business associate) and that requires access on a routine basis to such protected health information must be treated as a business associate for purposes of the Act and the HIPAA Privacy and Security Rules. Section 13408 also provides that a vendor that contracts with a covered entity to allow the covered entity to offer a personal health record to patients as part of the covered entity's electronic health record shall be treated as a business associate. Section 13408 requires that such organizations and vendors enter into a written business associate contract or other arrangement with the covered entity in accordance with the HIPAA Rules.

In accordance with the Act, we proposed to modify the definition of ''business associate'' to explicitly designate these persons as business associates. Specifically, we proposed to include in the definition: (1) A Health Information Organization, E-prescribing Gateway, or other person that provides data transmission services with respect

to protected health information to a covered entity and that requires routine access to such protected health information; and (2) a person who offers a personal health record to one or more individuals on behalf of a covered entity.

We proposed to refer to ''Health Information Organization'' in the NPRM rather than ''Health Information Exchange Organization'' as used in the Act because it is our understanding that ''Health Information Organization'' is the more widely recognized and accepted term to describe an organization that oversees and governs the exchange of health-related information among organizations.[2] The Act also specifically refers to Regional Health Information Organizations; however, we did not believe the inclusion of the term in the definition of ''business associate'' was necessary as a Regional Health Information Organization is simply a Health Information Organization that governs health information exchange among organizations within a defined geographic area.[3] Further, the specific terms of ''Health Information Organization'' and ''E-prescribing Gateway'' were included as merely illustrative of the types of organizations that would fall within this paragraph of the definition of ''business associate.'' We requested comment on the use of these terms within the definition and whether additional clarifications or additions were necessary.

Section 13408 also provides that the data transmission organizations that the Act requires to be treated as business associates are those that require access to protected health information on a routine basis. Conversely, data transmission organizations that do not require access to protected health information on a routine basis would not be treated as business associates. This is consistent with our prior interpretation of the definition of ''business associate,'' through which we have stated that entities that act as mere conduits for the transport of protected health information but do not access the information other than on a random or infrequent basis are not business associates. See *http://www.hhs.gov/ocr/privacy/hipaa/faq/providers/business/245.html*. In contrast, entities that manage the exchange of protected health information through a network, including providing record locator services and performing various oversight and governance functions for electronic health information exchange, have more than ''random'' access to protected health information and thus, would fall within the definition of ''business associate.''

Overview of Public Comments

Commenters generally supported the inclusion of Health Information Organizations, personal health record vendors, and similar entities in the definition of ''business associate.'' However, commenters sought various clarifications as discussed below.

Commenters generally supported use of the term Health Information Organization in lieu of more restrictive terms, such as Regional Health Information Organization. Some commenters suggested that the term Health Information Organization be defined, so as to avoid confusion as the industry develops, and suggested various alternatives for doing so. Several commenters recommended that the Office for Civil Rights (OCR) maintain a Web site link that lists current terms for entities that OCR considers to be Health Information Organizations.

Other commenters requested clarification on what it means to have ''access on a routine basis'' to protected health information for purposes of the definition and determining whether certain entities are excluded as mere conduits. For example, commenters asked whether the definition of business associate would include broadband suppliers or internet service providers, vendors that only have the potential to come into contact with protected health information, or entities contracted on a contingency basis that may at some point in the future have access to protected health information. Several document storage companies argued that entities like theirs should be characterized as conduits, as they do not view the protected health information they store.

Several commenters sought clarification regarding when personal health record vendors would be considered business associates. For example, commenters asked whether personal health record vendors would be business associates when the vendor provided the personal health record in collaboration with the covered entity, when the personal health record is linked to a covered entity's electronic health record, or when the personal health record is offered independently to the individual, among other scenarios. One commenter suggested that a vendor offering a personal health record to a patient on behalf of a covered entity only acts as a conduit because there is no access by the vendor to protected health information; another commenter suggested that personal health record vendors be business associates only when they have routine access to protected health information.

Final Rule

The final rule adopts the language that expressly designates as business associates: (1) A Health Information Organization, E-prescribing Gateway, or other person that provides data transmission services with respect to protected health information to a covered entity and that requires routine access to such protected health information; and (2) a person who offers a personal health record to one or more individuals on behalf of a covered entity.

We decline to provide a definition for Health Information Organization. We recognize that the industry continues to develop and thus the type of entities that may be considered Health Information Organizations continues to evolve. For this reason, we do not think it prudent to include in the regulation a specific definition at this time. We anticipate continuing to issue guidance in the future on our web site on the types of entities that do and do not fall within the definition of business associate, which can be updated as the industry evolves.

Regarding what it means to have ''access on a routine basis'' to protected health information with respect to determining which types of data transmission services are business associates versus mere conduits, such a determination will be fact specific based on the nature of the services provided and the extent to which the entity needs access to protected health information to perform the service for the covered entity. The conduit exception is a narrow one and is intended to exclude only those entities providing mere courier services, such as the U.S. Postal Service or United Parcel Service and their electronic equivalents, such as internet service providers (ISPs) providing mere data transmission services. As we have stated in prior guidance, a conduit transports information but does not access it other than on a random or infrequent basis as necessary to perform the transportation service or as required by other law. For example, a telecommunications company may have occasional, random access to protected health information when it reviews whether the data transmitted over its network is arriving

[2] Department of Health and Human Services Office of the National Coordinator for Health Information Technology, The National Alliance for Health Information Technology Report to the Office of the National Coordinator for Health Information Technology: Defining Key Health Information Terms, Pg. 24 (2008).

[3] *Id.* at 25.

at its intended destination. Such occasional, random access to protected health information would not qualify the company as a business associate. In contrast, an entity that requires access to protected health information in order to perform a service for a covered entity, such as a Health Information Organization that manages the exchange of protected health information through a network on behalf of covered entities through the use of record locator services for its participants (and other services), is not considered a conduit and, thus, is not excluded from the definition of business associate. We intend to issue further guidance in this area as electronic health information exchange continues to evolve.

We note that the conduit exception is limited to transmission services (whether digital or hard copy), including any temporary storage of transmitted data incident to such transmission. In contrast, an entity that maintains protected health information on behalf of a covered entity is a business associate and not a conduit, even if the entity does not actually view the protected health information. We recognize that in both situations, the entity providing the service to the covered entity has the opportunity to access the protected health information. However, the difference between the two situations is the transient versus persistent nature of that opportunity. For example, a data storage company that has access to protected health information (whether digital or hard copy) qualifies as a business associate, even if the entity does not view the information or only does so on a random or infrequent basis. Thus, document storage companies maintaining protected health information on behalf of covered entities are considered business associates, regardless of whether they actually view the information they hold. To help clarify this point, we have modified the definition of ''business associate'' to generally provide that a business associate includes a person who ''creates, receives, *maintains,* or transmits'' (emphasis added) protected health information on behalf of a covered entity.

Several commenters sought clarification on when a personal health record vendor would be providing a personal health record ''on behalf of'' a covered entity and thus, would be a business associate for purposes of the HIPAA Rules. As with data transmission services, determining whether a personal health record vendor is a business associate is a fact specific determination. A personal health record vendor is not a business associate of a covered entity solely by virtue of entering into an interoperability relationship with a covered entity. For example, when a personal health record vendor and a covered entity establish the electronic means for a covered entity's electronic health record to send protected health information to the personal health record vendor pursuant to the individual's written authorization, it does not mean that the personal health record vendor is offering the personal health record on behalf of the covered entity, even if there is an agreement between the personal health record vendor and the covered entity governing the exchange of data (such as an agreement specifying the technical specifications for exchanging of data or specifying that such data shall be kept confidential). In contrast, when a covered entity hires a vendor to provide and manage a personal health record service the covered entity wishes to offer its patients or enrollees, and provides the vendor with access to protected health information in order to do so, the personal health record vendor is a business associate.

A personal health record vendor may offer personal health records directly to individuals and may also offer personal health records on behalf of covered entities. In such cases, the personal health record vendor is only subject to HIPAA as a business associate with respect to personal health records that are offered to individuals on behalf of covered entities.

We also clarify that, contrary to one commenter's suggestion, a personal health record vendor that offers a personal health record to a patient on behalf of a covered entity does not act merely as a conduit. Rather, the personal health record vendor is maintaining protected health information on behalf of the covered entity (for the benefit of the individual). Further, a personal health record vendor that operates a personal health record on behalf of a covered entity is a business associate if it has access to protected health information, regardless of whether the personal health record vendor actually exercises this access. We believe the revisions to the definition of ''business associate'' discussed above clarify these points. As with other aspects of the definition of ''business associate,'' we intend to provide future guidance on when a personal health record vendor is a business associate for purposes of the HIPAA Rules.

Response to Other Public Comments

Comment: One commenter recommended that the term ''person'' used in describing who provides transmission services to a covered entity be clarified to apply also to entities and organizations.

Response: The term ''person'' as defined at § 160.103 includes entities as well as natural persons.

Comment: One commenter asked whether subcontractors that support business associates with personal health record related functions are subject to the breach notification requirements under the HIPAA Breach Notification Rule or that of the FTC.

Response: As discussed below, a subcontractor that creates, receives, maintains, or transmits protected health information on behalf of a business associate, including with respect to personal health record functions, is a HIPAA business associate and thus, is subject to the HIPAA Breach Notification Rule and not that of the FTC. The analysis of whether a subcontractor is acting on behalf of a business associate is the same analysis as discussed above with respect to whether a business associate is acting on behalf of a covered entity.

iii. Inclusion of Subcontractors

Proposed Rule

We proposed in the definition of ''business associate'' to provide that subcontractors of a covered entity, i.e., those persons that perform functions for or provide services to a business associate other than in the capacity as a member of the business associate's workforce, are also business associates to the extent that they require access to protected health information. We also proposed to define ''subcontractor'' in § 160.103 as a person who acts on behalf of a business associate, other than in the capacity of a member of the workforce of such business associate. Even though we used the term ''subcontractor,'' which implies there is a contract in place between the parties, the definition would apply to an agent or other person who acts on behalf of the business associate, even if the business associate has failed to enter into a business associate contract with the person. We requested comment on the use of the term ''subcontractor'' and its proposed definition.

The intent of the proposed extension of the Rules to subcontractors was to avoid having privacy and security protections for protected health information lapse merely because a function is performed by an entity that is a subcontractor rather than an entity

with a direct relationship with a covered entity. Allowing such a lapse in privacy and security protections could allow business associates to avoid liability imposed upon them by sections 13401 and 13404 of the Act. Further, applying HIPAA privacy and security requirements directly to subcontractors also ensures that the privacy and security protections of the HIPAA Rules extend beyond covered entities to those entities that create or receive protected health information in order for the covered entity to perform its health care functions. Therefore, we proposed that downstream entities that work at the direction of or on behalf of a business associate and handle protected health information would also be required to comply with the applicable Privacy and Security Rule provisions in the same manner as the primary business associate, and likewise would incur liability for acts of noncompliance. This proposed modification would not require the covered entity to have a contract with the subcontractor; rather, the obligation would remain on each business associate to obtain satisfactory assurances in the form of a written contract or other arrangement that a subcontractor will appropriately safeguard protected health information. For example, if a business associate, such as a third party administrator, hires a company to handle document and media shredding to securely dispose of paper and electronic protected health information, then the shredding company would be directly required to comply with the applicable requirements of the HIPAA Security Rule (e.g., with respect to proper disposal of electronic media) and the Privacy Rule (e.g., with respect to limiting its uses and disclosures of the protected health information in accordance with its contract with the business associate).

Overview of Public Comments

While some commenters generally supported extending the business associate provisions of the Rules to subcontractors, many opposed such an extension arguing, among other things, that doing so was not the intent of Congress and beyond the statutory authority of the Department, that confusion may ensue with covered entities seeking to establish direct business associate contracts with subcontractors or prohibiting business associates from establishing subcontractor relationships altogether, and/or that creating direct liability for subcontractors will discourage such entities from operating and participating in the health care industry. Some commenters asked how far down the ''chain'' of subcontractors do the HIPAA Rules apply—i.e., do the Rules apply only to the first tier subcontractor or to all subcontractors down the chain.

In response to our request for comment on this issue, several commenters were concerned that use of the term subcontractor was confusing and instead suggested a different term be used, such as business associate contractor or downstream business associate, to avoid confusion between primary business associates of a covered entity and subcontractors. Other commenters suggested changes to the definition of subcontractor itself to better clarify the scope of the definition.

Several commenters requested specific guidance on who is and is not a subcontractor under the definitions of ''business associate'' and ''subcontractor.'' For example, one commenter asked whether an entity that shreds documents for a business associate for the business associate's activities and not for the covered entity, would qualify as a subcontractor. Another commenter asked whether disclosures by a business associate of protected health information for its own management and administration or legal needs creates a subcontractor relationship. Other commenters recommended that subcontractors without routine access to protected health information, or who do not access protected health information at all for their duties, not be considered business associates.

Final Rule

The final rule adopts the proposal to apply the business associate provisions of the HIPAA Rules to subcontractors and thus, provides in the definition of ''business associate'' that a business associate includes a ''subcontractor that creates, receives, maintains, or transmits protected health information on behalf of the business associate.'' In response to comments, we clarify the definition of ''subcontractor'' in § 160.103 to provide that subcontractor means: ''a person to whom a business associate delegates a function, activity, or service, other than in the capacity of a member of the workforce of such business associate.'' Thus, a subcontractor is a person to whom a business associate has delegated a function, activity, or service the business associate has agreed to perform for a covered entity or business associate. A subcontractor is then a business associate where that function, activity, or service involves the creation, receipt, maintenance, or transmission of protected health information. We also decline to replace the term ''subcontractor'' with another, as we were not persuaded by any of the alternatives suggested by commenters (e.g., ''business associate contractor,'' ''downstream business associate,'' or ''downstream entity'').

We disagree with the commenters that suggested that applying the business associate provisions of the HIPAA Rules to subcontractors is beyond the Department's statutory authority. In the HITECH Act, Congress created direct liability under the HIPAA Privacy and Security Rules for persons that are not covered entities but that create or receive protected health information in order for a covered entity to perform its health care functions, to ensure individuals' personal health information remains sufficiently protected in the hands of these entities. As stated in the NPRM, applying the business associate provisions only to those entities that have a direct relationship with a covered entity does not achieve that intended purpose. Rather, it allows privacy and security protections for protected health information to lapse once a subcontractor is enlisted to assist in performing a function, activity, or service for the covered entity, while at the same time potentially allowing certain primary business associates to avoid liability altogether for the protection of the information the covered entity has entrusted to the business associate. Further, section 13422 of the HITECH Act provides that each reference in the Privacy subtitle of the Act to a provision of the HIPAA Rules refers to such provision as in effect on the date of enactment of the Act *or to the most recent update of such provision* (emphasis added). Thus, the Act does not bar the Department from modifying definitions of terms in the HIPAA Rules to which the Act refers. Rather, the statute expressly contemplates that modifications to the terms may be necessary to carry out the provisions of the Act or for other purposes.

Further, we do not agree that covered entities will be confused and seek to establish direct business associate contracts with subcontractors or will prohibit business associates from engaging subcontractors to perform functions or services that require access to protected health information. The final rule makes clear that a covered entity is not required to enter into a contract or other arrangement with a business associate that is a subcontractor. See §§ 164.308(b)(1) and 164.502(e)(1)(i). In addition, as commenters did not present direct evidence to the contrary, we do not believe that covered entities will begin

prohibiting business associates from engaging subcontractors as a result of the final rule, in cases where they were not doing so before. Rather, we believe that making subcontractors directly liable for violations of the applicable provisions of the HIPAA Rules will help to alleviate concern on the part of covered entities that protected health information is not adequately protected when provided to subcontractors.

The Department also believes that the privacy and security protections for an individual's personal health information and associated liability for noncompliance with the Rules should not lapse beyond any particular business associate that is a subcontractor. Thus, under the final rule, covered entities must ensure that they obtain satisfactory assurances required by the Rules from their business associates, and business associates must do the same with regard to subcontractors, and so on, no matter how far ''down the chain'' the information flows. This ensures that individuals' health information remains protected by all parties that create, receive, maintain, or transmit the information in order for a covered entity to perform its health care functions. For example, a covered entity may contract with a business associate (contractor), the contractor may delegate to a subcontractor (subcontractor 1) one or more functions, services, or activities the business associate has agreed to perform for the covered entity that require access to protected health information, and the subcontractor may in turn delegate to another subcontractor (subcontractor 2) one or more functions, services, or activities it has agreed to perform for the contractor that require access to protected health information, and so on. Both the contractor and all of the subcontractors are business associates under the final rule to the extent they create, receive, maintain, or transmit protected health information.

With respect to requests for specific guidance on who is and is not a subcontractor, we believe the above changes to the definition provide further clarity. We also provide the following in response to specific comments. Disclosures by a business associate pursuant to § 164.504(e)(4) and its business associate contract for *its own* management and administration or legal responsibilities do not create a business associate relationship with the recipient of the protected health information because such disclosures are made outside of the entity's role as a business associate. However, for such disclosures that are not required by law, the Rule requires that the business associate obtain reasonable assurances from the person to whom the information is disclosed that it will be held confidentially and used or further disclosed only as required by law or for the purposes for which it was disclosed to the person and the person notifies the business associate of any instances of which it is aware that the confidentiality of the information has been breached. See § 164.504(e)(4)(ii)(B).

In contrast, disclosures of protected health information by the business associate to a person who will assist the business associate in performing a function, activity, or service for a covered entity or another business associate may create a business associate relationship depending on the circumstances. For example, an entity hired by a business associate to appropriately dispose of documents that contain protected health information is also a business associate and subject to the applicable provisions of the HIPAA Rules. If the documents to be shredded do not contain protected health information, then the entity is not a business associate. We also clarify that the same interpretations that apply to determining whether a first tier contractor is a business associate also apply to determining whether a subcontractor is a business associate. Thus, our interpretation of who is and is not excluded from the definition of business associate as a conduit also applies in the context of subcontractors as well. We refer readers to the above discussion regarding transmission services and conduits.

iv. Exceptions to Business Associate

Proposed Rule

Sections 164.308(b)(2) and 164.502(e)(1)(ii) of the HIPAA Rules currently describe certain circumstances, such as when a covered entity discloses protected health information to a health care provider concerning the treatment of an individual, in which a covered entity is not required to enter into a business associate contract or other arrangement with the recipient of the protected health information. We proposed to move these provisions to the definition of ''business associate'' itself as exceptions to make clear that the Department does not consider the recipients of the protected health information in these circumstances to be business associates. The movement of these exceptions also was intended to help clarify that a person or an entity is a business associate if the person or entity meets the definition of ''business associate,'' even if a covered entity, or business associate with respect to a subcontractor, fails to enter into the required business associate contract with the person or entity.

Final Rule

The Department did not receive substantive public comment on this proposal. The final rule includes the exceptions within the definition of ''business associate.''

v. Technical Changes to the Definition

Proposed Rule

For clarity and consistency, we also proposed to change the term ''individually identifiable health information'' in the current definition of ''business associate'' to ''protected health information,'' since a business associate has no obligation under the HIPAA Rules with respect to individually identifiable health information that is not protected health information.

Final Rule

The Department did not receive substantive public comment on this proposal. The final rule adopts the proposed modification to the definition. Additionally, as indicated above, we have revised the definition of business associate to clarify that a business associate includes an entity that ''creates, receives, maintains, or transmits'' protected health information on behalf of a covered entity. This change is intended to make the definition more consistent with language at § 164.308(b) of the Security Rule and § 164.502(e) of the Privacy Rule, as well as to clarify that entities that maintain or store protected health information on behalf of a covered entity are business associates, even if they do not actually view the protected health information.

vi. Response to Other Public Comments

Comment: One commenter suggested that some covered entities do not treat third party persons that handle protected health information onsite as a business associate.

Response: A covered entity may treat a contractor who has his or her duty station onsite at a covered entity and who has more than incidental access to protected health information as either a member of the covered entity's workforce or as a business associate for purposes of the HIPAA Rules.

Comment: A few commenters asked for confirmation that researchers are not considered business associates. In addition, the Secretary's Advisory

Committee on Human Research Protections, in its November 23, 2010, letter to the Secretary providing comments on the NPRM, asked the Department to confirm that outsourced research review, approval, and continuing oversight functions (such as through using an external or independent Institutional Review Board) similarly do not give rise to a business associate relationship.

Response: A person or entity is a business associate only in cases where the person or entity is conducting a function or activity regulated by the HIPAA Rules on behalf of a covered entity, such as payment or health care operations, or providing one of the services listed in the definition of ''business associate,'' and in the performance of such duties the person or entity has access to protected health information. Thus, an external researcher is not a business associate of a covered entity by virtue of its research activities, even if the covered entity has hired the researcher to perform the research. See *http://www.hhs.gov/ocr/privacy/hipaa/faq/business_associates/239.html.* Similarly, an external or independent Institutional Review Board is not a business associate of a covered entity by virtue of its performing research review, approval, and continuing oversight functions.

However, a researcher may be a business associate if the researcher performs a function, activity, or service for a covered entity that does fall within the definition of business associate, such as the health care operations function of creating a de-identified or limited data set for the covered entity. See paragraph (6)(v) of the definition of ''health care operations.'' Where the researcher is also the intended recipient of the de-identified data or limited data set, the researcher must return or destroy the identifiers at the time the business associate relationship to create the data set terminates and the researcher now wishes to use the de-identified data or limited data set (subject to a data use agreement) for a research purpose.

Comment: A few commenters asked for clarification as to whether the business associate provisions applied to banking and financial institutions. Commenters sought clarification as to whether the exemption at § 1179 of the HIPAA statute for financial institutions was applicable to subcontractors.

Response: This final rule is not intended to affect the status of financial institutions with respect to whether they are business associates. The HIPAA Rules, including the business associate provisions, do not apply to banking and financial institutions with respect to the payment processing activities identified in § 1179 of the HIPAA statute, for example, the activity of cashing a check or conducting a funds transfer. Section 1179 of HIPAA exempts certain activities of financial institutions from the HIPAA Rules, to the extent that these activities constitute authorizing, processing, clearing, settling, billing, transferring, reconciling, or collecting payments for health care or health plan premiums. However, a banking or financial institution may be a business associate where the institution performs functions above and beyond the payment processing activities identified above on behalf of a covered entity, such as performing accounts receivable functions on behalf of a health care provider.

We clarify that our inclusion of subcontractors in the definition of business associate does not impact the exclusion of financial institutions from the definition of ''business associates'' when they are only conducting payment processing activities that fall under § 1179 of the HIPAA statute. Accordingly, a business associate need not enter into a business associate agreement with a financial institution that is solely conducting payment activities that are excluded under § 1179.

Comment: One commenter sought clarification of the status of a risk management group or malpractice insurance company that receives protected health information when contracted with a covered entity to mitigate the covered entity's risk and then contracts with legal groups to represent the covered entity during malpractice claims.

Response: A business associate agreement is not required where a covered entity purchases a health plan product or other insurance, such as medical liability insurance, from an insurer. However, a business associate relationship could arise if the insurer is performing a function on behalf of, or providing services to, the covered entity that does not directly relate to the provision of insurance benefits, such as performing risk management or assessment activities or legal services for the covered entity, that involve access to protected health information.

b. Definition of ''Electronic Media''

Proposed Rule

The term ''electronic media'' was originally defined in the Transactions and Code Sets Rule issued on August 17, 2000 (65 FR 50312) and was included in the definitions at § 162.103. That definition was subsequently revised and moved to § 160.103. The purpose of that revision was to clarify that the physical movement of electronic media from place to place is not limited to magnetic tape, disk, or compact disk, so as to allow for future technological innovation. We further clarified that transmission of information not in electronic form before the transmission (e.g., paper or voice) is not covered by this definition. See 68 FR 8339, Feb. 20, 2003.

In the NPRM, we proposed to revise the definition of ''electronic media'' in the following ways. First, we proposed to revise paragraph (1) of the definition to replace the term ''electronic storage media'' with ''electronic storage material'' to conform the definition of ''electronic media'' to its current usage, as set forth in the National Institute for Standards and Technology (NIST) ''Guidelines for Media Sanitization'' (*Definition of Medium,* NIST SP 800–88, Glossary B, p. 27 (2006)). The NIST definition, which was updated subsequent to the issuance of the Privacy and Security Rules, was developed in recognition of the likelihood that the evolution of the development of new technology would make use of the term ''electronic storage media'' obsolete in that there may be ''storage material'' other than ''media'' that house electronic data. Second, we proposed to add to paragraph (2) of the definition of ''electronic media'' a reference to intranets, to clarify that intranets come within the definition. Third, we proposed to change the word ''because'' to ''if'' in the final sentence of paragraph (2) of the definition of ''electronic media.'' The definition assumed that no transmissions made by voice via telephone existed in electronic form before transmission; the evolution of technology has made this assumption obsolete since some voice technology is digitally produced from an information system and transmitted by phone.

Overview of Public Comments

The Department received comments in support of the revised definition and the flexibility created to account for later technological developments. Certain other commenters raised concerns that changes to the definition could have unintended impacts when applied to the administrative transaction and code set requirements. One commenter specifically supported the change in language from ''because'' to ''if,'' noting the distinction was important to provide protection for digital audio recordings containing protected health information. One commenter suggested including the

word ''immediately'' in the final sentence of paragraph (2) to indicate that fax transmissions are excluded from the definition of electronic media if the information being exchanged did not exist in electronic form *immediately* before the transmission. Several commenters sought clarification as to whether data that is retained in office machines, such as facsimiles and photocopiers, is subject to the Privacy and Security Rules.

Final Rule

The final rule adopts the definition as proposed with two additional modifications. First, in paragraph (2) we remove the parenthetical language referring to ''wide open'' with respect to the Internet and ''using Internet technology to link a business with information accessible only to collaborating parties'' with respect to extranets and intranets. The parenthetical language initially helped clarify what was intended by key words within the definition. As these key words have become more generally understood and guidance has become available through the NIST regarding specific key terms, such as intranet, extranet, and internet, (see, for example, NIST IR 7298 Revision 1, Glossary of Key Information Security Terms, February 2011, available at *http://csrc.nist.gov/publications/nistir/ir7298-rev1/nistir-7298-revision1.pdf*), we believe the parenthetical language is no longer helpful. Second, we do accept the recommendation that we alter the language in paragraph (2) to include the word ''immediately,'' to exclude transmissions when the information exchanged did not exist in electronic form immediately before transmission. This modification clarifies that a facsimile machine accepting a hardcopy document for transmission is not a covered transmission even though the document may have originated from printing from an electronic file.

We do not believe these changes will have unforeseen impacts on the application of the term in the transactions and code sets requirements at Part 162.

In response to commenters' concerns that photocopiers, facsimiles, and other office machines may retain electronic data, potentially storing protected health information when used by covered entities or business associates, we clarify that protected health information stored, whether intentionally or not, in photocopier, facsimile, and other devices is subject to the Privacy and Security Rules. Although such devices are not generally relied upon for storage and access to stored information, covered entities and business associates should be aware of the capabilities of these devices to store protected health information and must ensure any protected health information stored on such devices is appropriately protected and secured from inappropriate access, such as by monitoring or restricting physical access to a photocopier or a fax machine that is used for copying or sending protected health information. Further, before removal of the device from the covered entity or business associate, such as at the end of the lease term for a photocopier machine, proper safeguards should be followed to remove the electronic protected health information from the media.

c. Definition of ''Protected Health Information''

Proposed Rule

For consistency with the proposed modifications to the period of protection for decedent information at § 164.502(f) (discussed below), the Department proposed to modify the definition of ''protected health information'' at § 160.103 to provide that the Privacy and Security Rules do not protect the individually identifiable health information of persons who have been deceased for more than 50 years.

Overview of Public Comment

The public comments received on this proposal are discussed and responded to below in the section describing the modifications to § 164.502(f).

Final Rule

For the reasons stated in the section regarding § 164.502(f), the final rule adopts the proposed modification to the definition of ''protected health information.''

d. Definition of ''State''

Proposed Rule

The HITECH Act at section 13400 includes a definition of ''State'' to mean ''each of the several States, the District of Columbia, Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Northern Mariana Islands.'' This definition varies from paragraph (2) of the HIPAA definition of ''State'' at § 160.103, which does not include reference to American Samoa and the Northern Mariana Islands. Thus, for consistency with the definition applied to the HIPAA Rules by the HITECH Act, we proposed to add reference to American Samoa and the Commonwealth of the Northern Mariana Islands in paragraph (2) of the definition of ''State'' at § 160.103.

Final Rule

The Department did not receive substantive public comment on this proposal and the final rule adopts the proposed modifications to the definition of ''State.''

e. Other Changes to the Definitions in Section 160.103

In addition to the changes discussed above, the final rule makes the following changes as proposed in the NPRM to various definitions in § 160.103:

(1) Relocates the definitions of ''administrative simplification provision,'' ''ALJ,'' ''civil money penalty,'' ''respondent,'' and ''violation or violate'' from § 160.302 to § 160.103 for ease of reference;

(2) Adds a reference to sections 13400–13424 of the HITECH Act to the definition of ''administrative simplification provision'';

(3) Removes a comma from the definition of ''disclosure'' inadvertently inserted into the definition in a prior rulemaking;

(4) Replaces the term ''individually identifiable health information'' with ''protected health information'' in the definition of ''standard'' to better reflect the scope of the Privacy and Security Rules;

(5) Adds a reference to ''business associate'' following the reference to ''covered entity'' in the definitions of ''respondent'' and ''compliance date,'' in recognition of the potential liability imposed on business associates for violations of certain provisions of the Privacy and Security Rules by sections 13401 and 13404 of the Act; and

(6) Revises the definition of ''workforce member'' in § 160.103 to make clear that the term includes the employees, volunteers, trainees, and other persons whose conduct, in the performance of work for a business associate, is under the direct control of the business associate, because some provisions of the Act and the Privacy and Security Rules place obligations on the business associate with respect to workforce members.

4. Subpart B—Preemption of State Law

a. Section 160.201—Statutory Basis

Proposed Rule

We proposed to modify § 160.201 regarding the statutory basis for the preemption of State law provisions to add a reference to section 264(c) of HIPAA, which contains the statutory basis for the exception to preemption at § 160.203(b) for State laws that are more stringent than the HIPAA Privacy Rule. We also proposed to add a reference to

section 13421(a) of the HITECH Act, which applies HIPAA's preemption rules to the HITECH Act's privacy and security provisions. Finally, we proposed to re-title the provision to read ''Statutory basis'' instead of ''Applicability.''

Overview of Public Comments

Several commenters expressed concerns about the lack of uniform Federal and State privacy laws and the resultant confusion and expense associated with determining which laws apply to a given circumstance, particularly as more and more health care entities operate across multiple state lines. Commenters recommended that the Department make efforts to engage States and other partners to examine divergent Federal and State requirements and to attempt to coordinate various disclosure rules to drive Federal-State consensus.

Final Rule

The final rule adopts the proposed modifications. In response to the comments concerned with the lack of uniform Federal and State privacy laws, we note that the preemption provisions of the HIPAA Rules are based on section 1178 of the Social Security Act and section 264(c)(2) of HIPAA. Through these statutory provisions, Congress made clear that the HIPAA privacy requirements are to supersede only contrary provisions of State law, and not even in all such cases, such as where the provision of State law provides more stringent privacy protections than the HIPAA Privacy Rule. Accordingly, the HIPAA Privacy Rule provides a Federal floor of privacy protections, with States free to impose more stringent privacy protections should they deem appropriate.

b. Section 160.202—Definitions

i. Definition of ''Contrary''

Proposed Rule

The term ''contrary'' is defined in § 160.202 to make clear when the preemption provisions of HIPAA apply to State law. For the reasons set forth on page 40875 of the July 2010 NPRM, we proposed to amend the definition of ''contrary'' by inserting references to business associates in paragraph (1) of the definition. We also expanded the reference to the HITECH statutory provisions in paragraph (2) of the definition to encompass all of the sections of subtitle D of the HITECH Act, rather than merely to section 13402, which was added by the breach notifications interim final rule. These changes would give effect to section 13421(a).

Final Rule

The Department did not receive substantive public comment on this proposal. The final rule adopts the proposed modifications.

ii. Definition of ''More Stringent''

Proposed Rule

The term ''more stringent'' is part of the statutory preemption language under HIPAA. HIPAA preempts State law that is contrary to a HIPAA privacy standard unless, among other exceptions, the State law is more stringent than the contrary HIPAA privacy standard. We proposed to amend the definition to add a reference to business associates.

Final Rule

The Department did not receive substantive public comment on this proposal. The final rule adopts the proposed modification.

B. Subparts C and D of Part 160: Amendments to the Enforcement Rule

Section 13410 of the HITECH Act made several amendments to the Social Security Act to strengthen the HIPAA Enforcement Rule, which applies to the Secretary's enforcement of all of the HIPAA Administrative Simplification Rules, as well as the Breach Notification Rule.

On October 30, 2009, the Department issued an interim final rule (IFR) revising the Enforcement Rule to incorporate the provisions of section 13410(d) of the HITECH Act that took effect immediately to apply to violations of the HIPAA Rules occurring after the enactment date of February 18, 2009. See 74 FR 56123. In general, section 13410(d) of the HITECH Act revised section 1176(a) of the Social Security Act to establish four categories of violations that reflect increasing levels of culpability and four corresponding tiers of penalty amounts that significantly increased the minimum penalty amount for each violation, with a maximum penalty amount of $1.5 million annually for all violations of an identical provision. Section 13410(d) also amended section 1176(b) of the Social Security Act by removing the previous affirmative defense to the imposition of penalties if the covered entity did not know and with the exercise of reasonable diligence would not have known of the violation (these violations are now punishable under the lowest tier of penalties), and by providing a prohibition on the imposition of penalties for any violation that is timely corrected, as long as the violation was not due to willful neglect. The IFR updated the HIPAA Enforcement Rule to reflect these statutory amendments. The IFR did not make amendments with respect to those enforcement provisions of section 13410 of the HITECH Act that were not effective immediately upon enactment.

In its July 2010 NPRM, the Department proposed a number of additional modifications to the Enforcement Rule to reflect other provisions of section 13410 of the HITECH Act, some of which became effective on February 18, 2010, or were to become effective at a later date: (1) Requiring that the Secretary formally investigate complaints indicating violations due to willful neglect, and impose civil money penalties upon finding violations due to willful neglect; (2) making business associates of covered entities directly liable for civil money penalties for violations of certain provisions of the HIPAA Rules; (3) requiring the Secretary to determine civil money penalty amounts based upon the nature and extent of the harm resulting from a violation; and (4) providing that the Secretary's authority to impose a civil money penalty will be barred only to the extent a criminal penalty has been imposed with respect to an act under Section 1177, rather than in cases in which the act constitutes an offense that is criminally punishable under Section 1177.

The following discussion describes the enforcement provisions of the IFR and the NPRM, responds to public comment received by the Department on both rules, and describes the final modifications to the Enforcement Rule adopted by this final rule. In addition to the modifications discussed below, this final rule also adopts the NPRM proposal to add the term ''business associate'' to the following provisions of the Enforcement Rule: §§ 160.300; 160.304; 160.306(a) and (c); 160.308; 160.310; 160.312; 160.316; 160.401; 160.402; 160.404(b); 160.406; 160.408(c) and (d); and 160.410(a) and (c). This is done to implement sections 13401 and 13404 of the Act, which impose direct civil money penalty liability on business associates for their violations of certain provisions of the HIPAA Rules.

1. Subpart C of Part 160—Compliance and Investigations

a. Sections 160.304, 160.306, 160.308, and 160.312—Noncompliance Due to Willful Neglect

Proposed Rule

Section 13410(a) of the HITECH Act adds a new subsection (c) to section 1176 of the Social Security Act, which requires the Department to formally investigate a complaint if a preliminary investigation of the facts of the complaint indicates a possible violation due to willful neglect (section 1176(c)(2)) and to impose a civil money penalty for a violation due to willful neglect (section 1176(c)(1)). The Department proposed a number of modifications to Subpart C of the Enforcement Rule to implement these provisions.

First, § 160.306(c) of the Enforcement Rule currently provides the Secretary with discretion to investigate HIPAA complaints through the use of the word ''may.'' As a practical matter, however, the Department currently conducts a preliminary review of every complaint received and proceeds with the investigation in every eligible case where its preliminary review of the facts indicates a possible violation of the HIPAA Rules. Nonetheless, to implement section 1176(c)(2), the Department proposed to add a new paragraph (1) to § 160.306(c) (and to make conforming changes to the remainder of § 160.306(c)) to make clear that the Secretary will investigate any complaint filed under this section when a preliminary review of the facts indicates a possible violation due to willful neglect. Under proposed § 160.306(c)(2), the Secretary would have continued discretion with respect to investigating any other complaints.

Second, the Department proposed to modify § 160.308 by adding a new paragraph (a) to provide that the Secretary will conduct a compliance review to determine whether a covered entity or business associate is complying with the applicable administrative simplification provision when a preliminary review of the facts indicates a possible violation due to willful neglect. Like § 160.306(c) with respect to complaints, the current § 160.308(c) provides the Secretary with discretion to conduct compliance reviews. While section 13410(a) of the HITECH Act specifically mentions complaints and not compliance reviews with respect to willful neglect, the Department proposed to treat compliance reviews in the same manner because it believed doing so would strengthen enforcement with respect to potential violations of willful neglect and would ensure that investigations, whether or not initiated by a complaint, would be handled in a consistent manner. Under proposed § 160.308(b), the Secretary would continue to have discretion to conduct compliance reviews in circumstances not indicating willful neglect.

Third, given the HITECH Act's requirement that the Secretary impose a penalty for any violation due to willful neglect, the Department proposed changes to § 160.312, which currently requires the Secretary to attempt to resolve investigations or compliance reviews indicating noncompliance by informal means. The NPRM proposed to provide instead in § 160.312(a) that the Secretary ''may'' rather than ''will'' attempt to resolve investigations or compliance reviews indicating noncompliance by informal means. This change would permit the Department to proceed with a willful neglect violation determination as appropriate, while also permitting the Department to seek resolution of complaints and compliance reviews that did not indicate willful neglect violations by informal means (e.g., where the covered entity or business associate did not know and by exercising reasonable diligence would not have known of a violation, or where the violation is due to reasonable cause).

Finally, the Department proposed a conforming change to § 160.304(a), which currently requires the Secretary to seek, to the extent practicable, the cooperation of covered entities in obtaining compliance with the HIPAA Rules. The NPRM proposed to clarify that the Secretary would continue to do so ''consistent with the provisions of this subpart'' in recognition of the new HITECH Act requirement to impose a civil money penalty for a violation due to willful neglect. While the Secretary often will still seek to correct indications of noncompliance through voluntary corrective action, there may be circumstances (such as circumstances indicating willful neglect), where the Secretary may proceed directly to formal enforcement.

Overview of Public Comments

One commenter supported maintaining the current language at §§ 160.306 and 160.308 of the Enforcement Rule, providing the Secretary with discretion to conduct complaint investigations and compliance reviews, regardless of indications of willful neglect. One commenter suggested that OCR look to whether facts indicate a ''probable,'' rather than ''possible,'' violation due to willful neglect to limit the likelihood of unnecessary formal investigations or compliance reviews. While one commenter supported the proposal to require a compliance review in circumstances indicating a possible violation due to willful neglect, others argued that requiring compliance reviews in such circumstances is not required by the statute, will detract from resources to investigate complaints, and will be duplicative if a formal complaint investigation is also underway.

Several commenters expressed concern over the proposal at § 160.312(a) to give the Secretary discretion, rather than to require the Secretary, to attempt to resolve investigations or compliance reviews indicating noncompliance by informal means, even in cases of noncompliance that did not involve willful neglect (e.g., cases involving reasonable cause or lack of knowledge of a violation). Commenters indicated support for the Department's seeking compliance through voluntary corrective action as opposed to formal enforcement proceedings and argued that the Department should retain the requirement for the Secretary to attempt informal resolution in all circumstances except those involving willful neglect. One commenter recommended that the Secretary be able to assess penalties regardless of whether corrective action was obtained.

Final Rule

The final rule adopts the modifications to §§ 160.304, 160.306, 160.308, and 160.312, as proposed in the NPRM. The Department believes these changes to the enforcement provisions to be appropriate given the HITECH Act's requirements at section 13410(a) with respect to circumstances indicating or involving noncompliance due to willful neglect. We do not provide in the Rule that the Secretary will investigate when a preliminary review of the facts indicates a ''probable'' rather than ''possible'' violation due to willful neglect as the statute requires an investigation even in cases indicating a ''possible'' violation due to willful neglect. In response to commenters concerned about requiring the Secretary to conduct compliance reviews in circumstances in which facts indicate a possible violation due to willful neglect, we continue to believe that, while not expressly required by the statute, doing so appropriately strengthens enforcement with respect to violations due to willful neglect and ensures consistency in the handling of complaints and compliance reviews in

which violations due to willful neglect are indicated. We emphasize that the Department retains discretion to decide whether to conduct a compliance review (or complaint investigation) where a preliminary review of the facts indicates a degree of culpability less than willful neglect. Further, with respect to commenter concerns about duplication between complaint investigations and compliance reviews, we clarify that the Department generally conducts compliance reviews to investigate allegations of violations of the HIPAA Rules brought to the Department's attention through a mechanism other than a complaint. For example, the Department may use a compliance review to investigate allegations of violations of the Rules brought to our attention through a media report, or from a State or another Federal agency. If the Department initiates an investigation of a complaint because its preliminary review of the facts indicates a possible violation due to willful neglect, the Department is not also required to initiate a compliance review under § 160.308 because doing so would initiate a duplicative investigation.

With respect to § 160.312, where the Rule previously mandated that the Secretary attempt to resolve indicated violations of the HIPAA Rules by informal means, the final rule now provides the Secretary with the discretion to do so, to reflect Section 13410 of the HITECH Act with regard to violations due to willful neglect. Nothing in Section 13410 of the HITECH Act limits the Secretary's ability to resolve such cases by informal means. However, through its introduction of higher penalties and its mandate for formal investigations with regard to possible violations due to willful neglect, Section 13410 strengthens enforcement and accordingly we have revised § 160.312 so that the Secretary may move directly to a civil money penalty without exhausting informal resolution efforts at her discretion, particularly in cases involving willful neglect violations.

Response to Other Public Comments

Comment: A number of commenters requested further clarification on the scope and depth of what constitutes a ''preliminary review of the facts'' for purposes of determining whether facts indicate a possible violation due to willful neglect and thus, warrant a formal complaint investigation or compliance review. Certain commenters suggested that a preliminary review of the facts should go beyond merely a review of the allegations asserted in a complaint.

Response: As noted above, currently the Department conducts a preliminary review of every complaint received and proceeds with the investigation in every eligible case where its preliminary review of the facts indicates a possible violation of the HIPAA Rules. The Department anticipates that some complaints, on their face, or reports or referrals that form the basis of a potential compliance review, will contain sufficient information to indicate a possible violation due to willful neglect, and some may not. In any event, the Department may on a case-by-case basis expand the preliminary review and conduct additional inquiries for purposes of identifying a possible violation due to willful neglect. Notwithstanding the scope of a preliminary review, OCR will determine if an indicated violation was due to willful neglect based on the evidence from its investigation of the allegations, even if a violation due to willful neglect was not indicated at the preliminary review stage.

b. Section 160.310—Protected Health Information Obtained by the Secretary

Proposed Rule

Section 160.310 requires that covered entities make information available to and cooperate with the Secretary during complaint investigations and compliance reviews. Section 160.310(c)(3) provides that any protected health information obtained by the Secretary in connection with an investigation or compliance review will not be disclosed by the Secretary, except as necessary for determining and enforcing compliance with the HIPAA Rules or as otherwise required by law. In the proposed rule, we proposed to modify this paragraph to also allow the Secretary to disclose protected health information if permitted under the Privacy Act at 5 U.S.C. 552a(b)(7). Section 5 U.S.C. 552a(b)(7) permits the disclosure of a record on an individual contained within a government system of records protected under the Privacy Act to another agency or instrumentality of any governmental jurisdiction within or under the control of the United States for a civil or criminal law enforcement activity if the activity is authorized by law and if the agency has made a written request to the agency that maintains the record. The proposed change would permit the Secretary to coordinate with other law enforcement agencies, such as the State Attorneys General pursuing civil actions to enforce the HIPAA Rules on behalf of State residents pursuant to section 13410(e) of the Act, or the FTC pursuing remedies under other consumer protection authorities.

Overview of Public Comments

One commenter requested clarification and transparency on how or if Federal regulators such as OCR and the FTC will collaborate, when such information sharing will be initiated or occur as a routine process, or whether Federal and State agencies will work together to enforce suspected violations.

Final Rule

To facilitate cooperation between the Department and other law enforcement agencies, the final rule adopts the modifications to § 160.310(c)(3) as proposed in the NPRM. In response to the comment regarding transparency in how the Department is or will cooperate with other agencies in enforcement, we note that the Department's web site at *http://www.hhs.gov/ocr/enforcement/* contains information about how the Department coordinates with the Department of Justice to refer cases involving possible criminal HIPAA violations and how the Department has worked with the FTC to coordinate enforcement actions for violations that implicate both HIPAA and the FTC Act. Further, the Department will be working closely with State Attorneys General to coordinate enforcement in appropriate cases, as provided under section 13410(e) of the HITECH Act. The Department will continue to update its web site as necessary and appropriate to maintain transparency with the public and the regulated community about these coordinated activities and its other enforcement actions and activities.

2. Subpart D—Imposition of Civil Money Penalties

a. Section 160.401—Definitions

Section 160.401 defines ''reasonable cause,'' ''reasonable diligence,'' and ''willful neglect.'' Given that section 13410(d) of the HITECH Act uses these terms to describe the increasing levels of culpability for which increasing minimum levels of penalties may be imposed, the Department moved these definitions in the IFR from their prior placement at § 160.410, which pertains only to affirmative defenses, to § 160.401, so that they would apply to the entirety of Subpart D of Part 160 and the provisions regarding the imposition of civil money penalties. The IFR did not modify the definitions themselves as the HITECH Act did not amend the definitions.

Even though the HITECH Act did not amend the definitions of these terms,

the Department in its NPRM proposed certain modifications to the definition of ''reasonable cause'' to clarify the mens rea (state of mind) required for this category of violations, and to avoid the situation where certain violations would not fall within one of the established penalty tiers. This modification is discussed below. The Department did not propose modifications to the definitions of ''reasonable diligence'' and ''willful neglect.''

In the NPRM, the Department also included examples and guidance as to how the Department planned to apply the definitions of ''reasonable cause,'' ''reasonable diligence,'' and ''willful neglect'' to distinguish among the tiers of culpability. 75 FR 40877–40879. As commenters generally found this guidance helpful, the Department intends to publish the guidance on its web site.

Modifications to the Definition of ''Reasonable Cause''

Proposed Rule

Reasonable cause is currently defined at § 160.401 to mean: ''circumstances that would make it unreasonable for the covered entity, despite the exercise of ordinary business care and prudence, to comply with the administrative simplification provision violated.'' This definition is consistent with the Supreme Court's ruling in *United States* v. *Boyle,* 469 U.S. 241, 245 (1985), which focused on whether circumstances were beyond the regulated person's control, thereby making compliance unreasonable. See 70 FR 20224, 20238. Prior to the HITECH Act, section 1176 of the Social Security Act provided an affirmative defense to the imposition of a civil money penalty if the covered entity established that its violation was due to reasonable cause and not willful neglect and was corrected within a 30-day period (or such additional period determined by the Secretary to be appropriate).

As described above, section 13410(d) of the HITECH Act revised section 1176 of the Social Security Act to establish four tiers of increasing penalty amounts to correspond to the levels of culpability associated with the violation. The first category of violation (and lowest penalty tier) covers situations where the covered entity or business associate did not know, and by exercising reasonable diligence would not have known, of a violation. The second category of violation (and next highest penalty tier) applies to violations due to reasonable cause and not to willful neglect. The third and fourth categories apply to circumstances where the violation was due to willful neglect that is corrected within a certain time period (second highest penalty tier) and willful neglect that is not corrected (highest penalty tier). The mens rea, or state of mind, associated with the tiers is clear with respect to the first, third, and fourth categories, in that there is no mens rea with respect to the lowest category of violation, while the existence of mens rea is presumed with respect to the third and fourth categories of violation.

However, the current definition of ''reasonable cause'' does not address mens rea with respect to the second category of violations. Therefore, the Department proposed to amend the definition of ''reasonable cause'' at § 160.401 to clarify the mens rea associated with the reasonable cause category of violations and to clarify the full scope of violations that will come within the category. Specifically, the Department proposed to modify the definition of ''reasonable cause'' to mean ''an act or omission in which a covered entity or business associate knew, or by exercising reasonable diligence would have known, that the act or omission violated an administrative simplification provision, but in which the covered entity or business associate did not act with willful neglect.'' Thus, the proposed definition would now include violations due both to circumstances that would make it unreasonable for the covered entity or business associate, despite the exercise of ordinary business care and prudence, to comply with the administrative simplification provision violated, as well as to other circumstances in which a covered entity or business associate has knowledge of a violation but lacks the conscious intent or reckless indifference associated with the willful neglect category of violations.

Overview of Public Comments

Commenters addressing the definition of ''reasonable cause'' expressed general support for the proposed clarifications to the scope of this category of violations.

Final Rule

The final rule adopts the proposed modifications to the definition.

b. Section 160.402—Basis for a Civil Money Penalty

Proposed Rule

Section 160.402(a) states generally that the Secretary will impose a civil money penalty upon a covered entity if the Secretary determines that the covered entity violated an administrative simplification provision. Section 164.402, in paragraphs (b) and (c), provides the basis for a civil money penalty against a covered entity where more than one covered entity is responsible for a violation, where an affiliated covered entity is responsible for a violation, and where an agent of a covered entity is responsible for a violation.

The proposed rule proposed to remove the exception at § 160.402(c) for covered entity liability for the acts of its agent in cases where the agent is a business associate, the relevant contract requirements have been met, the covered entity did not know of a pattern or practice of the business associate in violation of the contract, and the covered entity did not fail to act as required by the Privacy or Security Rule with respect to such violations. The proposed rule also proposed to add a parallel provision in a new paragraph (2) at § 160.402(c) that would provide for civil money penalty liability against a business associate for the acts of its agent. The existing language of § 160.402(c) regarding the liability of covered entities for the acts of their agents would be re-designated as paragraph (1).

These proposed changes would make covered entities and business associates liable under § 160.402(c) for the acts of their business associate agents, in accordance with the Federal common law of agency, regardless of whether the covered entity has a compliant business associate agreement in place. Section 160.402(c) closely tracks the language in section 1128A(l) of the Social Security Act, which is made applicable to HIPAA by section 1176(a)(2) of such Act, which states that ''a principal is liable for penalties * * * under this section for the actions of the principal's agents acting within the scope of the agency.'' One reason for removing the exception to the general provision at § 160.402(c), as we explained in the NPRM, is to ensure, where a covered entity or business associate has delegated out an obligation under the HIPAA Rules, that a covered entity or business associate would remain liable for penalties for the failure of its business associate agent to perform the obligation on the covered entity or business associate's behalf.

Overview of Public Comments

Several commenters requested that the Department clarify and provide additional guidance regarding how the Federal common law of agency applies to business associate relationships. These commenters expressed an overall concern that applying the Federal common law of agency to business

associate relationships would add unnecessary confusion to and place an undue burden on business associate relationships. Several commenters argued that the proposed change would require covered entities and business associates to determine whether their business associates or business associate subcontractors are agents, resulting in costly and burdensome challenges when drafting business associate contracts and monitoring ongoing relationships. One commenter argued that the Federal common law of agency should not be applied to covered entity and business associate relationships because it does not generally control when the parties have entered into a contractual agreement that specifies their respective rights and obligations. Instead, the commenter argued, the contractual provisions control, and are interpreted and enforced in accordance with State law specified by the contract.

Final Rule

This final rule adopts the proposed modifications to § 160.402(c). We do not believe that this change will place an undue burden on covered entities and business associates. As we explained in the NPRM, a covered entity's liability for acts of its agents is customary under common law. See 75 FR 40880. Further, section 1128A(l) of the Social Security Act, applicable to HIPAA covered entities and now business associates by section 1176(a)(2) of the Act, states that a principal is liable for civil money penalties for the actions of the principal's agent acting within the scope of agency. Before the changes to § 160.402(c) were finalized in this rule, if a covered entity failed to comply with the business associate provisions in the HIPAA Rules, a covered entity potentially would have been liable for the actions of its business associate agent. Thus, we believe that the notion that a principal is liable for the acts of its agent should not be an unfamiliar concept to covered entities and business associates. However, we appreciate and understand the commenters' concerns and take this opportunity to provide additional guidance.

While section 1128A(l) is silent as to how to define ''principal,'' ''agent,'' and ''scope of agency,'' § 160.402(c) references the Federal common law of agency. As we explained in the Enforcement Rule preamble, 71 FR 8390, 8403–04, adopting the Federal common law to determine the definitions and application of these terms achieves nationwide uniformity in the implementation of the HIPAA Rules. We believe that relying on the Federal common law is particularly important because of HIPAA's express objective of furthering the efficiency and effectiveness of the health care system as a whole. Further, adopting the Federal common law here is consistent with the precept that Federal statutes are meant to have uniform nationwide application. Therefore, we disagree with the comment that argued that Federal common law should not be applied with respect to relationships between covered entities and business associates.

An analysis of whether a business associate is an agent will be fact specific, taking into account the terms of a business associate agreement as well as the totality of the circumstances involved in the ongoing relationship between the parties. The essential factor in determining whether an agency relationship exists between a covered entity and its business associate (or business associate and its subcontractor) is the right or authority of a covered entity to control the business associate's conduct in the course of performing a service on behalf of the covered entity. The right or authority to control the business associate's conduct also is the essential factor in determining whether an agency relationship exists between a business associate and its business associate subcontractor. Accordingly, this guidance applies in the same manner to both covered entities (with regard to their business associates) and business associates (with regard to their subcontractors).

The authority of a covered entity to give interim instructions or directions is the type of control that distinguishes covered entities in agency relationships from those in non-agency relationships. A business associate generally would not be an agent if it enters into a business associate agreement with a covered entity that sets terms and conditions that create contractual obligations between the two parties. Specifically, if the only avenue of control is for a covered entity to amend the terms of the agreement or sue for breach of contract, this generally indicates that a business associate is not acting as an agent. In contrast, a business associate generally would be an agent if it enters into a business associate agreement with a covered entity that granted the covered entity the authority to direct the performance of the service provided by its business associate after the relationship was established. For example, if the terms of a business associate agreement between a covered entity and its business associate stated that ''a business associate must make available protected health information in accordance with § 164.524 based on the instructions to be provided by or under the direction of a covered entity,'' then this would create an agency relationship between the covered entity and business associate for this activity because the covered entity has a right to give interim instructions and direction during the course of the relationship. An agency relationship also could exist between a covered entity and its business associate if a covered entity contracts out or delegates a particular obligation under the HIPAA Rules to its business associate. As discussed above, whether or not an agency relationship exists in this circumstance again would depend on the right or authority to control the business associate's conduct in the performance of the delegated service based on the right of a covered entity to give interim instructions.

While these principles are well established under the Federal common law of agency, we again note that any analysis regarding scope of agency depends on the facts of each circumstance. Several factors are important to consider in any analysis to determine the scope of agency: (1) The time, place, and purpose of a business associate agent's conduct; (2) whether a business associate agent engaged in a course of conduct subject to a covered entity's control; (3) whether a business associate agent's conduct is commonly done by a business associate to accomplish the service performed on behalf of a covered entity; and (4) whether or not the covered entity reasonably expected that a business associate agent would engage in the conduct in question.

The terms, statements, or labels given to parties (e.g., independent contractor) do not control whether an agency relationship exists. Rather, the manner and method in which a covered entity actually controls the service provided decides the analysis. As mentioned above, an analysis of whether a business associate is an agent will be fact specific and consider the totality of the circumstances involved in the ongoing relationship between the parties. We note here several circumstances that are important. The type of service and skill level required to perform the service are relevant factors in determining whether a business associate is an agent. For example, a business associate that is hired to perform de-identification of protected health information for a small provider would likely not be an agent because the small provider likely would not have the expertise to provide interim instructions regarding this activity to the business associate. Also, an agency relationship would not likely exist when a covered entity is legally or

otherwise prevented from performing the service or activity performed by its business associate. For example, the accreditation functions performed by a business associate cannot be performed by a covered entity seeking accreditation because a covered entity cannot perform an accreditation survey or award accreditation. We also note that a business associate can be an agent of a covered entity: (1) Despite the fact that a covered entity does not retain the right or authority to control every aspect of its business associate's activities; (2) even if a covered entity does not exercise the right of control but evidence exists that it holds the authority to exercise that right; and (3) even if a covered entity and its business associate are separated by physical distance (e.g., if a covered entity and business associate are located in different countries).

Response to Other Public Comments

Comment: One commenter asked whether the Department intends to eliminate the exceptions afforded by the Federal common law of agency. This commenter also argued that if a business associate were an agent of a covered entity, and a HIPAA compliant business associate agreement was in place, any deviation from the terms in the agreement would be by definition outside the scope of agency.

Response: As we discussed above, § 160.402(c) provides that covered entities and business associates are liable for the acts of their business associate agents, in accordance with the Federal common law of agency. Section 160.402(c) is derived from section 1128A(l) of the Social Security Act which states that ''a principal is liable for penalties * * * under this section for the actions of the principal's agents acting within the scope of the agency.'' Accordingly, § 160.402(c) incorporates the Federal common law of agency, which includes the understanding that for a principal to be liable for the actions of an agent, the agent must be acting within the scope of agency. Thus, the exceptions to the Federal common law of agency (as the commenter identified them) are incorporated in the final rule at § 160.402(c).

We do not agree with the commenter that any deviation from the terms in a business associate contract would be by definition outside the scope of agency. A business associate agent's conduct generally is within the scope of agency when its conduct occurs during the performance of the assigned work or incident to such work, regardless of whether the work was done carelessly, a mistake was made in the performance, or the business associate disregarded a covered entity's specific instruction. For example, a business associate agent would likely be acting within the scope of agency if it impermissibly disclosed more than the minimum necessary information to a health plan for purposes of payment, even if the disclosure is contrary to clear instructions of the covered entity. In contrast, a business associate agent's conduct generally is outside the scope of agency when its conduct is solely for its own benefit (or that of a third party), or pursues a course of conduct not intended to serve any purpose of the covered entity.

Comment: One commenter stated that the proposed change would impose strict liability on covered entities for the actions of third parties not under their control. Another commenter stated that an agent would always fall within the scope of a workforce member, which by definition is not a business associate.

Response: We disagree with both comments and believe that the comments may reflect a misunderstanding of the proposed change. First, as explained above, § 160.402(c) closely tracks the language in section 1128A(l) of the Social Security Act, which is made applicable to HIPAA by section 1176(a)(2) of such Act. It does not make a covered entity or business associate liable for the acts of third parties that are not under its control because such third parties are not its agents. With regard to the second comment, an agent could always fall within the definition of a workforce member because of the direct control requirement in that definition, but the definition of business associate excludes a workforce member. This definitional exclusion allows the covered entity to determine whether, for example, to provide training to the agent under the Privacy Rule. A covered entity would be required to provide training to a workforce member but not to a business associate agent. However, the covered entity is required to enter into a business associate agreement with a business associate agent that it does not treat as a workforce member. The proposed change to § 160.402(c) simply makes the covered entity or business associate liable for the acts of its agents acting within the scope of agency, whether the agents are workforce members or business associates. See the definitions of ''business associate'' and ''workforce member'' at § 160.103.

c. Section 160.404—Amount of a Civil Monetary Penalty

Interim Final Rule

The IFR amended § 160.404 to revise the range of potential civil money penalty amounts a covered entity (or business associate) will be subject to for violations occurring on or after February 18, 2009, as a result of section 13410(d) of the HITECH Act.

Prior to the HITECH Act, section 1176(a) of the Social Security Act authorized the Secretary to impose a civil money penalty of not more than $100 for each violation, with the total amount imposed on a covered entity for all violations of an identical requirement or prohibition during a calendar year not to exceed $25,000. As described above, section 13410(d) of the HITECH Act modified section 1176(a) to establish tiers of increasing penalty amounts for violations based on increasing levels of culpability associated with each tier.

Accordingly, the IFR adopted at § 160.404(b) the new penalty scheme provided for at section 13410(d) of the HITECH Act for violations occurring on or after February 18, 2009. The IFR retained the pre-HITECH maximum penalty amounts of not more than $100 per violation and $25,000 for identical violations during a calendar year, for violations occurring before February 18, 2009.

In adopting the HITECH Act's penalty scheme, the Department recognized that section 13410(d) contained apparently inconsistent language (i.e., its reference to two penalty tiers ''for each violation,'' each of which provided a penalty amount ''for all such violations'' of an identical requirement or prohibition in a calendar year). To resolve this inconsistency, with the exception of violations due to willful neglect that are not timely corrected, the IFR adopted a range of penalty amounts between the minimum given in one tier and the maximum given in the second tier for each violation and adopted the amount of $1.5 million as the limit for all violations of an identical provision of the HIPAA rules in a calendar year. For violations due to willful neglect that are not timely corrected, the IFR adopted the penalty amount of $50,000 as the minimum for each violation and $1.5 million for all such violations of an identical requirement or prohibition in a calendar year.

Specifically, the IFR revised § 160.404 to provide, for violations occurring on or after February 18, 2009, the new HITECH penalty scheme, as follows: (1) For violations in which it is established that the covered entity did not know

and, by exercising reasonable diligence, would not have known that the covered entity violated a provision, an amount not less than $100 or more than $50,000 for each violation; (2) for a violation in which it is established that the violation was due to reasonable cause and not to willful neglect, an amount not less than $1000 or more than $50,000 for each violation; (3) for a violation in which it is established that the violation was due to willful neglect and was timely corrected, an amount not less than $10,000 or more than $50,000 for each violation; and (4) for a violation in which it is established that the violation was due to willful neglect and was not timely corrected, an amount not less than $50,000 for each violation; except that a penalty for violations of the same requirement or prohibition under any of these categories may not exceed $1,500,000 in a calendar year. See Table 2 below.

TABLE 2—CATEGORIES OF VIOLATIONS AND RESPECTIVE PENALTY AMOUNTS AVAILABLE

Violation category—Section 1176(a)(1)	Each violation	All such violations of an identical provision in a calendar year
(A) Did Not Know	$100–$50,000	$1,500,000
(B) Reasonable Cause	1,000–50,000	1,500,000
(C)(i) Willful Neglect-Corrected	10,000–50,000	1,500,000
(C)(ii) Willful Neglect-Not Corrected	50,000	1,500,000

In applying these amounts, the Department will not impose the maximum penalty amount in all cases but rather will determine the penalty amounts as required by the statute at section 1176(a)(1) and the regulations at § 160.408 (i.e., based on the nature and extent of the violation, the nature and extent of the resulting harm, and the other factors set forth at § 160.408).

Further, for counting violations, the Department continues to utilize the methodology discussed in prior preambles of the Enforcement Rule. See 70 FR 20224, 20233–55 (April 18, 2005) and 71 FR 8390, 8404–07 (February 16, 2006). For violations that began prior to February 18, 2009, and continue after that date, the Department will treat violations occurring before February 18, 2009, as subject to the penalties in effect prior to February 18, 2009, and violations occurring on or after February 18, 2009, as subject to the penalties in effect on or after February 18, 2009.

Overview of Public Comments

Most comments on the civil money penalty amounts expressed concern with the new penalty structure set forth in the IFR. A few of these commenters expressed a generalized concern about the potential impact the available penalty amounts might have on covered entities, particularly smaller entities. One commenter argued that the Secretary should not fine entities for violations of which a covered entity had no knowledge or those due to reasonable cause, and that civil money penalties should only be imposed as a last resort. A few commenters expressed concern with the Secretary's wide range of discretion in determining a civil money penalty amount and suggested that the regulations or guidance should further define how the Secretary would determine such an amount.

Some commenters specifically expressed concern about the maximum penalty amounts set forth for each violation (i.e., $50,000) and for all violations of an identical provision in a calendar year ($1,500,000). Commenters argued that the IFR's penalty scheme is inconsistent with the HITECH Act's establishment of different tiers based on culpability because the outside limits were the same for all culpability categories and this ignored the outside limits set forth by the HITECH Act within the lower penalty tiers, rendering those limits meaningless. A few commenters expressed particular concern with what they believed to be the unfair ability of the Secretary to impose the maximum penalty amounts to violations falling within the two lowest categories of culpability (i.e., did not know violations and violations due to reasonable cause and not willful neglect).

Final Rule

This final rule retains the revised penalty structure in § 160.404(b) as implemented by the IFR. We continue to believe the penalty amounts are appropriate and reflect the most logical reading of the HITECH Act, which provides the Secretary with discretion to impose penalties for each category of culpability up to the maximum amount described in the highest penalty tier.

With respect to those comments expressing concern about the discretion available to the Secretary under the adopted scheme we emphasize again that the Department will not impose the maximum penalty amount in all cases but will rather determine the amount of a penalty on a case-by-case basis, depending on the nature and extent of the violation and the nature and extent of the resulting harm, as required by the HITECH Act, as well as the other factors set forth at § 160.408. In response to those commenters particularly concerned about the impact of penalties on smaller entities, we note that the other factors include both the financial condition and size of the covered entity or business associate. These factors are discussed more fully below.

In addition, with respect to comments expressing specific concern about fairness regarding those violations of which an entity did not know or by exercising reasonable diligence would not have known or for which there was a reasonable cause and not willful neglect, we note that in both cases an entity may establish that an affirmative defense applies under § 160.410, where the entity corrects the violation within 30 days from the date the entity had knowledge of the violation or with the exercise of reasonable diligence would have had knowledge of the violation, or during a period determined appropriate by the Secretary based upon the nature and extent of the entity's failure to comply. These affirmative defenses are described more fully below.

In addition, Section 13410(d) of the HITECH Act and Section 1176(a) of the Social Security Act, give the Secretary further ability to waive a civil money penalty, in whole or in part, under certain circumstances. Thus, to the extent an entity fails to correct such violations within the mandated timeframe, the Secretary may also utilize her waiver authority provided for at § 160.412, to waive the penalty amount in whole or in part, to the extent that payment of the penalty would be excessive relative to the violation.

Further, pursuant to 42 U.S.C. 1320a–7a(f), the Secretary always has the discretion to settle any issue or case or to compromise the amount of a civil money penalty assessed for a violation of the HIPAA Rules.

Finally, in the event an entity believes that a civil money penalty has been imposed unfairly, the entity could exercise its right under § 160.504 to appeal the imposition of a civil money penalty in a hearing before an administrative law judge.

Response to Other Public Comments

Comment: We received a few comments in response to the IFR and NPRM requesting clarification as to how the Secretary will count violations for purposes of calculating civil money penalties. One commenter requested clarification as to how the numbers of ''occurrences'' are determined, suggesting that penalties could be very significant, and vary significantly, depending on the counting methodology utilized. The Department also received one comment asking whether a violation is defined as one event. This commenter queried, for example, whether the loss of unsecured electronic media would be considered as a single violation, even if the media contained several hundred records. The commenter also asked for confirmation that $1,500,000 is the aggregate limit of all fines for all violations in a given calendar year which would apply across an entire enterprise, regardless of violations occurring in different business units.

Response: How violations are counted for purposes of calculating a civil money penalty vary depending on the circumstances surrounding the noncompliance. Generally speaking, where multiple individuals are affected by an impermissible use or disclosure, such as in the case of a breach of unsecured protected health information, it is anticipated that the number of identical violations of the Privacy Rule standard regarding permissible uses and disclosures would be counted by the number of individuals affected. Further, with respect to continuing violations, such as lack of appropriate safeguards for a period of time, it is anticipated that the number of identical violations of the safeguard standard would be counted on a per day basis (i.e., the number of days the entity did not have appropriate safeguards in place to protect the protected health information). Note also that in many breach cases, there will be both an impermissible use or disclosure, as well as a safeguards violation, for each of which the Department may calculate a separate civil money penalty. We refer readers to prior Enforcement Rule preambles for additional discussion on the counting methodology. See 70 FR 20224, 20233–55 (April 18, 2005) and 71 FR 8390, 8404–07 (February 16, 2006).

With respect to whether the aggregate CMP limit of $1.5 million would apply to all violations in a given calendar year, across an entire enterprise, regardless of violations occurring in different business units of the enterprise, we note that the Enforcement Rule's penalty scheme, and thus the limit for identical violations in a calendar year applies to the legal entity that is a covered entity or business associate. However, as we indicated above, a covered entity or business associate may be liable for multiple violations of multiple requirements, and a violation of each requirement may be counted separately. As such, one covered entity or business associate may be subject to multiple violations of up to a $1.5 million cap for each violation, which would result in a total penalty above $1.5 million.

d. Section 160.408—Factors Considered in Determining the Amount of a Civil Money Penalty

Proposed Rule

Section 160.408 implements section 1176(a)(2) of the Social Security Act, which requires the Secretary, when imposing a civil money penalty, to apply the provisions of section 1128A of the Social Security Act ''in the same manner as such provisions apply to the imposition of a civil money penalty under section 1128A.'' In determining a penalty amount, section 1128A requires the Secretary to take into account the nature of the claims and the circumstances under which they were presented; the degree of culpability, history of prior offenses and financial condition of the person presenting the claims; and such other matters as justice may require.

Section 160.408 adopted these factors and provided a more specific list of circumstances within each. Because the Enforcement Rule applies to a number of rules, which apply to an enormous number of entities and circumstances, the Secretary has the discretion to decide whether and how to consider the factors (i.e., as either aggravating or mitigating) in determining the amount of a civil money penalty.

As previously indicated, section 13410(d) of the HITECH Act modified section 1176(a)(1) of the Social Security Act to require that the Department base determinations of appropriate penalty amounts on the nature and extent of the violation and the nature and extent of the harm resulting from such violation. However, the HITECH Act did not modify section 1176(a)(2),which continues to require application of the factors in section 1128A.

The proposed rule proposed to revise the structure and list of factors at § 160.408 to make explicit the new HITECH Act requirement that the Secretary consider the nature and extent of the violation and the nature and extent of the harm resulting from the violation, in addition to those factors enumerated in section 1128A. We proposed to exclude, however, the factor at § 160.408(c) regarding the degree of culpability of the covered entity, which originated in section 1128A, because culpability is now reflected in the penalty tiers.

Specifically, the Department proposed to revise § 160.408(a) to identify ''the nature and extent of the violation,'' ''the nature and extent of the harm resulting from the violation,'' and the ''history of prior compliance with the administrative simplification provision, including violations by the covered entity or business associate,'' the ''financial condition of the covered entity or business associate,'' and ''such other matters as justice may require,'' as the five general factors the Secretary will consider in determining a civil money penalty. Under each of these categories, we proposed to reorganize and list the specific factors that may be considered.

In addition, in the first, second, and third factors, we proposed to add certain circumstances which may be considered in determining a penalty amount. Under the first factor, we proposed to add ''the number of individuals affected'' as relevant to the extent of a violation. Under the second factor, we proposed to add ''reputational harm'' to the specific circumstances which may be considered, to make clear that reputational harm is as cognizable a form of harm as physical or financial harm. Finally, in the third factor, the Department proposed to modify the phrase ''prior violations'' to ''indications of noncompliance,'' because use of the term ''violation'' is generally reserved for instances where the Department has made a formal finding of a violation through a notice of proposed determination. However, a covered entity's general history of HIPAA compliance is relevant in determining the amount of a civil money penalty within the penalty range.

The Department did not propose to modify the Secretary's discretion in how to apply the factors—i.e., as either mitigating or aggravating.

Overview of Public Comments

We received one comment requesting that the Department limit the number of mitigating factors it will consider when determining penalty amounts and apply

civil money penalties in every case of noncompliance, including where resolution and compliance have been achieved by informal means. The commenter also argued that a covered entity's or business associate's financial condition or financial difficulties should not be considered as mitigating factors in determining the amount of civil money penalties. The commenter recommended that penalties should apply to all violators except those who despite due diligence could not discover the violation, who reported the violation immediately, and who fully corrected the problem within 30 days of discovery.

We received two comments in support of considering reputational harm in the computation of civil money penalties. One commenter emphasized that reputational harm addresses harm to individuals' dignity interest and recommended the inclusion of ''other'' harm as well. However, another covered entity expressed concern that damages for reputational harm are difficult to quantify and, therefore, claims might lead to protracted litigation and expensive settlements, ultimately increasing the costs of health care. Finally, we received one comment requesting examples of situations involving a cognizable claim of reputational harm.

We also received several comments requesting that the Department continue to consider the degree of culpability when determining the amount of a civil money penalty. One commenter specifically recommended that the Department consider whether unauthorized access has occurred when determining civil money penalty amounts. We also received one comment suggesting that the Department revise proposed § 160.408(c) to recognize as a mitigating factor whether the current violation is inconsistent with an entity's prior history of compliance.

With respect to the evaluation of a covered entity's or business associate's history of prior compliance, we received a number of comments expressing concern that replacing ''violations'' with ''indications of noncompliance'' would create ambiguity, and would not adequately inform covered entities and business associates of the factors that the Department will consider when determining civil money penalty amounts. The commenters expressed concern that expanding the evaluation of prior compliance beyond documented, formal findings of noncompliance would permit the Department to rely on information of dubious credibility. Commenters requested that, to prevent uncertainty, the Department either retain the term ''violations'' or provide a clear definition, including examples, of ''indications of noncompliance.''

Finally, we received several comments requesting additional examples and guidance on how the Department will apply the factors in assessing penalty amounts.

Final Rule

The final rule adopts the proposed modifications. We do not eliminate the factors concerning an entity's financial condition, as such factors are based on the requirement in section 1128A(d) of the Social Security Act. We emphasize that the goal of enforcement is to ensure that violations do not recur without impeding access to care. Further, we note that an entity's financial condition can affect a civil money penalty in either direction, that is, while an entity in poor financial condition may face a lesser penalty if its financial condition affected its ability to comply, an entity with greater financial resources could be subject to higher penalties for violations, in part because it had the resources to maintain compliance.

When considering the nature of the violation, the Department intends to consider factors such as the time period during which the violation(s) occurred and the number of individuals affected. Such considerations reflect the nature of the violation, specifically with respect to potential violations that affect a large number of individuals, for example, where disclosure of protected health information in multiple explanation of benefits statements (EOBs) that were mailed to the wrong individuals resulted from one inadequate safeguard but affected a large number of beneficiaries. However, we do recognize that these specific circumstances might also be considered under § 160.406, with respect to counting violations. See 71 FR 8390, 8409.

Whether reputational harm is implicated in a HIPAA violation will be a fact-specific inquiry. We emphasize, however, that we do not consider reputational harm to arise solely from the unlawful disclosure of protected health information relating to medical diagnoses that may be considered especially sensitive, such as sexually transmitted infections or mental health disorders. Rather, the facts of the situation will determine whether reputational harm has occurred, such as whether the unlawful disclosure resulted in adverse effects on employment, standing in the community, or personal relationships. With respect to requests to consider ''other'' harm or whether unauthorized access has occurred, we reiterate that, in determining the nature and extent of the harm involved, we may consider all relevant factors, not just those expressly included in the text of the regulation.

Regarding the shift in terminology from ''history of violations'' to ''prior indications of noncompliance,'' we note that use of the terms ''violation'' or ''violate'' generally indicates that the Department has made a formal finding of a violation through a notice of proposed determination. Because the Department has a number of enforcement tools, such as informal resolution through a corrective action plan, the number of ''violations'' incurred by a covered entity or business associate does not constitute an accurate picture of a covered entity's or business associate's general history of compliance with all HIPAA Rules, which is relevant in determining the amount of a civil money penalty within the penalty range. See 71 FR 8390, 8408. As such, the Department modified the provision to reflect the Department's policy of considering the covered entity's or business associate's general history of compliance with the HIPAA Rules when determining a civil money penalty.

With regard to the phrase ''indications of noncompliance,'' we first clarify that a mere complaint does not constitute an indication of noncompliance. Instead, prior indications of noncompliance may refer to the number of times the Department has investigated an entity in the past and discovered indications of noncompliance that the Department resolved by informal means, such as satisfactory corrective action voluntarily taken by the covered entity. Finally, we agree that an entity's history of compliance—not only a history of noncompliance—is important, and will consider such a factor.

e. Section 160.410—Affirmative Defenses

Interim Final Rule and Proposed Rule

As noted above, the IFR made changes to the affirmatives defenses found in the Enforcement Rule at § 160.410 to implement the modifications to section 1176(b) of the Social Security Act made by section 13410(d) of the HITECH Act. Specifically, the IFR removed the previous affirmative defense to the imposition of penalties if the covered entity did not know and with the exercise of reasonable diligence would not have known of the violation (since such violations are now punishable under the lowest tier of penalties), and by providing a prohibition on the

imposition of penalties for any violation that is corrected within a 30-day time period, as long as the violation was not due to willful neglect.

The proposed rule included additional modifications to § 160.410 to conform to the changes made to section 1176(b) by the HITECH Act. Specifically, we proposed to implement the revision of section 1176(b)(1) of the Social Security Act by providing in § 160.410(a)(1) and (2) that the affirmative defense of criminally ''punishable'' is applicable to penalties imposed prior to February 18, 2011, and on or after February 18, 2011, the Secretary's authority to impose a civil money penalty will only be barred to the extent a covered entity or business associate can demonstrate that a criminal penalty has been imposed. Additionally, the Department also proposed modifications to the affirmative defenses in § 160.410 for violations occurring prior to February 18, 2009, to ensure the prior definition of ''reasonable cause'' continued to apply in such circumstances and avoiding any potential issues regarding a retroactive application of the revised term.

Final Rule

The final rule adopts the proposed modifications to § 160.410. The Department did not receive any comments in response to the NPRM's proposed revisions to this section.

f. Section 160.412—Waiver

Prior to February 18, 2009, § 160.412 stated that ''[f]or violations described in § 160.410(b)(3)(i) that are not corrected within the period described in § 160.410(b)(3)(ii), the Secretary may waive the civil money penalty, in whole or in part, to the extent that payment of the penalty would be excessive relative to the violation.'' This language implicitly recognized a covered entity's ability to claim an affirmative defense to the imposition of a civil money penalty, under what was then § 160.410(b)(2), by establishing that it did not have knowledge of the violation, determined in accordance with the Federal common law of agency, and by exercising reasonable diligence, would not have known that the violation occurred. While section 13410(d) of the HITECH Act revised section 1176(b) of the Social Security Act to eliminate the affirmative defense for such violations, absent corrective action during a 30-day period, it did not revise the Secretary's waiver authority. As a result, the Enforcement IFR amended § 160.412 to reflect the revisions made to § 160.410 to provide that ''[r]egardless of whether violations occur before, on, or after February 18, 2009, the Secretary had the authority to provide a waiver for violations due to reasonable cause and not willful neglect that are not timely corrected (pursuant to the correction period in revised § 160.410(a)(3)(ii) or (b)(2)(ii), as applicable).'' See 74 FR 56129.

The proposed rule included conforming changes to § 160.412 to align the provision with the revisions to § 160.410. See 75 FR 40881. The proposed revision would effectively provide the Secretary with the authority to waive a civil money penalty, in whole or in part, for violations described in § 160.410(b)(2) (occurring prior to February 18, 2009, and due to circumstances that would make it unreasonable for the covered entity, despite the exercise of ordinary business care and prudence, to comply with the administrative simplification provision violated) or § 160.410(c) (occurring on or after February 18, 2009, and involving an establishment to the satisfaction of the Secretary that the violation is not due to willful neglect) and that are not corrected within the period specified under such paragraphs.

Overview of Public Comments

The Department received a few comments in response to the IFR regarding the Secretary's authority to waive the imposition of a civil money penalty for violations occurring on or after February 18, 2009, each of which urged that the Secretary's waiver authority be extended to apply also to penalties for violations of which a covered entity did not know, or through the exercise of reasonable diligence, would not have known, in addition to reasonable cause violations, because ''did not know'' violations are a less culpable category of violation than reasonable cause violations.

Final Rule

The final rule adopts the modifications to § 160.412 proposed in the NPRM, which addresses the concerns of the above commenters on the IFR.

g. Section 160.418—Penalty Not Exclusive

Proposed Rule

We proposed to revise this section to incorporate a reference to the provision of PSQIA at 42 U.S.C. 299b–22 that provides that penalties are not to be imposed under both PSQIA and the HIPAA Privacy Rule for the same violation.

Final Rule

The Department did not receive substantive public comment on this proposal. The final rule adopts the proposed modification to § 160.418.

h. Section 160.420—Notice of Proposed Determination

Interim Final Rule

The Enforcement IFR also amended § 160.420(a)(4) to add the requirement that, in addition to the proposed penalty amount, the Secretary identify in a notice of proposed determination the applicable violation category in § 160.404 upon which the proposed penalty amount is based. While not statutorily required, the Enforcement IFR included this amendment to provide covered entities and business associates with additional information that would increase their understanding of the violation findings in the notice of proposed determination.

Overview of Public Comment

The Department received three comments supporting this amendment.

Final Rule

The final rule retains the provision as modified in the IFR.

i. Calculation of the 30-Day Cure Period for Willful Neglect Violations

Interim Final Rule

In its discussion of the HITECH Act's revision of affirmative defenses, the Department noted that section 1176(b)(2)(A) of the Social Security Act still operates to exclude violations due to willful neglect from those that, if timely corrected, would be exempt from the Secretary's imposition of a civil money penalty. However, a covered entity's timely action to correct still would be determinative with respect to which of the two tiers of willful neglect penalty amounts would apply. To determine the appropriate penalty tier for such violations, the Department stated it would calculate the 30-day cure period in the same manner as described for determining whether an affirmative defense applied. That is, the Department would look at when a covered entity first had actual or constructive knowledge of a violation due to willful neglect, based on evidence gathered during its investigation, on a case-by-case basis. See 74 FR 56128 (October 30, 2009), 70 FR 20224, 20237–8 (April 18, 2005) and 71 FR 8390, 8410 (February 16, 2006) for prior, more detailed discussions about the Department's determination of when knowledge exists.

Because the Department recognized that the minimum penalty amount under the HITECH Act of a violation due to willful neglect that is corrected during the 30-day cure period is significantly less than that for a violation due to willful neglect that is not timely corrected (equating to a $40,000 minimum penalty amount difference), the IFR specifically requested comment on whether there are alternative approaches to calculating the beginning of the 30-day cure period for this purpose.

Overview of Public Comments

While a few commenters expressed support for utilizing the current scheme in determining which tier should apply to a violation due to willful neglect, other commenters expressed concerns with this approach due to the uncertainty with determining exactly when the cure period begins and that a business associate's knowledge of a violation could be imputed to the covered entity prior to the business associate notifying the covered entity, as well as concerns if the Secretary does not notify an entity of a potential violation in a timely manner. A few commenters suggested that the 30-day cure period begin once the Department notifies the covered entity of a complaint.

Final Rule

The final rule retains the policy that the 30-day cure period for violations due to willful neglect, like those not due to willful neglect, begins on the date that an entity first acquires actual or constructive knowledge of the violation and will be determined based on evidence gathered by the Department during its investigation, on a case-by-case basis.

First, the requirement that an entity have knowledge that a ''violation'' has occurred, and not only of the facts underlying the violation, is a higher standard than that which is often required by other law. Also, as a practical matter, the date an entity has actual or constructive knowledge of a violation will vary depending on the circumstances involved, and may be the result of notice by a workforce member or business associate, a complaint received by a health care consumer, or notification by the Department that a complaint has been filed. However, other sources of information exist that could establish knowledge, including internal indications of a potential noncompliance such as unusual access or audit log activity.

While we understand commenters' concerns relating to the uncertainty inherent to constructive knowledge, we believe that it provides an appropriate incentive that is consistent with the strengthened enforcement of the HIPAA Rules, as provided in the HITECH Act. Reliance on notification by a complainant or the Department would not encourage self-correction or an entity's establishment of a compliance program that proactively prevents, detects and corrects indications of noncompliance. If the cure period were solely based on external notification, it is quite possible that entities would have little or no incentive to make corrections of noncompliance until long after an incident occurred, if ever. In response to concerns that constructive knowledge may be imputed to the principal when an agent fails to notify the responsible entity, we note that an agent must be acting within the scope of agency for a covered entity or a business associate to be liable for the agent's acts or failures to act. An agent that fails to notify a covered entity or business associate may be acting outside its scope of authority as an agent. In such a circumstance, the agent's knowledge is not imputed to the principal under the Federal Common Law of Agency.

Finally, an entity will have the opportunity to submit evidence establishing its knowledge or lack of knowledge, during the Department's investigation. Entities will also have a right to request a hearing to appeal a finding about knowledge in a notice of proposed determination to the extent they believe the finding is not based on a preponderance of the evidence. An administrative law judge would then review the finding and affirm or modify it.

Response to Other Public Comments

Comment: A few commenters suggested that 30 days may not be sufficient for a covered entity to complete corrective action, particularly with respect to large organizations with complex systems, structures and relationships. One commenter suggested there should be a process available to allow an organization to apply for a reasonable extension to complete the cure.

Response: In response to commenters' concern about the length of the 30-day cure period, we note that this time period is defined by statute at section 1176(b) of the Social Security Act, and was not modified by section 13410(d) of the HITECH Act. Thus, we believe there is no authority upon which to base a modification to the length of the cure period.

Comment: One commenter requested that the Department clarify whether the new enforcement provisions will apply to violations of all HIPAA Administrative Simplification provisions or just to the privacy and security requirements.

Response: The enforcement regulations at 45 CFR Part 160, Subparts C, D, and E, relate to compliance with, and the enforcement of, all of the Administrative Simplification regulations adopted under subtitle F of Title II of HIPAA, including the Standards for Electronic Transactions and Code Sets (Transactions and Code Sets Rule(s) (referred to in both a singular and plural sense); Standards for Privacy of Individually Identifiable Health Information (HIPAA Privacy Rule); Standard Unique Employer Identifier (EIN Rule); Security Standards (HIPAA Security Rule); and Standard Unique Health Identifier for Health Care Providers (NPI Rule). In addition, the Enforcement Rule applies to the Breach Notification Rule for HIPAA covered entities and business associates.

C. Subparts A and C of Part 164: General Provisions and Modifications to the Security Rule

We proposed implementing modifications to the Security Rule as a result of the HITECH Act and to make certain other changes. Below we respond to comments received on the proposed changes as well as describe the final rule provisions. We also discuss the final technical and conforming changes to the general provisions in Subpart A of Part 164, which applies to the Security, Privacy, and Breach Notification Rules, and respond to comments where substantive comments were received on these changes.

1. Technical Changes to Subpart A—General Provisions

a. Section 164.102—Statutory Basis

This section sets out the statutory basis of Part 164. We proposed and include in this final rule a technical change to include a reference to the provisions of sections 13400 through 13424 of the HITECH Act upon which the regulatory changes discussed below are based.

b. Section 164.104—Applicability

This section sets out to whom Part 164 applies. We proposed to replace the existing paragraph (b) with an applicability statement for business associates, consistent with the provisions of the HITECH Act. Paragraph (b) makes clear that, where provided, the standards, requirements, and implementation specifications of the HIPAA Privacy, Security, and

Breach Notification Rules apply to business associates. We also proposed to remove as unnecessary the existing language in § 164.104(b) regarding the obligation of a health care clearinghouse to comply with § 164.105 relating to organizational requirements of covered entities. This final rule adopts these changes as proposed.

c. Section 164.105—Organizational Requirements

Section 164.105 outlines the organizational requirements and implementation specifications for health care components of covered entities and for affiliated covered entities. As § 164.105 now also applies to Subpart D of Part 164 regarding breach notification for unsecured protected health information, we proposed to remove several specific references to Subparts C and E throughout this section to make clear that the provisions of this section also apply to Subpart D of Part 164. The final rule adopts these modifications.

In addition, we proposed the following modifications to this section.

i. Section 164.105(a)(2)(ii)(C)–(E)

Proposed Rule

As a covered entity's obligation to ensure that a health care component complies with the Privacy and Security Rules is already set out at § 164.105(a)(2)(ii), we proposed to modify this section to remove as unnecessary paragraphs (C) and (D), which pertain to the obligation of a covered entity to ensure that any component that performs business associate-like activities and is included in the health care component complies with the requirements of the Privacy and Security Rules, and to re-designate paragraph (E) as (C). Additionally, we requested comment on whether we should require, rather than permit as was the case at § 164.105(a)(2)(iii)(C), a covered entity that is a hybrid entity to include a component that performs business associate-like activities within its health care component so that such components are directly subject to the Rules.

Overview of Public Comments

Several commenters recommended that hybrid entities should retain the flexibility to either include or exclude business associates from the healthcare component. Two of these commenters stated this option would allow the covered entity to distinguish the functions and responsibilities of the business associate as separate from the health care component, which would result in better compliance, as covered entities would evaluate each business associate separately for compliance purposes. Further, commenters argued that, as the covered entity is ultimately legally liable for compliance on the part of the organization, such a modification is not necessary.

Additionally, several commenters stated that requiring a hybrid entity to include business associate departments is excessive and burdensome. Some of these commenters further stated that business associate departments of a hybrid entity will likely commit limited time, personnel, and staff hours to Privacy and Security Rule compliance and suggested that the hybrid entity should implement applicable entity-wide policies and procedures and separately ensure that business associate departments implement specific practices scaled to the business associate's use or disclosure of protected health information.

In contrast, several commenters supported the proposed change. Several of these commenters suggested that the modification would better facilitate compliance, because requiring the covered entity to include the business associate department in the health care component would better protect the protected health information held by the business associate and would ensure consistent standards within the health care component of the covered entity.

Final Rule

Many covered entities perform both covered and non-covered functions as part of their business operations. For such covered entities, the entire entity is generally required to comply with the Privacy Rule. However, the hybrid entity provisions of the HIPAA Rules permit the entity to limit the application of the Rules to the entity's components that perform functions that would make the component a ''covered entity'' if the component were a separate legal entity. Specifically, this provision allows an entity to designate a health care component by documenting the components of its organization that perform covered entity functions. The effect of such a designation is that most of the requirements of the HIPAA Rules apply only to the designated health care component of the entity and not to the functions the entity performs that are not included in the health care component. While most of the HIPAA Rules' requirements apply only to the health care component, the hybrid entity retains certain oversight, compliance, and enforcement obligations.

We explained in the preamble to the 2002 modifications to the Privacy Rule that the Rule provides hybrid entities with discretion as to whether or not to include business associate divisions within the health care component. However, a disclosure of protected health information from the health care component to any other division that is not part of the health care component, including a business associate division, is treated the same as a disclosure outside the covered entity. As a result, because an entity generally cannot have a business associate agreement with itself, a disclosure from the health care component to the business associate division(s) of the entity likely would require individual authorization. See 67 FR 53182, 53205 (Aug. 14, 2002).

Importantly, after this final rule, business associates, by definition, are separately and directly liable for violations of the Security Rule and for violations of the Privacy Rule for impermissible uses and disclosures pursuant to their business associate contracts. With respect to a hybrid entity, however, not including business associate functions within the health care component of a hybrid entity could avoid direct liability and compliance obligations for the business associate component. Thus, we agree with the commenters that supported requiring inclusion of business associate functions inside the health care component of a hybrid entity. As such, the final rule requires that the health care component of a hybrid entity include all business associate functions within the entity.

Response to Other Public Comments

Comment: One commenter requested that the Department revise the definitions of ''hybrid entity'' to permit business associates to designate a health care component.

Response: A business associate performs one or more functions on behalf of a covered entity (or, in this final rule, another business associate). As a business associate is only subject to the HIPAA Rules with respect to the protected health information it maintains, uses, or discloses on behalf of a covered entity (or business associate) and not to other information it may maintain, including health information, there is no need for a business associate to designate one or more health care components.

Comment: One commenter asked whether an employer that operates an on-site clinic for the treatment of employees functions as a hybrid entity.

Response: An entity that maintains an on-site clinic to provide health care to one or more employees may be a HIPAA covered provider to the extent the clinic performs one or more covered

transactions electronically, such as billing a health plan for the services provided. If covered, the entity need not become a hybrid entity so as to avoid applying the Privacy Rule to health information the entity holds in its role as employer, such as sick leave requests of its employees. Such information is already excluded from the definition of ''protected health information'' as employment records and thus, the Privacy Rule does not apply to this information. However, the identifiable health information the entity holds as a covered health care provider (e.g., the information the clinic holds about employees who have received treatment) is protected health information and generally may not be shared with the employer for employment purposes without the individual's authorization.

ii. Section 164.105(a)(2)(iii)(C)

We proposed to modify this section to re-designate § 164.105(a)(2)(iii)(C) as (D), and to include a new paragraph (C), which makes clear that, with respect to a hybrid entity, the covered entity itself, and not merely the health care component, remains responsible for complying with §§ 164.314 and 164.504 regarding business associate arrangements and other organizational requirements. Hybrid entities may need to execute legal contracts and conduct other organizational matters at the level of the legal entity rather than at the level of the health care component. The final rule adopts this change.

iii. Section 164.105(b)(1)

The final rule fixes a minor typographical error in this paragraph by redesignating the second paragraph (1) as paragraph (2).

iv. Section 164.105(b)(2)(ii)

The final rule simplifies this paragraph by collapsing subparagraphs (A), (B), and (C) regarding the obligations of an affiliated entity to comply with the Privacy and Security Rules into one provision.

d. Section 164.106—Relationship to Other Parts

The final rule adds a reference in this provision to business associates, consistent with their inclusion elsewhere throughout the other HIPAA Rules.

2. Modifications to the HIPAA Security Rule in Subpart C

a. Business Associates

Proposed Rule

Before the HITECH Act, the Security Rule did not directly apply to business associates of covered entities. However, section 13401 of the HITECH Act provides that the Security Rule's administrative, physical, and technical safeguards requirements in §§ 164.308, 164.310, and 164.312, as well as the Rule's policies and procedures and documentation requirements in § 164.316, apply to business associates in the same manner as these requirements apply to covered entities, and that business associates are civilly and criminally liable for violations of these provisions.

To implement section 13401 of the HITECH Act, we proposed to insert references in Subpart C to ''business associate'' following references to ''covered entity,'' as appropriate, to make clear that these provisions of the Security Rule also apply to business associates. In addition, we proposed additional changes to §§ 164.306, 164.308, 164.312, 164.314, and 164.316 of the Security Rule, as discussed below.

Overview of Public Comments

Some commenters argued that the time, implementation expense, transaction cost, and liability cost burdens on business associates and subcontractors to comply with the Security Rule, especially small and mid-size entities, would be significant. Other commenters supported the direct application of the Security Rule to business associates and subcontractors.

Final Rule

We adopt the modifications to the Security Rule as proposed to implement the HITECH Act's provisions extending direct liability for compliance with the Security Rule to business associates. In response to the concerns raised regarding the costs of compliance, we note that the Security Rule currently requires a covered entity to establish a business associate agreement that requires business associates to implement administrative, physical, and technical safeguards that reasonably and appropriately protect the confidentiality, integrity, and availability of the electronic protected health information that they create, receive, maintain, or transmit on behalf of the covered entity as required by the Security Rule; and to ensure that any agent, including a subcontractor, to whom they provide such information agrees to implement reasonable and appropriate safeguards to protect it. See § 164.314(a). Consequently, business associates and subcontractors should already have in place security practices that either comply with the Security Rule, or that require only modest improvements to come into compliance with the Security Rule requirements.

Moreover, the requirements of the Security Rule were designed to be technology neutral and scalable to all different sizes of covered entities and business associates. Covered entities and business associates have the flexibility to choose security measures appropriate for their size, resources, and the nature of the security risks they face, enabling them to reasonably implement any given Security Rule standard. In deciding which security measures to use, a covered entity or business associate should take into account its size, capabilities, the costs of the specific security measures, and the operational impact. Thus, the costs of implementing the Security Rule for large, mid-sized, or small business associates will be proportional to their size and resources.

Notwithstanding the above, based on the comments, we acknowledge that some business associates, particularly the smaller or less sophisticated business associates that may have access to electronic protected health information for limited purposes, may not have engaged in the formal administrative safeguards such as having performed a risk analysis, established a risk management program, or designated a security official, and may not have written policies and procedures, conducted employee training, or documented compliance as the statute and these regulations would now require. For these business associates, we include an estimate for compliance costs below in the regulatory impact analysis. We also refer these business associates to our educational papers and other guidance on compliance with the HIPAA Security Rule found at: *http://www.hhs.gov/ocr/privacy/hipaa/administrative/securityrule*. These materials provide guidance on conducting risk analyses and implementing the other administrative safeguards required by the Security Rule, which may prove helpful to these business associates and facilitate their compliance efforts.

b. Section 164.306—Security Standards: General Rules

Proposed Rule

Section 164.306 sets out the general rules that apply to all of the security

standards and implementation specifications that follow in the Security Rule. We proposed technical revisions to § 164.306(e) to more clearly indicate that covered entities and business associates must review and modify security measures as needed to ensure the continued provision of reasonable and appropriate protection of electronic protected health information, and update documentation of such security measures accordingly.

Final Rule

The Department did not receive substantive public comment on this proposal. The final rule adopts the modifications to § 164.306 as proposed.

c. Section 164.308—Administrative Safeguards

Proposed Rule

We proposed a technical change to § 164.308(a)(3)(ii)(C) regarding security termination procedures for workforce members, to add the words ''or other arrangement with'' after ''employment of'' in recognition of the fact that not all workforce members are employees (e.g., some may be volunteers) of a covered entity or business associate. We also proposed a number of modifications to § 164.308(b) to conform to modifications proposed in the definition of ''business associate.'' Section 164.308(b) provides that a covered entity may permit a business associate to create, receive, maintain, or transmit electronic protected health information only if the covered entity has a contract or other arrangement in place to ensure the business associate will appropriately safeguard the protected health information. Section164.308(b)(2) contains several exceptions to this general rule for certain situations that do not give rise to a business associate relationship, such as where a covered entity discloses electronic protected health information to a health care provider concerning the treatment of an individual. We proposed to remove these exceptions from this provision, since as discussed above, they would now be established as exceptions to the definition of ''business associate.''

In addition, we proposed to modify § 164.308(b)(1) and (2) to clarify that covered entities are not required to obtain satisfactory assurances in the form of a contract or other arrangement with a business associate that is a subcontractor; rather, it is the business associate that must obtain the required satisfactory assurances from the subcontractor to protect the security of electronic protected health information.

Finally, we proposed to remove the provision at § 164.308(b)(3), which provides that a covered entity that violates the satisfactory assurances it provided as a business associate of another covered entity will be in noncompliance with the Security Rule's business associate provisions, as a covered entity's actions as a business associate of another covered entity would now be directly regulated by the Security Rule's provisions that apply to business associates.

Overview of Public Comments

One commenter asked for confirmation that the changes to § 164.308 would require a covered entity to enter into a business associate agreement with its own business associate and not any subcontractors of those business associates.

Final Rule

The final rule adopts the proposed modifications to § 164.308. Section 164.308(b) expressly provides that a covered entity is not required to enter into a business associate agreement with a business associate that is a subcontractor; rather, this is the obligation of the business associate that has engaged the subcontractor to perform a function or service that involves the use or disclosure of protected health information.

d. Section 164.314—Organizational Requirements

Proposed Rule

While Section 13401 of the HITECH Act does not expressly include § 164.314 among the provisions for which business associates are directly liable, it states that § 164.308 of the Security Rule applies to business associates ''in the same manner'' that the provision applies to covered entities. Section 164.308(b) requires a covered entity's business associate agreements to conform to the requirements of § 164.314. Accordingly, in order for § 164.308(b) to apply to business associates in the same manner as it applies to covered entities, we proposed to revise § 164.314 to reflect that it is also applicable to agreements between business associates and subcontractors that create, receive, maintain, or transmit electronic protected health information.

We also proposed a number of modifications to streamline the requirements of § 164.314. First, since a business associate for purposes of the Security Rule is also always a business associate for purposes of the Privacy Rule, we proposed to remove contract provisions that were merely duplicative of parallel provisions in the Privacy Rule's business associate contract provisions at § 164.504. We also proposed to remove the specific requirements under § 164.314(a)(2)(ii) for other arrangements, such as a memorandum of understanding when both a covered entity and business associate are governmental entities, and instead simply refer to the parallel Privacy Rule requirements at § 164.504(e)(3).

Second, we proposed conforming modifications to the remaining contract requirements in § 164.314(a)(2)(i) to provide that such contracts must require a business associate to comply with the Security Rule, to ensure any subcontractors enter into a contract or other arrangement to protect the security of electronic protected health information; and with respect to the reporting of security incidents by business associates to covered entities, to report to the covered entity breaches of unsecured protected health information as required by § 164.410 of the breach notification rules.

Third, we proposed to add a provision at § 164.314(a)(2)(iii) that provides that the requirements of this section for contracts or other arrangements between a covered entity and business associate would apply in the same manner to contracts or other arrangements between business associates and subcontractors required by the proposed requirements of § 164.308(b)(4). For example, under these provisions, a business associate contract between a business associate and a business associate subcontractor would need to provide that the subcontractor report any security incident of which it becomes aware, including breaches of unsecured protected health information as required by § 164.410, to the business associate. This would mean that if a breach of unsecured protected health information occurs at or by a second tier subcontractor, the subcontractor must notify the business associate subcontractor with which it contracts of the breach, which then must notify the business associate which contracts with the covered entity of the breach, which then must notify the covered entity of the breach. The covered entity then notifies the affected individuals, the Secretary, and, if applicable, the media, of the breach, unless it has delegated such responsibilities to a business associate. Finally, we proposed to remove the reference to subcontractors in § 164.314(b)(2)(iii) regarding amendment of group health plan documents as a condition of disclosure of protected health information to a plan sponsor, as unnecessary and to avoid

confusion with the use of the term subcontractor when referring to subcontractors that are business associates.

Final Rule

The Department did not receive substantive public comment on these proposed changes. The final rule adopts the modifications as proposed.

Response to Other Public Comments

Comment: One commenter suggested that business associate agreements should be an ''addressable'' requirement under the Security Rule.

Response: The HITECH Act does not remove the requirements for business associate agreements under the HIPAA Rules. Therefore, we decline to make the execution of business associate agreements an ''addressable'' requirement under the Security Rule.

Comment: One commenter recommended that the Department remove the ''addressable'' designation from the Security Rule, because such designations lead to ambiguity in the application of the Security Rule in the health care industry.

Response: We decline to adopt this recommendation. The Security Rule is structured to be both scalable and flexible, so that entities of different types and sizes can implement the standards and implementation specifications in a manner that is reasonable and appropriate for their circumstances. We do not mandate the use of specific technologies, or require uniform policies and procedures for compliance, because we recognize the diversity of regulated entities and appreciate the unique characteristics of their environments.

Comment: Two commenters suggested providing subcontractors with additional time to comply with the provisions of the Security Rule.

Response: We decline to delay application of the requirements under the Security Rule to subcontractors beyond the compliance dates provided by this final rule. As we emphasized above, the Security Rule already requires covered entities to establish business associate agreements that require business associates to ensure that their subcontractors implement reasonable and appropriate safeguards to protect the security of electronic protected health information they handle.

Comment: A few commenters proposed alternative ways to apply security requirements to subcontractors, such as exempting subcontractors from compliance with the Security Rule if they have already completed security assessments and met the security requirements under other State and Federal laws or only requiring subcontractors to comply with the minimum necessary standard and to utilize ''reasonable'' security measures with regard to protected health information.

Response: We decline to adopt an exemption or otherwise limit subcontractors' responsibility to safeguard individuals' electronic protected health information. To ensure appropriate and strong security protections for electronic protected health information, subcontractors are required to comply with the Security Rule to the same extent as business associates with a direct relationship with a covered entity.

D. Subpart E of Part 164: Modifications to the Privacy Rule

The NPRM proposed a number of changes to the Privacy Rule to implement certain provisions of the HITECH Act, as well as certain modifications to improve the workability and effectiveness of the Rule and to conform the Privacy Rule to PSQIA. The section-by-section description below of the final rule discusses the proposed and final changes and responds to public comments

1. Section 164.500—Applicability

Section 13404 of the HITECH Act makes specific requirements of the Privacy Rule applicable to business associates and creates direct liability for noncompliance by business associates with regard to those requirements.

Proposed Rule

In accordance with section 13404 of the HITECH Act, we proposed language in § 164.500 to clarify that, where provided, the standards, requirements, and implementation specifications of the Privacy Rule apply to business associates.

Overview of Public Comments

One commenter suggested that the Department expand the applicability of the Privacy Rule to all entities that handle individually identifiable health information. Some commenters requested clarification as to which provisions of the Privacy Rule apply directly to business associates, and one commenter recommended applying all of the provisions of the Privacy Rule to business associates, including requiring business associates to implement reasonable safeguards, train employees, and designate a privacy official.

Final Rule

The final rule implements the proposed revisions to § 164.500. While we understand commenters' concerns regarding the uses and disclosures of health information by entities not covered by the Privacy Rule, the Department is limited to applying the HIPAA Rules to those entities covered by HIPAA (i.e., health plans, health care clearinghouses, and health care providers that conduct covered transactions) and to business associates, as provided under the HITECH Act.

As we discuss further below, section 13404 of the HITECH Act creates direct liability for impermissible uses and disclosures of protected health information by a business associate of a covered entity ''that obtains or creates'' protected health information ''pursuant to a written contract or other arrangement described in § 164.502(e)(2)'' and for compliance with the other privacy provisions in the HITECH Act. Section 13404 does not create direct liability for business associates with regard to compliance with all requirements under the Privacy Rule (i.e., does not treat them as covered entities). Therefore, under the final rule, a business associate is directly liable under the Privacy Rule for uses and disclosures of protected health information that are not in accord with its business associate agreement or the Privacy Rule. In addition, a business associate is directly liable for failing to disclose protected health information when required by the Secretary to do so for the Secretary to investigate and determine the business associate's compliance with the HIPAA Rules, and for failing to disclose protected health information to the covered entity, individual, or individual's designee, as necessary to satisfy a covered entity's obligations with respect to an individual's request for an electronic copy of protected health information. See § 164.502(a)(3) and (a)(4). Further, a business associate is directly liable for failing to make reasonable efforts to limit protected health information to the minimum necessary to accomplish the intended purpose of the use, disclosure, or request. See § 164.502(b). Finally, business associates are directly liable for failing to enter into business associate agreements with subcontractors that create or receive protected health information on their behalf. See § 164.502(e)(1)(ii). As was the case under the Privacy Rule before the HITECH Act, business associates remain contractually liable for all other Privacy Rule obligations that are included in

their contracts or other arrangements with covered entities.

2. Section 164.501—Definitions

a. Definition of ''Health Care Operations''

Proposed Rule

PSQIA provides, among other things, that Patient Safety Organizations (PSOs) are to be treated as business associates of covered health care providers. Further, PSQIA provides that the patient safety activities of PSOs are deemed to be health care operations of covered health care providers under the Privacy Rule. See 42 U.S.C. 299b–22(i). To conform to these statutory provisions, we proposed to amend paragraph (1) of the definition of ''health care operations'' to include an express reference to patient safety activities, as defined in the PSQIA implementing regulation at 42 CFR 3.20. Many health care providers participating in the voluntary patient safety program authorized by PSQIA are HIPAA covered entities. PSQIA acknowledges that such providers must also comply with the Privacy Rule and deems patient safety activities to be health care operations under the Privacy Rule. While such types of activities are already encompassed within paragraph (1) of the definition, which addresses various quality activities, we proposed to expressly include patient safety activities within paragraph (1) of the definition of health care operations to conform the definition to PSQIA and to eliminate the potential for confusion. This modification also addresses public comments the Department received during the rulemaking period for the PSQIA implementing regulations, which urged the Department to modify the definition of ''health care operations'' in the Privacy Rule to expressly reference patient safety activities so that the intersection of the Privacy and PSQIA Rules would be clear. See 73 FR 70732, 70780 (Nov. 21, 2008).

Overview of Public Comments

The Department received comments supporting the inclusion of patient safety activities in the definition of ''health care operations.''

Final Rule

The final rule adopts the proposed modification.

b. Definition of ''Marketing''

Proposed Rule

The Privacy Rule requires covered entities to obtain a valid authorization from individuals before using or disclosing protected health information to market a product or service to them. See § 164.508(a)(3). Section 164.501 defines ''marketing'' as making a communication about a product or service that encourages recipients of the communication to purchase or use the product or service. Paragraph (1) of the definition includes a number of exceptions to marketing for certain health-related communications: (1) Communications made to describe a health-related product or service (or payment for such product or service) that is provided by, or included in a plan of benefits of, the covered entity making the communications, including communications about: The entities participating in a healthcare provider network or health plan network; replacement of, or enhancements to, a health plan; and health-related products or services available only to a health plan enrollee that add value to, but are not part of, a plan of benefits; (2) communications made for the treatment of the individual; and (3) communications for case management or care coordination for the individual, or to direct or recommend alternative treatments, therapies, health care providers, or settings of care to the individual. A covered entity is permitted to make these excepted communications without an individual's authorization as either treatment or health care operations communications, as appropriate, under the Privacy Rule. In addition, the Privacy Rule does not require a covered entity to obtain individual authorization for face-to-face communications or to provide only promotional gifts of nominal value to the individual. See § 164.508(a)(3)(i). However, a covered entity must obtain prior written authorization from an individual to send communications to the individual about non-health related products or services or to give or sell the individual's protected health information to a third party for marketing. Still, concerns have remained about the ability under these provisions for a third party to pay a covered entity to send health-related communications to an individual about the third party's products or services.

Section 13406(a) of the HITECH Act limits the health-related communications that may be considered health care operations and thus, that are excepted from the definition of ''marketing'' under the Privacy Rule, to the extent a covered entity receives or has received direct or indirect payment in exchange for making the communication. In cases where the covered entity would receive such payment, the HITECH Act at section 13406(a)(2)(B) and (C) requires that the covered entity obtain the individual's valid authorization prior to making the communication, or, if applicable, prior to its business associate making the communication on its behalf in accordance with its written contract. Section 13406(a)(2)(A) of the HITECH Act includes an exception to the payment limitation for communications that describe only a drug or biologic that is currently being prescribed to the individual as long as any payment received by the covered entity in exchange for making the communication is reasonable in amount. Section 13406(a)(3) of the Act provides that the term ''reasonable in amount'' shall have the meaning given to such term by the Secretary in regulation. Finally, section 13406(a)(4) of the Act clarifies that the term ''direct or indirect payment'' does not include any payment for treatment of the individual. We believe Congress intended that these provisions curtail a covered entity's ability to use the exceptions to the definition of ''marketing'' in the Privacy Rule to send communications to the individual that are motivated more by commercial gain or other commercial purpose rather than for the purpose of the individual's health care, despite the communication being about a health-related product or service.

To implement the marketing limitations of the HITECH Act, we proposed a number of modifications to the definition of ''marketing'' at § 164.501. In paragraph (1) of the definition of ''marketing,'' we proposed to maintain the general concept that ''marketing'' means ''to make a communication about a product or service that encourages recipients of the communication to purchase or use the product or service.'' In paragraph (2) of the definition, we proposed to include three exceptions to this definition to encompass certain treatment and health care operations communications about health-related products or services. First, we proposed to exclude from the definition of ''marketing'' certain health care operations communications, except where, as provided by the HITECH Act, the covered entity receives financial remuneration in exchange for making the communication. This would encompass communications to describe a health-related product or service (or payment for such product or service) that is provided by, or included in a plan of benefits of, the covered entity making the communication, as well as communications for case management

or care coordination, contacting of individuals with information about treatment alternatives, and related functions (to the extent these activities did not constitute ''treatment'').

Although the HITECH Act uses the term ''direct or indirect payment'' to describe the limitation on permissible health care operations disclosures, the proposed rule substituted the term ''financial remuneration'' to avoid confusion with the term ''payment,'' which is defined in the Privacy Rule to mean payment for health care, and for consistency with the Privacy Rule's current authorization requirement for marketing at § 164.508(a)(3), which uses the term ''remuneration.'' We proposed to define ''financial remuneration'' in paragraph (3) of the definition of ''marketing'' to mean direct or indirect payment from or on behalf of a third party whose product or service is being described. We also proposed to make clear, in accordance with section 13406(a)(4) of the HITECH Act, that financial remuneration does not include any direct or indirect payment for the treatment of an individual.

Additionally, because the HITECH Act refers expressly to ''payment,'' rather than remuneration more generally, the proposed rule specified that only the receipt of financial remuneration in exchange for making a communication, as opposed to in-kind or any other type of remuneration, is relevant for purposes of the definition of marketing. We also proposed a conforming change to the required authorization provisions for marketing communications at § 164.508(a)(3) to add the term ''financial'' before ''remuneration'' and to refer to the new definition of ''financial remuneration.''

The proposed rule emphasized that financial remuneration for purposes of the definition of ''marketing'' must be in exchange for making the communication itself and be from or on behalf of the entity whose product or service is being described. Thus, under these proposed provisions, an authorization would be required prior to a covered entity making a communication to its patients regarding the acquisition of, for example, new state of the art medical equipment if the equipment manufacturer paid the covered entity to send the communication to its patients; but not if a local charitable organization, such as a breast cancer foundation, funded the covered entity's mailing to patients about new state of the art mammography screening equipment. Furthermore, it would not constitute marketing and no authorization would be required if a hospital sent flyers to its patients announcing the opening of a new wing where the funds for the new wing were donated by a third party, since the financial remuneration to the hospital from the third party was not in exchange for the mailing of the flyers.

Second, we proposed to include the statutory exception to marketing at section 13406(a)(2)(A) for communications regarding refill reminders or otherwise about a drug or biologic that is currently being prescribed for the individual, provided any financial remuneration received by the covered entity for making the communication is reasonably related to the covered entity's cost of making the communication. The Act expressly identifies these types of communications as being exempt from the remuneration limitation only to the extent that any payment received for making the communication is reasonable in amount. We requested comment on the scope of this exception, that is, whether communications about drugs that are related to the drug currently being prescribed, such as communications regarding generic alternatives or new formulations of the drug, should fall within the exception. We also requested comment on the types and amount of costs that should be allowed under this provision. We noted that we had considered proposing a requirement that a covered entity could only receive financial remuneration for making such a communication to the extent it did not exceed the actual cost to make the communication. However, because we were concerned that such a requirement would impose the additional burden of calculating the costs of making each communication, we proposed to allow costs that are reasonably related to a covered entity's cost of making the communication.

Third, we proposed to exclude from marketing treatment communications about health-related products or services by a health care provider to an individual, including communications for case management or care coordination for the individual, or to direct or recommend alternative treatments, therapies, health care providers, or settings of care to the individual, provided, however, that if the communications are in writing and financial remuneration is received in exchange for making the communications, certain notice and opt out conditions are met. While section 13406(a) of the HITECH Act expressly provides that a communication to an individual about a health-related product or service where the covered entity receives payment from a third party in exchange for making the communication shall not be considered a *health care operation* (emphasis added) under the Privacy Rule, and thus is marketing, it is unclear how Congress intended these provisions to apply to treatment communications between a health care provider and a patient. Specifically, it is unclear whether Congress intended to restrict only those subsidized communications about products and services that are less essential to an individual's health care (i.e., those classified as health care operations communications) or all subsidized communications about products and services, including treatment communications. Given this ambiguity and to avoid undue interference with treatment communications between the individual and a health care provider, we proposed to continue to allow subsidized treatment communications, but conditioned on providing the individual with notice and an opportunity to opt out of receiving such communications. Specifically, to ensure the individual is aware that he or she may receive subsidized treatment communications from his or her provider and has the opportunity to elect not to receive them, the proposed rule would have required at § 164.514(f)(2) that: (1) The covered health care provider's notice of privacy practices include a statement informing individuals that the provider may send treatment communications to the individual concerning treatment alternatives or other health-related products or services where the provider receives financial remuneration from a third party in exchange for making the communication, and the individual has a right to opt out of receiving such communications; and (2) the treatment communication itself disclose the fact of remuneration and provide the individual with a clear and conspicuous opportunity to elect not to receive any further such communications. We requested comment on how the opt out should apply to future subsidized treatment communications (i.e., should the opt out prevent all future subsidized treatment communications by the provider or just those dealing with the particular product or service described in the current communication?). We also requested comment on the workability of requiring health care providers that intend to send subsidized treatment communications to individuals to provide an individual with the opportunity to opt out of receiving such communications prior to the individual receiving the first communication and what mechanisms

could be put into place to implement such a requirement.

Given that the new marketing limitations on the receipt of remuneration by a covered entity would apply differently depending on whether a communication is for treatment or health care operations purposes, and that distinguishing such communications may in many cases call for close judgments, we requested comment on the alternatives of excluding treatment communications altogether even if they involve financial remuneration from a third party or requiring individual authorization for both treatment and health care operations communications made in exchange for financial remuneration.

Finally, we proposed to remove the language defining as marketing an arrangement between a covered entity and any other entity in which the covered entity discloses protected health information to the other entity, in exchange for remuneration, for the other entity or its affiliate to make a communication about its own product or service that encourages recipients of the communication to purchase or use that product or service, since such activity would now constitute a prohibited ''sale'' of protected health information under section 13405(d) of the HITECH Act and the proposed rule.

Overview of Public Comments

Several commenters asked as a general matter that the final rule retain the current definition of ''marketing'' and that no changes to this provision be implemented. With respect to subsidized treatment communications, many commenters expressed support for the decision in the NPRM to not require authorizations for such communications, and several argued for removing even the opt out requirement. Other commenters believed that all communications in which the covered entity receives financial remuneration for making the communication, regardless of whether the communication is for treatment purposes, should be considered marketing and require authorization.

While many commenters were generally in support of not requiring authorization for treatment communications, at the same time, several commenters expressed concern with the difficulty of distinguishing between treatment communications and communications for health care operations purposes. These commenters stated that additional clarification regarding this distinction would be needed to be able to implement the NPRM's marketing provisions. Several commenters stated that while the distinction may be clear in some limited circumstances, there are other circumstances where it may be difficult for covered entities to determine what type of communication they are sending and whether authorization or just disclosure in the notice of privacy practices and the opportunity to opt out would be required. For example, while the NPRM stated that whether a communication is being made for treatment purposes or for health care operations purposes would depend on the extent to which the covered entity is making the communication in a population-based fashion (health care operations) or to further the treatment of a particular individual's health care status or condition (treatment), many commenters stated that there may be circumstances in which a covered entity provides a population-based communication to further the treatment of the health care status or condition of an entire group of individuals. Other commenters suggested that the distinction between communications for treatment and those for health care operations purposes should be made based on the entity providing the communication: If a health care provider is providing the communication, it should be deemed for treatment purposes; however, if the communication is made by a covered entity other than a health care provider, the determination should be based on whether the communication is individual (treatment) or population based (health care operations).

With respect to the subsidized treatment communications, commenters opposed to the opt out notification generally took one of three positions: All such communications should require authorizations to best protect patient privacy; an opt in method would better permit individuals to make more informed choices about whether to receive such communications; or a covered entity should be permitted to make these communications without an opportunity to opt out, because of unintended effects that may adversely affect the quality of care provided. Some commenters asked, if the opt out requirement is retained, that OCR ensure that covered entities are given significant flexibility in determining how best to implement the opt out requirement.

Additionally, the vast majority of commenters did not believe there should be an opportunity to opt out of receiving subsidized treatment communications prior to receipt of the first such communication. The commenters believed that requiring an opportunity to opt out prior to the first communication would be too costly and burdensome for most covered entities. Many also noted that the statement in the notice of privacy practices, which would inform individuals of their option to opt out of receiving subsidized treatment communications, could serve as an opportunity to opt out before the first communication. Some commenters expressed concern even with including a statement in the notice of privacy practices because of the cost associated with modifying notices to do so.

With respect to the scope of the proposed opt out, most commenters believed that the opt out should apply only to subsidized treatment communications related to a specific product or service and should not apply universally to all similar future communications from the covered entity. These commenters stated that it would be difficult for an individual to elect, in a meaningful way, not to receive all future subsidized treatment communications because he or she would not know exactly what he or she is opting out of without receiving at least one communication. Other commenters believed that while a product or service-specific application of the opt out would be ideal, it is simply unrealistic and infeasible for covered entities to be able to implement such a policy. These commenters stated that a universal opt out, which would apply to all future subsidized treatment communications, would be much simpler and easier for covered entities to implement. Additionally, while some commenters believed that individuals should be able to decide whether they want to opt out of specific subsidized treatment communications or all future such communications, most commenters supported giving covered entities the flexibility to determine the scope of this opt out provision based on their own specific capabilities. Many of these commenters also suggested that the final rule permit individuals who have opted out of receiving such communications to opt back in to receive future notices using the same methods through which the individuals had opted out.

The Department also received several comments on the definition of ''financial remuneration.'' Several commenters supported the NPRM's definition of ''financial remuneration''; however, many commenters asked for clarification regarding the scope of the definition and the meaning of the phrase ''direct or indirect payment.'' For example, some commenters asked for confirmation that non-financial benefits did not constitute financial

remuneration, while other commenters wanted the exception for refill reminders (that is, the communication is not marketing as long as the financial remuneration does not exceed the related costs of the communication) to apply more broadly to all marketing communications. Additionally, some commenters suggested that the final rule clarify that only financial remuneration in exchange for sending a communication triggers either the authorization or the statement of notice and opt out requirement and not the exchange of financial remuneration for the development or funding for programs, which may include the sending of a communication. These commenters generally suggested that the final rule give covered entities the flexibility to determine whether the financial remuneration received is truly in exchange for making the communication.

We received a great deal of public comment on the exception to the definition of ''marketing'' for providing refill reminders or to otherwise communicate about a drug or biologic currently being prescribed for the individual where the only financial remuneration received by the covered entity in exchange for making the communication is reasonably related to the covered entity's cost of making the communication. In general, most commenters supported this exception; however, a few commenters disagreed with the exception and felt that refill reminders should be treated as treatment communications requiring a statement in the notice and an opportunity to opt out if the communication is subsidized. Many commenters expressed the need for guidance on the scope of this exception and stated that certain communications should fall into the exception, such as communications about generic alternatives and drug adherence, and communications related to every component of a drug or biologic delivery system (especially where patients must self-administer medication). Some commenters specifically asked that the final rule exclude certain types of communications from this exception.

With respect to the proposed cost limitation on the refill reminder exception, while some commenters suggested that the cost be limited to either the actual cost or the fair market value of providing the communication, generally, most commenters supported the position that reasonably related costs should not be limited to actual costs. Many of the commenters in support of a broad interpretation of costs ''reasonably related'' to providing the communication suggested specific costs that should be permitted under this exception, such as costs of personnel, data storage, data processing, data analysis, data security, software, hardware, employee training, message content development, clinical review, postage, materials, drug adherence program development, formulary development, and the creation and implementation of analytics to measure the effectiveness of the communication. Several commenters noted that it would be unrealistic to expect a covered entity to perform such non-essential functions as sending refill reminders and other related communications if they could not recoup both their direct and indirect costs as well as a modest profit.

Final Rule

The final rule significantly modifies the proposed rule's approach to marketing by requiring authorization for all treatment and health care operations communications where the covered entity receives financial remuneration for making the communications from a third party whose product or service is being marketed. Many of the comments we received in response to the proposed marketing provisions concerned the distinction between communications for treatment and those for health care operations purposes and sought clarification on the line between such communications. We acknowledge that the distinction between what constitutes a treatment versus a health care operations communication may be difficult to make with precision in all cases, placing covered entities at risk for violating the authorization requirement for marketing communications. We, therefore, believe that requiring authorizations for all subsidized communications that market a health related product or service is the best policy. Such a policy will ensure that all such communications are treated as marketing communications, instead of requiring covered entities to have two processes in place based on whether the communication provided to individuals is for a treatment or a health care operations purpose. We decline to retain the Privacy Rule's definition of what constitutes ''marketing'' unchanged, as suggested by some commenters, as doing so would be inconsistent with the provisions of the Section 13406(a) of the HITECH Act.

Because the final rule treats subsidized treatment communications as marketing communications that require authorization, we have not adopted the notice requirement at proposed § 164.520(b)(1)(iii)(A) that a covered entity's notice of privacy practices include a statement informing individuals that the provider may send treatment communications to the individual concerning treatment alternatives or other health-related products or services where the provider receives financial remuneration from a third party in exchange for making the communication, and the individual has a right to opt out of receiving such communications. We also do not retain the notice requirement that existed at § 164.520(b)(1)(iii) prior to this final rule that a covered entity include in its notice of privacy practices a statement that the covered entity may contact the individual to provide appointment reminders or information about treatment alternatives or other health-related benefits and services that may be of interest to the individual. Where the sending of such communications involves financial remuneration, the individual will be notified of such communications through the authorization process. Other communications for such purposes that do not involve financial remuneration are adequately captured in a covered entity's description in its notice of privacy practices of treatment and health care operations. However, covered entities that wish to continue to include such a specific statement in their notices of privacy practices may do so. For further discussion about the Notice of Privacy Practices, please see the discussion addressing the provisions at § 164.520 below.

We adopt the term ''financial remuneration'' and its definition as proposed without modification in the final rule. Most commenters were generally satisfied with the proposed use of the term and its definition. There was, however, some confusion among commenters as to what constitutes direct or indirect payment from or on behalf of a third party. We clarify that under this provision direct payment means financial remuneration that flows from the third party whose product or service is being described directly to the covered entity. In contrast, indirect payment means financial remuneration that flows from an entity on behalf of the third party whose product or service is being described to a covered entity.

We also clarify that where a business associate (including a subcontractor), as opposed to the covered entity itself, receives financial remuneration from a third party in exchange for making a communication about a product or service, such communication also requires prior authorization from the individual. The HITECH Act at Section 13406(a)(2)(C) provides that a business

associate may make such communications on behalf of a covered entity if consistent with the written contract required by the Privacy Rule between the business associate and covered entity. The Privacy Rule a § 164.504(e)(2)(i) provides that the contract may not authorize the business associate to further use or disclose the protected health information in a manner that would violate the Rule if done by the covered entity (except in two limited circumstances not relevant here). Thus, individual authorization also must be obtained if a business associate is to send these communications instead of the covered entity.

We also confirm, in response to comments, that the term ''financial remuneration'' does not include non-financial benefits, such as in-kind benefits, provided to a covered entity in exchange for making a communication about a product or service. Rather, financial remuneration includes only payments made in exchange for making such communications. In addition, we continue to emphasize that the financial remuneration a covered entity receives from a third party must be for the purpose of making a communication and such communication must encourage individuals to purchase or use the third party's product or service. If the financial remuneration received by the covered entity is for any purpose other than for making the communication, then this marketing provision does not apply. For example, if a third party provides financial remuneration to a covered entity to implement a program, such as a disease management program, the covered entity could provide individuals with communications about the program without obtaining individual authorization as long as the communications are about the covered entity's program itself. There, the communications would only be encouraging individuals to participate in the covered entity's disease management program and would not be encouraging individuals to use or purchase the third party's product or service.

Under the final rule, for marketing communications that involve financial remuneration, the covered entity must obtain a valid authorization from the individual before using or disclosing protected health information for such purposes, and such authorization must disclose the fact that the covered entity is receiving financial remuneration from a third party. See § 164.508(a)(3). The scope of the authorization need not be limited only to subsidized communications related to a single product or service or the products or services of one third party, but rather may apply more broadly to subsidized communications generally so long as the authorization adequately describes the intended purposes of the requested uses and disclosures (i.e., the scope of the authorization) and otherwise contains the elements and statements of a valid authorization under § 164.508. This includes making clear in the authorization that the individual may revoke the authorization at any time he or she wishes to stop receiving the marketing material.

Because the final rule will treat all subsidized treatment communications as marketing communications for which an authorization is required, the final rule also removes the language at proposed § 164.514(f)(2), which proposed to require that such communications be accompanied by a statement in the notice and an opportunity for the individual to opt out of receiving such communications. We believe that the removal of the notice and opt out requirements for such communications and the addition of the requirement to obtain an authorization will provide covered entities with a more uniform system for treating all remunerated communications. Because the individual must now sign an authorization before the covered entity can make subsidized treatment communications, there is no longer any need to require each such communication to contain a clear and conspicuous opportunity for the individual to elect not to receive any more of these communications. Where the individual signs an authorization to receive such communications, the covered entity may use and disclose the individual's protected health information for the purposes of making such communications unless or until the individual revokes the authorization pursuant to § 164.508(a)(5). If the individual does not authorize the covered entity to use and disclose the individual's protected health information for the purposes of making subsidized treatment communications, then the covered entity is prohibited from doing so.

We clarify that the final rule does nothing to modify the exceptions to the authorization requirement for marketing communications at § 164.508(a)(3)(i)(A) and (B). Therefore, no authorization is required where a covered entity receives financial remuneration from a third party to make a treatment or health care operations communication (or other marketing communication), if the communication is made face-to-face by a covered entity to an individual or consists of a promotional gift of nominal value provided by the covered entity. For example, a health care provider could, in a face to face conversation with the individual, recommend, verbally or by handing the individual written materials such as a pamphlet, that the individual take a specific alternative medication, even if the provider is otherwise paid by a third party to make such communications. However, communications made over the phone (as well as all communications sent through the mail or via email) do not constitute face to face communications, and as such, these communications require individual authorization where the covered entity receives remuneration in exchange for making the communications.

With respect to the exception for refill reminders or to otherwise communicate about a drug or biologic currently being prescribed to the individual, we adopt the exception as proposed. We continue to provide a stand-alone exception for refill reminders, given that the HITECH Act expressly does so. We therefore decline to adopt the suggestions of commenters to consider these communications to specifically be treatment communications (which would have required, under the provisions of the proposed rule, notice and an opportunity to opt out where the covered entity receives financial remuneration), or health care operations communications (which require authorization if financial remuneration is received).

Many commenters asked for guidance and clarification regarding the scope of this exception, and we received a wide array of examples of communications that commenters suggested should fall within this exception. At this time, we clarify that we consider communications about the generic equivalent of a drug being prescribed to an individual as well as adherence communications encouraging individuals to take their prescribed medication as directed fall within the scope of this exception. Additionally, we clarify that where an individual is prescribed a self-administered drug or biologic, communications regarding all aspects of a drug delivery system, including, for example, an insulin pump, fall under this exception. With respect to the array of other examples and suggestions provided by commenters as to what should fall within or outside of the exception, we intend to provide future guidance to address these questions.

The proposed rule contained the Act's limitation that the financial

remuneration received in exchange for providing a refill reminder or to otherwise communicate about a drug or biologic currently being prescribed to the individual must be ''reasonable in amount,'' by providing that such remuneration must be reasonably related to the covered entity's cost of making the communication for the exception from marketing to apply. We adopt this provision in the final rule. In response to comments regarding what types of costs fall within permissible remuneration, we clarify that we consider permissible costs for which a covered entity may receive remuneration under this exception are those which cover only the costs of labor, supplies, and postage to make the communication. Where the financial remuneration a covered entity receives in exchange for making the communication generates a profit or includes payment for other costs, such financial remuneration would run afoul of the Act's ''reasonable in amount'' language. Thus, under this final rule, if a pharmacy receives financial remuneration from a drug manufacturer to provide refill reminders to individuals taking a particular drug that covers only the pharmacy's cost of drafting, printing, and mailing the refill reminders, the exception would apply and no authorization would be required. However, where the drug manufacturer also provides the pharmacy with a financial incentive beyond the cost of making the communication to encourage the pharmacy's continued willingness to send such communications on behalf of the drug manufacturer, the exception would not apply and the pharmacy must obtain individual authorization. We note, however, that if a pharmacy provides refill reminders to individuals only when they visit the pharmacy (in face to face encounters), such communications would be permitted under § 164.508(a)(3)(i)(A) and thus, authorization would not be required even if the pharmacy receives financial remuneration above and beyond what is reasonably related to the pharmacy's cost of making the communication.

Finally, in addition to the communications that fall within the refill reminder exception, two other types of communications continue to be exempt from the marketing provisions. First, as explained in the NPRM, communications promoting health in general and that do not promote a product or service from a particular provider, such as communications promoting a healthy diet or encouraging individuals to get certain routine diagnostic tests, such as annual mammograms, do not constitute marketing and thus, do not require individual authorization.

Second, communications about government and government-sponsored programs do not fall within the definition of ''marketing'' as there is no commercial component to communications about benefits through public programs. Therefore, a covered entity may use and disclose protected health information to communicate with individuals about eligibility for programs, such as Medicare, Medicaid, or the State Children's Health Insurance Program (CHIP) without obtaining individual authorization.

Response to Other Public Comments

Comment: One commenter asked whether it is marketing where an entity promotes its discounts on covered benefits or member-exclusive value-added health products and services by paying a mailing house that is the health plan's business associate to send its written promotional material to health plan members. The commenter stated that only the mailing house, and not the covered entity, is paid to send the communications.

Response: Even where a business associate of a covered entity, such as a mailing house, rather than the covered entity itself, receives the financial remuneration from the entity whose product or service is being promoted to health plan members, the communication is a marketing communication for which prior authorization is required. As stated above, under the Privacy Rule, a business associate generally may not use or disclose protected health information in a manner that would be impermissible if done by the covered entity. We note, however, that non-financial or in-kind remuneration may be received by the covered entity or its business associate and it would not implicate the new marketing restrictions. Thus, if the materials describing a member-exclusive value-added health product or service were provided by the entity to the health plan or its business associate and no payment was made by the entity relating to the mailing or distribution of the materials, the covered entity or its business associate would be able to provide the material to its members without requiring an authorization.

3. Business Associates

a. Section 164.502(a) and (b)—Permitted and Required Uses and Disclosures and Minimum Necessary

Before the HITECH Act, the Privacy Rule did not govern business associates directly. However, section 13404 of the HITECH Act makes specific requirements of the Privacy Rule applicable to business associates, and creates direct liability for noncompliance by business associates with regard to those Privacy Rule requirements. Specifically, section 13404(a) of the HITECH Act creates direct liability for uses and disclosures of protected health information by business associates that do not comply with its business associate contract or other arrangement under the Privacy Rule. Additionally, section 13404(a) applies the other privacy requirements of the HITECH Act directly to business associates just as they apply to covered entities. Section 13404(b) applies the provision of § 164.504(e)(1)(ii) regarding knowledge of a pattern of activity or practice that constitutes a material breach or violation of a contract to business associates. Finally, section 13404(c) applies the HIPAA civil and criminal penalties to business associates. We discuss the modifications to the Privacy Rule pursuant to paragraphs (a) and (b) of section 13404 of the HITECH Act below. We address the modifications made to the Enforcement Rule by section 13404(c) regarding the application of penalties to violations by business associates above in the discussion of the changes to the Enforcement Rule.

We note that we have not added references to ''business associate'' to all provisions of the Privacy Rule that address uses and disclosures by covered entities. Such additions to the Privacy Rule are unnecessary, as a business associate generally may only use or disclose protected health information in the same manner as a covered entity. Therefore, any Privacy Rule limitation on how a covered entity may use or disclose protected health information automatically extends to a business associate.

i. Permitted and Required Uses and Disclosures

Proposed Rule

We proposed to modify § 164.502(a) of the Privacy Rule containing the general rules for uses and disclosures of protected health information to address the permitted and required uses and disclosures of protected health information by business associates. First, we proposed to modify

§ 164.502(a) to provide that a business associate, like a covered entity, may not use or disclose protected health information except as permitted or required by the Privacy Rule or the Enforcement Rule. Second, we proposed to add new provisions at § 164.502(a)(4) and (5) to specify the permitted and required uses and disclosures of protected health information by business associates.

In accordance with section 13404(a) of the HITECH Act, we proposed in § 164.502(a)(4) to allow business associates to use or disclose protected health information only as permitted or required by their business associate contracts or other arrangements pursuant to § 164.504(e) or as required by law. Any other use or disclosure would violate the Privacy Rule. Proposed § 164.502(a)(4) also provided that a business associate would not be permitted to use or disclose protected health information in a manner that would violate the Privacy Rule if done by the covered entity, except that the business associate would be permitted to use or disclose protected health information for the proper management and administration of the business associate and to provide data aggregation services for the covered entity, as specified at § 164.504(e)(2)(i)(A) and (B), if such uses and disclosures are permitted by its business associate contract or other arrangement.

In § 164.502(a)(5), we proposed to require that a business associate disclose protected health information either: (1) When required by the Secretary under Subpart C of Part 160 to investigate or determine the business associate's compliance with this subchapter; or (2) to the covered entity, individual, or individual's designee, as necessary to satisfy a covered entity's obligations under § 164.524(c)(2)(ii) and (3)(ii), as modified, with respect to an individual's request for an electronic copy of protected health information. Section 13405(e) of the HITECH Act requires covered entities that maintain protected health information in an electronic health record to provide an individual, or the individual's designee, with a copy of such information in an electronic format, if the individual so chooses. We proposed to include a similar direct requirement on business associates in § 164.502(a)(5), as section 13404(a) of the HITECH Act also applies section 13405(e) to business associates.

We also proposed a conforming change to revise the titles of § 164.502(a)(1) and (a)(2) to make clear that these provisions setting out permitted uses and disclosures of protected health information apply only to covered entities, as well as a technical change to § 164.502(a)(2)(ii) to replace the term ''subpart'' with ''subchapter'' to make clear that a covered entity is required to disclose protected health information to the Secretary as needed to determine compliance with any of the HIPAA Rules and not just the Privacy Rule.

Overview of Public Comments

Several commenters expressed concern about the increased liability for business associates under the rule and requested clarification on when business associate liability for impermissible uses and disclosures would attach. Several commenters asked for clarification as to what a business associate is directly liable for under the Privacy Rule, and some expressed specific confusion regarding the liability of business associates for the provision of e-access under the rule.

Final Rule

The final rule adopts the proposed modifications to § 164.502(a). The provisions specifying a business associate's permitted and required uses and disclosures of protected health information are renumbered from § 164.502(a)(4) and (a)(5), as proposed, to § 164.502(a)(3) and (a)(4), as § 164.502(a)(5) of the final rule now includes provisions to address prohibited uses and disclosures. Section 164.502(a)(5) is discussed below in the sections describing the prohibitions on the sale of protected health information and the use or disclosure of genetic information for underwriting purposes.

In response to specific comments asking for clarification regarding when business associate liability would attach, we provide the following. As we discussed above, the final rule provides that a business associate is a person who performs functions or activities on behalf of, or certain services for, a covered entity or another business associate that involve the use or disclosure of protected health information. The final rule establishes that a person becomes a business associate by definition, not by the act of contracting with a covered entity or otherwise. Therefore, liability for impermissible uses and disclosures attaches immediately when a person creates, receives, maintains, or transmits protected health information on behalf of a covered entity or business associate and otherwise meets the definition of a business associate.

Liability also does not depend on the type of protected health information that a business associate creates, receives, maintains, or transmits on behalf of a covered entity or another business associate, or on the type of entity performing the function or service, except to the extent the entity falls within one of the exceptions at paragraph 4 of the definition of business associate. First, protected health information created, received, maintained, or transmitted by a business associate may not necessarily include diagnosis-specific information, such as information about the treatment of an individual, and may be limited to demographic or other information not indicative of the type of health care services provided to an individual. If the information is tied to a covered entity, then it is protected health information by definition since it is indicative that the individual received health care services or benefits from the covered entity, and therefore it must be protected by the business associate in accordance with the HIPAA Rules and its business associate agreement. Second, the definition of business associate is contingent on the fact that the business associate performs certain activities or functions on behalf of, or provides certain services to, a covered entity or another business associate that involve the use or disclosure of protected health information. Therefore, any person, defined in the HIPAA Rules as a natural person, trust or estate, partnership, corporation, professional association or corporation, or other entity, public or private, who performs these functions or activities or services is a business associate for purposes of the HIPAA Rules, regardless of whether such person has other professional or privilege-based duties or responsibilities.

Finally, while we understand commenters' concerns about the increased liability for business associates under the HIPAA Rules, such direct liability for violations of certain HIPAA provisions is expressly provided for by the HITECH Act.

In response to comments requesting clarification on with which HIPAA provisions a business associate is directly liable for compliance, we provide the following. Business associates are directly liable under the HIPAA Rules for impermissible uses and disclosures,[4] for a failure to provide breach notification to the covered entity,[5] for a failure to provide access to a copy of electronic protected health information to either the covered entity, the individual, or the individual's designee (whichever is specified in the

[4] See § 164.502(a)(3).

[5] See § 164.410.

business associate agreement),[6] for a failure to disclose protected health information where required by the Secretary to investigate or determine the business associate's compliance with the HIPAA Rules,[7] for a failure to provide an accounting of disclosures,[8] and for a failure to comply with the requirements of the Security Rule.[9] Business associates remain contractually liable for other requirements of the business associate agreement (see below for a discussion of the business associate agreement provisions).

With respect to a business associate's direct liability for a failure to provide access to a copy of electronic protected health information, business associates are liable for providing electronic access in accordance with their business associate agreements. Therefore, business associates may provide electronic access directly to individuals or their designees, or may provide the electronic protected health information to the covered entity (which then provides the electronic access to individuals or their designees). As with many other provisions in the HIPAA Rules, the Department leaves the details to the contracting parties, and is concerned only that access is provided to the individual, not with which party provides the access.

ii. Minimum Necessary

Proposed Rule

We proposed to modify the minimum necessary standard at § 164.502(b) to require that when business associates use, disclose, or request protected health information from another covered entity, they limit protected health information to the minimum necessary to accomplish the intended purpose of the use, disclosure, or request. Applying the minimum necessary standard is a condition of the permissibility of many uses and disclosures of protected health information. Thus, a business associate is not making a permitted use or disclosure under the Privacy Rule if it does not apply the minimum necessary standard, where appropriate. Additionally, the HITECH Act at section 13405(b) addresses the application of minimum necessary and, in accordance with 13404(a), also applies such requirements to business associates.

Overview of Public Comments

While the Department received general support for application of the minimum necessary standard to requests and uses and disclosures by business associates, several commenters requested clarification on such application.

Final Rule

The final rule adopts the proposal to apply the minimum necessary standard directly to business associates when using or disclosing protected health information or when requesting protected health information from another covered entity. The final rule also makes clear that requests directed to another business associate, in addition to those directed to another covered entity, must also be limited to the minimum necessary. Covered entities and business associates disclosing protected health information in response may reasonably rely on such requests as requesting the minimum necessary for the disclosure.

How a business associate will apply the minimum necessary standard will vary based on the circumstances. As is the case today, a business associate agreement must limit the business associate's uses and disclosures of protected health information to be consistent with the covered entity's minimum necessary policies and procedures. We leave it to the discretion of the parties to determine to what extent the business associate agreement will include specific minimum necessary provisions to ensure a business associate's uses and disclosures and requests for protected health information are consistent with the covered entity's minimum necessary policies and procedures. The Department intends to issue future guidance on the minimum necessary standard in accordance with section 13405(b) of the HITECH Act that will consider the specific questions posed by commenters with respect to business associates' application of the minimum necessary standard.

b. Sections 164.502(e) and 164.504(e)—Business Associate Agreements

Proposed Rule

Section 164.502(e) permits a covered entity to disclose protected health information to a business associate and may allow a business associate to create or receive protected health information on its behalf, if the covered entity obtains satisfactory assurances, in the form of a written contract or other written arrangement with the business associate that meets the requirements of § 164.504(e), that the business associate will appropriately safeguard the information. We proposed a parallel provision in § 164.502(e) that would allow a business associate to disclose protected health information to a business associate that is a subcontractor, and to allow the subcontractor to create or receive protected health information on its behalf, if the business associate obtains similar satisfactory assurances that the subcontractor will appropriately safeguard the information. Consistent with the proposal with respect to Security Rule requirements and business associates, we proposed to make clear in § 164.502(e) that a covered entity would not be required to obtain satisfactory assurances from business associates that are subcontractors. Rather, a business associate would be required to obtain such assurances from a subcontractor. Thus, the proposed provisions would not change the parties to the contracts. For example, a covered entity may choose to contract with a business associate (contractor) to use or disclose protected health information on its behalf, the business associate may choose to obtain the services of (and exchange protected health information with) a subcontractor (subcontractor 1), and that subcontractor may, in turn, contract with another subcontractor (subcontractor 2) for services involving protected health information. The contractor and subcontractors 1 and 2 would now be business associates with direct liability under the HIPAA Rules, and would be required to obtain business associate agreements with the parties with whom they contract for services that involve access to protected health information. (Note, however, as discussed above with respect to the definition of ''business associate,'' direct liability under the HIPAA Rules would attach regardless of whether the contractor and subcontractors have entered into the required business associate agreements.)

We also proposed to remove § 164.502(e)(1)(iii), which provides that a covered entity that violates the satisfactory assurances it provided as a business associate of another covered entity will be in noncompliance with the Privacy Rule's business associate agreement provisions, given that proposed changes to § 164.502 would now restrict directly the uses and disclosures of protected health information by a business associate, including a covered entity acting as a business associate, to those uses and disclosures permitted by its business associate agreement.

[6] See § 164.502(a)(4)(ii).

[7] See § 164.502(a)(4)(i).

[8] *See* 76 FR 31426 (May 31, 2011).

[9] See Subpart C of Part 164.

Finally, as discussed above with respect to the definition of business associate, we proposed to move the current exceptions to business associate to the definition itself in § 160.103.

Section 164.504(e) contains the specific requirements for business associate contracts and other arrangements. We proposed a number of modifications to § 164.504(e) to implement section 13404 of the HITECH Act and to reflect the Department's new regulatory authority with respect to business associates, as well as to reflect a covered entity's and business associate's new obligations under Subpart D of Part 164 of the Privacy Rule to provide for notification in the case of breaches of unsecured protected health information.

Section 164.504(e)(1)(ii) provides that a covered entity is not in compliance with the business associate requirements if the covered entity knew of a pattern of activity or practice of the business associate that constituted a material breach or violation of the business associate's obligation under the contract or other arrangement, unless the covered entity took reasonable steps to cure the breach or end the violation, as applicable, and if such steps were unsuccessful, terminated the contract or arrangement or, if termination is not feasible, reported the problem to the Secretary. We proposed to remove the requirement that covered entities report to the Secretary when termination of a business associate agreement is not feasible. In light of a business associate's direct liability for civil money penalties for certain violations of the business associate agreement and both a covered entity's and business associate's obligations under Subpart D to report breaches of unsecured protected health information to the Secretary, we have other mechanisms through which we expect to learn of such breaches and misuses of protected health information by a business associate.

We also proposed to add a new provision at § 164.504(e)(1)(iii) applicable to business associates with respect to subcontractors to mirror the requirements on covered entities at § 164.504(e)(1)(ii) (minus the requirement to report to the Secretary if termination of a contract is not feasible). Thus, a business associate that is aware of noncompliance by its business associate subcontractor would be required to respond to the situation in the same manner as a covered entity that is aware of noncompliance by its business associate. We believe this provision would implement section 13404(b) of the HITECH Act, and would align the requirements for business associates with regard to business associate subcontractors with the requirements for covered entities with regard to their business associates.

We also proposed changes to the specific business associate agreement provisions at § 164.504(e). First, we proposed to revise § 164.504(e)(2)(ii)(B) through (D) to provide that the contract will require that: in (B), business associates comply, where applicable, with the Security Rule with regard to electronic protected health information; in (C), business associates report breaches of unsecured protected health information to covered entities, as required by § 164.410; and in (D), in accordance with § 164.502(e)(1)(ii), business associates ensure that any subcontractors that create or receive protected health information on behalf of the business associate agree to the same restrictions and conditions that apply to the business associate with respect to such information. These revisions were proposed to align the requirements for the business associate agreement with the requirements in the HITECH Act and elsewhere within the HIPAA Rules.

Additionally, we proposed to add a new agreement provision at § 164.504(e)(2)(ii)(H) (and to renumber the current paragraphs (H) and (I) accordingly) to requires that, to the extent the business associate is to carry out a covered entity's obligation under this subpart, the business associate must comply with the requirements of the Privacy Rule that apply to the covered entity in the performance of such obligation. This provision would clarify that when a covered entity delegates a responsibility under the Privacy Rule to the business associate, the business associate would be contractually required to comply with the requirements of the Privacy Rule in the same manner as they apply to the covered entity. For example, if a third party administrator, as a business associate of a group health plan, fails to distribute the plan's notice of privacy practices to participants on a timely basis, the third party administrator would not be directly liable under the HIPAA Rules, but would be contractually liable, for the failure. However, even though the business associate is not directly liable under the HIPAA Rules for failure to provide the notice, the covered entity remains directly liable for failure to provide the individuals with its notice of privacy practices because it is the covered entity's ultimate responsibility to do so, despite its having hired a business associate to perform the function.

We also proposed to add a new § 164.504(e)(5) that would apply the requirements at § 164.504(e)(2) through (e)(4) to the contract or other arrangement between a business associate and its business associate subcontractor as required by § 164.502(e)(1)(ii) in the same manner as such requirements apply to contracts or other arrangements between a covered entity and its business associate. Thus, a business associate would be required by § 164.502(e)(1)(ii) and by this section to enter into business associate agreements or other arrangements that comply with the Privacy and Security Rules with their business associate subcontractors, in the same manner that covered entities are required to enter into contracts or other arrangements with their business associates.

Finally, we proposed a few other minor changes. We proposed in § 164.504(e)(3) regarding other arrangements for governmental entities to include references to the Security Rule requirements for business associates to avoid having to repeat such provisions in the Security Rule. We also proposed to remove the reference to subcontractors in § 164.504(f)(2)(ii)(B) (regarding disclosures to plan sponsors) and in § 164.514(e)(4)(ii)(C)(4) (regarding data use agreements for limited data sets) to avoid confusion since the term ''subcontractor'' is now a defined term under the HIPAA Rules with a particular meaning that is related to business associates. The proposed removal of the term was not intended as a substantive change to the provisions.

Overview of Public Comments

Several commenters expressed confusion regarding the need for business associate agreements, considering the provisions for direct liability from the HITECH Act and in the proposed rule. Many of these commenters suggested that all of the requirements of the Privacy Rule apply to business associates, as is the case with the Security Rule.

A few commenters requested clarification about what constitutes ''satisfactory assurances'' pursuant to the rule, asking whether, for example, there were expectations on covered entities to ensure that business associates (including subcontractors) have appropriate controls in place besides business associate agreements or whether a covered entity must obtain from a business associate satisfactory assurance that any business associate subcontractors are complying with the Rules. Several commenters requested clarification on the appropriateness of

indemnification clauses in business associate agreements.

Finally, several commenters requested that the Department provide a model business associate agreement.

Final Rule

The final rule adopts the proposed modifications to §§ 164.502(e) and 164.504(e). As we discussed above, while section 13404 of the HITECH Act provides that business associates are now directly liable for civil money penalties under the HIPAA Privacy Rule for impermissible uses and disclosures and for the additional HITECH requirements in Subtitle D that are made applicable to covered entities, it does not apply all of the requirements of the Privacy Rule to business associates and thus, the final rule does not. Therefore, business associates are not required to comply with other provisions of the Privacy Rule, such as providing a notice of privacy practices or designating a privacy official, unless the covered entity has chosen to delegate such a responsibility to the business associate, which would then make it a contractual requirement for which contractual liability would attach.

Concerning commenters' questions about the continued need for business associate agreements given the new direct liability on business associates for compliance, we note that section 13404 of the HITECH Act expressly refers and ties business associate liability to making uses and disclosures in accordance with the uses and disclosures laid out in such agreements, rather than liability for compliance with the Privacy Rule generally. Further, section 13408 of the HITECH Act requires certain data transmission and personal health record vendors to have in place business associate agreements with the covered entities they serve. We also continue to believe that, despite the business associate's direct liability for certain provisions of the HIPAA Rules, the business associate agreement is necessary to clarify and limit, as appropriate, the permissible uses and disclosures by the business associate, given the relationship between the parties and the activities or services being performed by the business associate. The business associate agreement is also necessary to ensure that the business associate is contractually required to perform certain activities for which direct liability does not attach (such as amending protected health information in accordance with § 164.526). In addition, the agreement represents an opportunity for the parties to clarify their respective responsibilities under the HIPAA Rules, such as by establishing how the business associate should handle a request for access to protected health information that it directly receives from an individual. Finally, the business associate agreement serves to notify the business associate of its status under the HIPAA Rules, so that it is fully aware of its obligations and potential liabilities.

With respect to questions about ''satisfactory assurances,'' § 164.502(e) provides that covered entities and business associates must obtain and document the ''satisfactory assurances'' of a business associate through a written contract or other agreement, such as a memorandum of understanding, with the business associate that meets the applicable requirements of § 164.504(e). As discussed above, § 164.504(e) specifies the provisions required in the written agreement between covered entities and business associates, including a requirement that a business associate ensure that any subcontractors agree to the same restrictions and conditions that apply to the business associate by providing similar satisfactory assurances. Beyond the required elements at § 164.504(e), as with any contracting relationship, business associates and covered entities may include other provisions or requirements that dictate and describe their business relationship, and that are outside the governance of the Privacy and Security Rules. These may or may not include additional assurances of compliance or indemnification clauses or other risk-shifting provisions.

We also clarify with respect to the satisfactory assurances to be provided by subcontractors, that the agreement between a business associate and a business associate that is a subcontractor may not permit the subcontractor to use or disclose protected health information in a manner that would not be permissible if done by the business associate. For example, if a business associate agreement between a covered entity and a contractor does not permit the contractor to de-identify protected health information, then the business associate agreement between the contractor and a subcontractor (and the agreement between the subcontractor and another subcontractor) cannot permit the de-identification of protected health information. Such a use may be permissible if done by the covered entity, but is not permitted by the contractor or any subcontractors if it is not permitted by the covered entity's business associate agreement with the contractor. In short, each agreement in the business associate chain must be as stringent or more stringent as the agreement above with respect to the permissible uses and disclosures.

Finally, in response to the comments requesting a model business associate agreement, we note that the Department has published sample business associate provisions on its web site. The sample language is designed to help covered entities comply with the business associate agreement requirements of the Privacy and Security Rules. However, use of these sample provisions is not required for compliance with the Rules, and the language should be amended as appropriate to reflect actual business arrangements between the covered entity and the business associate (or a business associate and a subcontractor).

Response to Other Public Comments

Comment: Commenters requested guidance on whether a contract that complies with the requirements of the Graham Leach Bliley Act (GLBA) and incorporates the required elements of the HIPAA Rules may satisfy both sets of regulatory requirements. The commenters urged the Department to permit a single agreement rather than requiring business associates and business associate subcontractors to enter into separate GLBA agreements and business associate agreements.

Response: While meeting the requirements of the GLBA does not satisfy the requirements of the HIPAA Rules, covered entities may use one agreement to satisfy the requirements of both the GLBA and the HIPAA Rules.

Comment: A few commenters recommended adding an exception to having a business associate agreement for a person that receives a limited dataset and executes a data use agreement for research, health care operations, or public health purposes.

Response: We have prior guidance that clarifies that if only a limited dataset is released to a business associate for a health care operations purpose, then a data use agreement suffices and a business associate agreement is not necessary. To make this clear in the regulation itself, we are adding to § 164.504(e)(3) a new paragraph (iv) that recognizes that a data use agreement may qualify as a business associate's satisfactory assurance that it will appropriately safeguard the covered entity's protected health information when the protected health information disclosed for a health care operations purpose is a limited data set. A similar provision is not necessary or appropriate for disclosures of limited data sets for research or public health purposes since such disclosures would

not otherwise require business associate agreements.

Comment: A few commenters requested that the Department delete § 164.504(e)(2)(ii)(H), which provides that to the extent the business associate is to carry out a covered entity's obligation under the HIPAA Rules, the business associate must comply with the requirements of the HIPAA Rules that apply to the covered entity in the performance of the obligation on behalf of the covered entity. Alternatively, commenters suggested that the Department clarify that the requirements of the section need not be included in business associate agreements and that this section does not limit the ability of covered entities and business associates to negotiate responsibilities with regard to other sections of the Privacy Rule.

Response: The Department declines to delete § 164.504(e)(2)(ii)(H). If a business associate contracts to provide services to the covered entity with regard to fulfilling individual rights or other obligations of the covered entity under the Privacy Rule, then the business associate agreement must require the business associate to fulfill such obligation in accordance with the Privacy Rule's requirements. We do clarify, however, that if the covered entity does not delegate any of its responsibilities under the Privacy Rule to the business associate, then § 164.504(e)(2)(ii)(H) is not applicable and the parties are not required to include such language.

Comment: One commenter requested that the Department modify § 164.502(a)(4)(i) to permit business associates to use and disclose protected health information for their own health care operations purposes, and another commenter requested that the Department clarify whether § 164.504(e)(4) provides that a business associate may use or disclose protected health information as a covered entity would use or disclose the information.

Response: The Department declines to make the suggested modification. Business associates do not have their own health care operations (see the definition of health care operations at § 164.501, which is limited to activities of the covered entity). While a business associate does not have health care operations, it is permitted by § 164.504(e)(2)(i)(A) to use and disclose protected health information as necessary for its own management and administration if the business associate agreement permits such activities, or to carry out its legal responsibilities. Other than the exceptions for the business associate's management and administration and for data aggregation services relating to the health care operations of the covered entity, the business associate may not use or disclose protected health information in a manner that would not be permissible if done by the covered entity (even if such a use or disclosure is permitted by the business associate agreement).

Comment: One commenter suggested requiring subcontractors to return or destroy all protected health information received from or created for a business associate when the contract with the business associate is terminated.

Response: The final rule at § 164.504(e)(5) does apply the requirements at § 164.504(e)(2) through (4) (which set forth the requirements for agreements between covered entities and their business associates) to agreements between business associates and their subcontractors. This includes § 164.504(e)(2)(ii)(J), which requires the business associate to return or destroy all protected health information received from, or created or received on behalf of, the covered entity at the termination of the contract, if feasible. When this requirement is applied to the agreement between the business associate and its business associate subcontractor, the effect is a contractual obligation for the business associate subcontractor to similarly return or destroy protected health information at the termination of the contract, if feasible.

Comment: One commenter suggested requiring a business associate to disclose all subcontractors of the business associate to a covered entity within thirty days of the covered entity's request.

Response: The Department declines to adopt this suggestion as a requirement of the HIPAA Rules, because such a requirement would impose an undue disclosure burden on business associates. However, covered entities and business associates may include additional terms and conditions in their contracts beyond those required by § 164.504.

Comment: One commenter suggested establishing a certification process of business associates and subcontractors with regard to HIPAA compliance.

Response: The Department declines to establish or endorse a certification process for HIPAA compliance for business associates and subcontractors. Business associates and subcontractors are free to enlist the services of outside entities to assess their compliance with the HIPAA Rules and certification may be a useful compliance tool for entities, depending on the rigor of the program. However, certification does not guarantee compliance and therefore ''certified'' entities may still be subject to enforcement by OCR.

Comment: One commenter requested clarification on when it is not feasible for a business associate to terminate a contract with a subcontractor.

Response: Whether it is feasible for a business associate to terminate an agreement with a business associate subcontractor is a very fact-specific inquiry that must be examined on a case-by-case basis. For example, termination is not feasible for a business associate with regard to a subcontractor relationship where there are no other viable business alternatives for the business associate (when the subcontractor, for example, provides a unique service that is necessary for the business associate's operations). See our prior guidance on this issue as it applies to covered entities and business associates in Frequently Asked Question #236, available at *http://www.hhs.gov/ocr/privacy/hipaa/faq/business_associates/236.html.*

c. Section 164.532—Transition Provisions

Proposed Rule

We understand that covered entities and business associates are concerned with the anticipated administrative burden and cost to implement the revised business associate agreement provisions of the Privacy and Security Rules. Covered entities may have existing contracts that are not set to terminate or expire until after the compliance date of the modifications to the Rules, and we understand that a six month compliance period may not provide enough time to reopen and renegotiate all contracts. In response to these concerns, we proposed to relieve some of the burden on covered entities and business associates in complying with the revised business associate provisions by adding a transition provision to grandfather certain existing contracts for a specified period of time. The Department's authority to add the transition provision is set forth in § 160.104(c), which allows the Secretary to establish the compliance date for any modified standard or implementation specification, taking into account the extent of the modification and the time needed to comply with the modification. The proposed transition period would prevent rushed and hasty changes to thousands of on-going existing business associate agreements. We addressed the issue of the business associate transition provisions as follows.

We proposed new transition provisions at § 164.532(d) and (e) to allow covered entities and business associates (and business associates and business associate subcontractors) to continue to operate under certain existing contracts for up to one year beyond the compliance date of the revisions to the Rules. The additional transition period would be available to a covered entity or business associate if, prior to the publication date of the modified Rules, the covered entity or business associate had an existing contract or other written arrangement with a business associate or subcontractor, respectively, that complied with the prior provisions of the HIPAA Rules and such contract or arrangement was not renewed or modified between the effective date and the compliance date of the modifications to the Rules. The proposed provisions were intended to allow those covered entities and business associates with valid contracts with business associates and subcontractors, respectively, to continue to disclose protected health information to the business associate or subcontractor, or to allow the business associate or subcontractor to continue to create or receive protected health information on behalf of the covered entity or business associate, for up to one year beyond the compliance date of the modifications, regardless of whether the contract meets the applicable contract requirements in the modifications to the Rules. With respect to business associates and subcontractors, the proposal would grandfather existing written agreements between business associates and subcontractors entered into pursuant to § 164.504(e)(2)(ii)(D) (which requires the business associate to ensure that its agents with access to protected health information agree to the same restrictions and conditions that apply to the business associate). The Department proposed to deem such contracts to be compliant with the modifications to the Rules until either the covered entity or business associate has renewed or modified the contract following the compliance date of the modifications, or until the date that is one year after the compliance date, whichever is sooner.

In cases where a contract renews automatically without any change in terms or other action by the parties (also known as ''evergreen contracts''), the Department intended that such evergreen contracts would be eligible for the extension and that deemed compliance would not terminate when these contracts automatically rolled over. These transition provisions would have applied to covered entities and business associates only with respect to written contracts or other written arrangements as specified above, and not to oral contracts or other arrangements.

These transition provisions would have only applied to the requirement to amend contracts; they would not affect any other compliance obligations under the HIPAA Rules. For example, beginning on the compliance date of this rule, a business associate may not use or disclose protected health information in a manner that is contrary to the Privacy Rule, even if the business associate's contract with the covered entity has not yet been amended.

Overview of Public Comments

Many commenters supported the 1-year extended timeframe for compliance with the business associate agreement provisions. Some commenters suggested longer timeframes, citing cost and resource limitations. Some commenters suggested that the Department should deem compliant all business associate agreements that have been renegotiated in good faith to meet the February 2010 effective date of the applicable provisions in the HITECH Act. Some commenters suggested that the Department recognize as compliant business associate agreements with provisions requiring compliance with all applicable laws.

Final Rule

The final rule adopts the proposal, adding new transition provisions at § 164.532(d) and (e) to allow covered entities and business associates (and business associates and business associate subcontractors) to continue to operate under certain existing contracts for up to one year beyond the compliance date of the revisions to the Rules.

We decline to provide a longer time for compliance with the business associate agreement provisions. We provided a similar transition period for revising agreements in the 2002 modifications to the HIPAA Rules, and it was our experience that such time was sufficient to ease burden on the entities and allow most agreements to be modified at the time they would otherwise come up for renewal or renegotiation.

With respect to those business associate agreements that already have been renegotiated in good faith to meet the applicable provisions in the HITECH Act, covered entities should review such agreements to determine whether they meet the final rule's provisions. If they do not, these covered entities then have the transition period to make whatever additional changes are necessary to conform to the final rule. The transition period is also available to those agreements that require compliance with all applicable laws (to the extent the agreements were otherwise in compliance with the HIPAA Rules prior to this final rule), but that do not fully meet the new requirements in this final rule. However, we do not deem such contracts as compliant beyond the transition period because they would not sufficiently reflect the new requirements.

4. Section 164.508—Uses and Disclosures for Which an Authorization Is Required

a. Sale of Protected Health Information

Proposed Rule

Section 164.508 of the Privacy Rule permits a covered entity to use and disclose protected health information for purposes not otherwise permitted by the Rule if it has obtained a valid written authorization from the individual who is the subject of the information. This section also specifies two circumstances in which authorization from the individual must be obtained: (1) Most uses and disclosures of psychotherapy notes; and (2) uses and disclosures for marketing purposes.

Section 13405(d) of the HITECH Act added a third circumstance that requires authorization, specifically the sale of protected health information. Section 13405(d)(1) prohibits a covered entity or business associate from receiving direct or indirect remuneration in exchange for the disclosure of protected health information unless the covered entity has obtained an individual's authorization pursuant to § 164.508 that states whether the protected health information can be further exchanged for remuneration by the entity receiving the information.

Section 13405(d)(2) contains several exceptions to the authorization requirement for circumstances where the purpose of the exchange is for: (1) Public health activities, as described at § 164.512(b) of the Privacy Rule; (2) research purposes as described at §§ 164.501 and 164.512(i) of the Rule, if the price charged for the information reflects the cost of preparation and transmittal of the data; (3) treatment of the individual; (4) the sale, transfer, merger or consolidation of all or part of a covered entity and for related due diligence; (5) services rendered by a business associate pursuant to a

business associate agreement and at the specific request of the covered entity; (6) providing an individual with access to his or her protected health information pursuant to § 164.524; and (7) other purposes as the Secretary deems necessary and appropriate by regulation. Section 13405(d)(4) of the Act provides that the prohibition on sale of protected health information applies to disclosures occurring six months after the date of the promulgation of the final regulations implementing this section.

To implement section 13405(d) of the HITECH Act, we proposed to add a general rule at § 164.508(a)(4) requiring a covered entity to obtain an authorization for any disclosure of protected health information in exchange for direct or indirect remuneration from or on behalf of the recipient of the information and to require that the authorization state that the disclosure will result in remuneration to the covered entity. Consistent with the HITECH Act, the NPRM proposed to exclude several disclosures of protected health information made in exchange for remuneration from this general rule. As provided in the Act, these requirements would also apply to business associates of covered entities.

In the NPRM we did not include language at § 164.508(a)(4) to require that the authorization under § 164.508 specify whether the protected health information disclosed by the covered entity for remuneration could be further exchanged for remuneration by the entity receiving the information. The statute refers to obtaining a valid authorization that includes a remuneration statement in accordance with § 164.508. The remuneration statement required by § 164.508 is whether remuneration will be received by the covered entity with respect to the disclosures subject to the authorization. This puts the individual on notice that the disclosure involves remuneration and thus, enables the individual to make an informed decision as to whether to sign the authorization. Thus, we interpreted the statute to mean that the authorization must include a statement that the covered entity is receiving direct or indirect remuneration in exchange for the protected health information. We note that these exact words do not need to be used in the statement. We provide discretion for covered entities to craft appropriate language that reflects, for example, the specific type of remuneration they receive. As we explained in the NPRM, with respect to the recipient of the information, if protected health information is disclosed for remuneration by a covered entity or business associate to another covered entity or business associate in compliance with the authorization requirements at proposed § 164.508(a)(4)(i), the recipient covered entity or business associate could not redisclose the protected health information in exchange for remuneration unless a valid authorization was obtained in accordance with proposed § 164.508(a)(4)(i). We requested comment on these provisions.

At proposed § 164.508(a)(4)(ii), we set forth the exceptions to the authorization requirement. We proposed the exceptions provided for by section 13405(d)(2) of the HITECH Act, and also proposed to exercise the authority granted to the Secretary in section 13405(d)(2)(G) to include additional exceptions that we deemed to be similarly necessary and appropriate. These exceptions are discussed below. We requested comment on whether there were additional exceptions that should be included in the final regulation.

First, we proposed to include an exception to cover exchanges for remuneration for public health activities pursuant to §§ 164.512(b) or 164.514(e). We added the reference to § 164.514(e) of the Privacy Rule to ensure that disclosures of protected health information for public health activities in limited data set form would also be excepted from the authorization requirement, in addition to disclosures that may occur under § 164.512(b) with more identifiable information. With respect to the exception for public health disclosures, section 13405(d)(3)(A) of the HITECH Act requires that the Secretary evaluate the impact on public health activities of restricting this exception to require that the price charged for the data reflects only the costs of preparation and transmittal of the data, including those conducted by or for the use of the Food and Drug Administration (FDA). Section 13405(d)(3)(B) further provides that if the Secretary finds that such further restriction will not impede public health activities, the restriction may then be included in the regulations. We did not propose to include such a restriction on remuneration in the Rule, but requested public comment to assist us in evaluating the impact of doing so.

The NPRM also included an exception for disclosures of protected health information for research purposes, pursuant to §§ 164.512(i) or 164.514(e), in exchange for which the covered entity receives only a reasonable, cost based fee to cover the cost to prepare and transmit the information for research purposes. Like the public health exception, we proposed to add a reference to § 164.514(e) to ensure that this exception would also apply to the disclosure of protected health information in limited data set form for research purposes. We requested public comment on the types of costs that should be permitted under this provision.

We proposed to create an exception from the authorization requirement for disclosures of protected health information for treatment and payment purposes. Though the Act only addressed treatment, we proposed to also except disclosures for payment for health care from the remuneration prohibition to make clear that the exchange of protected health information to obtain ''payment,'' as such term is defined in the Privacy Rule at § 164.501, would not be considered a sale of protected health information.

Consistent with section 13405(d)(2)(D) of the HITECH Act, we proposed to except from the authorization requirement disclosures described in paragraph (6)(iv) of the definition of health care operations at § 164.501, that is, disclosures for the sale, transfer, merger, or consolidation of all or part of a covered entity, or an entity that following such activity will become a covered entity, and due diligence related to such activity.

We proposed to provide an exception from the authorization requirement for disclosures of protected health information to or by a business associate for activities that the business associate undertakes on behalf of a covered entity pursuant to §§ 164.502(e) and 164.504(e) of the Privacy Rule, as long as the only remuneration provided is by the covered entity to the business associate for the performance of such activities. This exception would exempt from the authorization requirement at § 164.508(a)(4)(i) a disclosure of protected health information by a covered entity to a business associate or by a business associate to a third party on behalf of the covered entity as long as any remuneration received by the business associate was for the activities performed by the business associate pursuant to a business associate contract.

We proposed to except from the authorization requirement disclosures of protected health information by a covered entity to an individual when requested under §§ 164.524 (providing a right to access protected health information) or 164.528 (providing a right to receive an accounting of

disclosures). While section 13405(d)(2)(F) of the HITECH Act explicitly refers only to disclosures under § 164.524, we exercised our authority under section 13405(d)(2)(G) of the HITECH Act to likewise include in the exception disclosures to the individual under § 164.528. Section 164.524 permits a covered entity to impose a reasonable, cost-based fee for the provision of access to an individual's protected health information upon request. Section 164.528 requires a covered entity to provide a requesting individual with an accounting of disclosures without charge in any 12-month period but permits a covered entity to impose a reasonable, cost-based fee for each subsequent request for an accounting of disclosures during that 12-month period. Therefore, a disclosure of protected health information under § 164.528 is similar to a disclosure under § 164.524 in that a covered entity may be paid a fee for making the disclosure.

Pursuant to the authority granted to the Secretary in section 13405(d)(2)(G) of the HITECH Act, we proposed an additional exception for disclosures that are required by law as permitted under § 164.512(a) of the Privacy Rule.

Finally, we proposed an exception, pursuant to the authority granted to the Secretary in section 13405(d)(2)(G), for disclosures of protected health information for any other purpose permitted by and in accordance with the applicable requirements of the Privacy Rule, as long as the only remuneration received by the covered entity is a reasonable, cost based fee to cover the cost to prepare and transmit the protected health information for such purpose or is a fee otherwise expressly permitted by other law. We proposed this exception to ensure that the authorization requirement would not deter covered entities from disclosing protected health information for permissible purposes under the Privacy Rule just because they routinely receive payment equal to the cost of preparing, producing, and transmitting the protected health information. We emphasized that this proposed exception would not apply if a covered entity received remuneration above the actual cost incurred to prepare, produce, and transmit the protected health information for the permitted purpose, unless such fee is expressly permitted by other law.

As explained in the NPRM, we recognize that many States have laws in place to limit the fees a health care provider can charge to prepare, copy, and transmit medical records. Under these laws, there is great variation regarding the types of document preparation activities for which a provider can charge as well as the permissible fee schedules for such preparation activities. Some States simply require any reasonable costs incurred by the provider in making copies of the medical records to be paid for by the requesting party, while other States set forth specific cost limitations with respect to retrieval, labor, supplies, and copying costs and allow charges equal to actual mailing or shipping costs. Many of these State laws set different cost limitations based on the amount and type of information to be provided, taking into account whether the information is in paper or electronic form as well as whether the requested material includes x-rays, films, disks, tapes, or other diagnostic imaging. The proposed exception would permit recoupment of fees expressly permitted by these other laws.

Overview of Public Comments

Many commenters asked for clarification on the scope of activities that constitute a ''sale of protected health information.'' Several of these commenters asked that the final rule include a definition of ''sale of protected health information'' and argued that the proposed language at § 164.508(a)(4) was too broad and had the potential to capture a number of activities that should not constitute a ''sale'' of protected health information. Commenters made a variety of suggestions in this regard, including suggesting that a definition of sale should focus on the transfer of ownership of protected health information and thus exclude disclosures pursuant to an access agreement, license, or lease that appropriately limits a recipient's uses or disclosures of the information; or that a definition of sale should more clearly capture those disclosures where remuneration is provided in exchange for protected health information, rather than all disclosures that may involve remuneration. A number of commenters were concerned that fees paid for services or programs that involve the disclosure of protected health information but that are not fees to purchase the data themselves nonetheless would turn such disclosure into a sale of protected health information. For example, some commenters were concerned that the disclosure of research results to a research sponsor would be a sale of protected health information because the sponsor paid the covered entity for its services in conducting the research study or project. Other commenters expressed concern about the authorization requirements for the sale of protected health information applying to programs for which a covered entity receives funding and, as a condition of that funding, is required to report data, such as under the Medicare and Medicaid incentive payment programs for meaningful users of certified electronic health record technology and certain State grant programs. A few commenters were concerned that the exchange of protected health information through a health information exchange (HIE) that is paid for through fees assessed on HIE participants could be considered sale of protected health information.

Commenters also asked for clarification on the meaning and scope of the term ''direct and indirect remuneration,'' and some were particularly concerned that ''indirect remuneration'' meant nonfinancial benefits provided in exchange for protected health information could turn a disclosure into a sale of protected health information. Some commenters stated that prohibiting the receipt of indirect remuneration or nonfinancial benefits may eliminate any incentive for covered entities to participate in certain collaborative research or quality activities, in which covered entities contribute data to a centralized database to create aggregate data sets and in return may receive a number of nonfinancial benefits, such as the ability to use the aggregated information for research or access to quality assurance/quality improvement tools. Certain commenters argued that the term indirect in the statute modifies the ''receipt'' of remuneration (i.e., that the statute also applies to the situation where the remuneration is provided by a third party on behalf of the recipient of the protected health information) and not the type of remuneration.

The public health exception to the remuneration prohibition received a significant amount of support from commenters. Several commenters expressed specific support for the proposal to expand the exception to also apply to disclosures of limited data sets for public health purposes. With respect to the request for comment on the impact of restricting this exception to require that the price charged for the data reflects on the costs of preparing and transmitting the data, commenters were generally opposed to imposing such a restriction. Commenters stated that it may be difficult and burdensome to determine if some of a covered entity's routine public health reporting involve any type of remuneration and

that a cost-based restriction on remuneration would discourage and impede covered entities from making important public health disclosures. One commenter was opposed to the public health exception altogether, stating that it is a privacy loophole that eliminates consumer control over their protected health information.

Many respondents to the proposed sale prohibition commented on the proposed exception for research. While most commenters supported including an exception for research disclosures, including disclosures of limited data sets for research, many argued that the exception should not be limited to the receipt of a reasonable cost-based fee to prepare and transmit the data as such a fee limitation could impede important research efforts. A number of commenters specifically opposed imposing a fee limitation on the disclosure of limited data sets. If a fee limitation were retained, commenters argued that it should be broadly construed. The majority of commenters on this issue supported the proposed exceptions to the remuneration prohibition for treatment and health care payment purposes, as necessary so as not to impede these core health care functions. Overall, support was also expressed by those who commented on the exception for the sale, transfer, merger, or consolidation of a covered entity. Further, commenters generally agreed that a covered entity should be permitted to disclose protected health information without individual authorization as required by law, even if remuneration is received in exchange for the disclosure.

Commenters also submitted a number of comments and questions regarding the ability of business associates to receive fees under both the proposed exception specifically for fees paid by a covered entity to a business associate and the general exception that would allow a covered entity to receive a reasonable, cost-based fee to cover the costs to prepare and transmit the data or a fee otherwise expressly permitted by other law for any disclosure permitted by the Privacy Rule. While commenters generally supported these exceptions, commenters were concerned that these exceptions appeared not to cover the common situation where a business associate, rather than the covered entity, receives remuneration from a third party for making a permitted disclosure under the Privacy Rule. For example, a number of commenters stated that covered entities often outsource to release of information (ROI) vendors the processing of requests for copies of medical records from third parties and that these vendors and not the covered entities bill for the reasonable costs of providing the records to the requestors. Commenters asked that the final rule clarify that business associates can continue to receive payment of costs from third parties for providing this service on behalf of covered entities. Another commenter requested that the final rule clarify that the exception for remuneration to a business associate for activities performed on behalf of a covered entity also applies to remuneration received by subcontractors performing services on behalf of business associates.

Finally, several commenters also responded to the proposed rule's request for comment on the general exception at § 164.508(a)(4)(ii)(H) by suggesting costs that they believed should be permitted, including but not limited to costs for: preparing, producing, and transmitting protected health information; retrieval, labor, supplies, and copying costs; personnel and overhead costs; investments and indirect costs; and any costs that are in compliance with State law.

Final Rule

The final rule adopts the HITECH Act's prohibition on the sale of protected health information but makes certain changes to the provisions in the proposed rule to clarify the scope of the provisions and otherwise address certain of commenters' concerns. First, we have moved the general prohibition on the sale of protected health information by a covered entity or business associate to § 164.502(a)(5)(ii) and created a definition of ''sale of protected health information.'' Numerous commenters requested that the Privacy Rule include a definition of sale to better clarify what types of transactions fall within the scope of the provisions. Accordingly, § 164.502(a)(5)(ii)(B)(*1*) defines ''sale of protected health information'' to generally mean ''a disclosure of protected health information by a covered entity or business associate, if applicable, where the covered entity or business associate directly or indirectly receives remuneration from or on behalf of the recipient of the protected health information in exchange for the protected health information.'' Section 164.502(a)(5)(ii)(B)(*2*) then excludes from the definition the various exceptions that were in the proposed rule (discussed further below).

We do not limit a ''sale'' to those transactions where there is a transfer of ownership of protected health information as some commenters suggested. The HITECH Act does not include such a limitation and the Privacy Rule rights and protections apply to protected health information without regard to ownership interests over the data. Thus, the sale provisions apply to disclosures in exchange for remuneration including those that are the result of access, license, or lease agreements.

In addition, we do not consider sale of protected health information in this provision to encompass payments a covered entity may receive in the form of grants, or contracts or other arrangements to perform programs or activities, such as a research study, because any provision of protected health information to the payer is a byproduct of the service being provided. Thus, the payment by a research sponsor to a covered entity to conduct a research study is not considered a sale of protected health information even if research results that may include protected health information are disclosed to the sponsor in the course of the study. Further, the receipt of a grant or funding from a government agency to conduct a program is not a sale of protected health information, even if, as a condition of receiving the funding, the covered entity is required to report protected health information to the agency for program oversight or other purposes. (Certain of these disclosures would also be exempt from the sale requirements, depending on whether the requirement to report data was included in regulation or other law.) Similarly, we clarify that the exchange of protected health information through a health information exchange (HIE) that is paid for through fees assessed on HIE participants is not a sale of protected health information; rather the remuneration is for the services provided by the HIE and not for the data itself. (Such disclosures may also be exempt from these provisions under the exception for disclosures to or by a business associate that is being compensated by a covered entity for its services.) In contrast, a sale of protected health information occurs when the covered entity primarily is being compensated to supply data it maintains in its role as a covered entity (or business associate). Thus, such disclosures require the individual's authorization unless they otherwise fall within an exception at § 164.502(a)(5)(ii)(B)(*2*). For example, a disclosure of protected health information by a covered entity to a third party researcher that is conducting the research in exchange for remuneration would fall within these provisions, unless the only

remuneration received is a reasonable, cost-based fee to cover the cost to prepare and transmit the data for such purposes (see below).

In response to questions by commenters, we also clarify the scope of the term ''remuneration.'' The statute uses the term ''remuneration,'' and not ''payment,'' as it does in the marketing provisions at section 13406(a). Because the statute uses different terms, we do not believe that remuneration as applied to the sale provisions is limited to financial payment in the same way it is so limited in the marketing provisions. Thus, the prohibition on sale of protected health information applies to the receipt of nonfinancial as well as financial benefits. In response to commenters who indicated that the statute's terms ''direct and indirect'' apply to how the remuneration is received rather than the remuneration itself, we agree and have moved the terms in the definition to further make clear that the provisions prohibit the receipt of remuneration not only from the third party that receives the protected health information but also from another party on behalf of the recipient of the protected health information. However, this does not change the scope of the term ''remuneration.'' As discussed above, we interpret the statute to mean that nonfinancial benefits are included in the prohibition. Thus, a covered entity or business associate may not disclose protected health information in exchange for in kind benefits, unless the disclosure falls within one of the exceptions discussed below. Consider, for example, a covered entity that is offered computers in exchange for disclosing protected health information. The provision of protected health information in exchange for the computers would not be considered a sale of protected health information if the computers were solely used for the purpose of preparing and transmitting protected health information to the person collecting it and were returned when such disclosure was completed. However, if the covered entity is permitted to use the computers for other purposes or to keep the computers even after the disclosures have been made, then the covered entity has received in kind remuneration in exchange for the protected health information above what is needed to make the actual disclosures.

We retain in the final rule the broad exception for disclosures for public health purposes made pursuant to §§ 164.512(b) and 164.514(e). Based on the concerns from the public comment that narrowing the exception could discourage voluntary public health reporting, we do not limit the exception to only those disclosures where all the covered entity receives as remuneration is a cost-based fee to cover the cost to prepare and transmit the data.

With respect to the exception for research disclosures, the final rule adopts the language as proposed, including the cost-based fee limitation provided for in the HITECH Act. Thus, disclosures for research purposes are excepted from the remuneration prohibition to the extent that the only remuneration received by the covered entity or business associate is a reasonable cost-based fee to cover the cost to prepare and transmit the protected health information for such purposes. We do not remove the fee limitation as requested by some commenters; the statutory language included in Section 13405(d)(2)(B) of the HITECH Act clearly states that any remuneration received in exchange for research disclosures must reflect only the cost of preparation and transmittal of the data for such purpose.

In response to comments about the types of costs that are permitted in the reasonable cost-based fee to prepare and transmit the data, we clarify that this may include both direct and indirect costs, including labor, materials, and supplies for generating, storing, retrieving, and transmitting the protected health information; labor and supplies to ensure the protected health information is disclosed in a permissible manner; as well as related capital and overhead costs. However, fees charged to incur a profit from the disclosure of protected health information are not allowed. We believe allowing a profit margin would not be consistent with the language contained in Section 13405 of the HITECH Act. We intend to work with the research community to provide guidance and help the research community reach a common understanding of appropriate cost-based limitations on remuneration.

We retain the exceptions proposed for treatment and payment disclosures without modification and agree with commenters that these exceptions are necessary to make clear that these core health care functions may continue. Similarly, we retain the exception to the remuneration prohibition for disclosures for the transfer, merger, or consolidation of all or part of a covered entity with another covered entity, or an entity that following such activity will become a covered entity, and related due diligence, to ensure that such disclosures may continue to occur in accordance with the Privacy Rule. We retain the proposed exception for disclosures that are otherwise required by law to ensure a covered entity can continue to meet its legal obligations without imposing an authorization requirement. We also retain the exception for disclosures to the individual to provide the individual with access to protected health information or an accounting of disclosures, where the fees charged for doing so are in accord with the Privacy Rule.

We adopt the exceptions for remuneration paid by a covered entity to a business associate for activities performed on behalf of a covered entity, as well as the general exception permitting a covered entity to receive remuneration in the form of a reasonable, cost-based fee to cover the cost to prepare and transmit the protected health information for any disclosure otherwise permitted by the Privacy Rule. However, we make a number of clarifications to address commenters questions and concerns regarding the ability of a business associate rather than a covered entity to receive the permitted remuneration. First, we add the term ''business associate'' in the general exception permitting reasonable, cost-based fees to prepare and transmit data (or fees permitted by State laws) to make clear that business associates may continue to recoup fees from third party record requestors for preparing and transmitting records on behalf of a covered entity, to the extent such fees are reasonable, cost-based fees to cover the cost to prepare and transmit the protected health information or otherwise expressly permitted by other law. Second, we clarify in the business associate exception that the exception would also cover remuneration by a business associate to its subcontractor for activities performed by the subcontractor on behalf of the business associate. Finally, we add the term ''business associate'' to the general prohibition on sale of protected health information for consistency, even though, without the addition, a business associate still would not be permitted to sell protected health information as a business associate may generally only make uses and disclosures of protected health information in manners in which a covered entity would be permitted under the Privacy Rule.

With respect to the types of costs that would be permitted as part of a reasonable, cost-based fee under this provision, we clarify that the final rule permits the same types of costs under this exception as the research exception, as well as costs that are in compliance with a fee schedule provided by State

law or otherwise expressly permitted by other applicable law. Thus, costs may include the direct and indirect costs to prepare and transmit the data, including labor, materials, and supplies, but not a profit margin. We intend to continue to work with interested stakeholders to develop more guidance on direct and indirect costs and on remuneration.

Response to Other Public Comments

Comment: Several commenters suggested that we make clear in the final rule that redisclosures of information by a recipient covered entity or business associate even for remuneration that are set forth in the original authorization are not restricted by this provision. Another commenter argued that the original authorization form should indicate whether the recipient of the protected health information will further exchange the information for remuneration.

Response: It is expected to be the usual case that if a covered entity or business associate that receives protected health information in exchange for remuneration wishes to further disclose that information in exchange for remuneration, then an additional authorization in accordance with § 164.508 must be obtained because such disclosures will not be encompassed by the original authorization. However, it may be possible that redisclosures of information for remuneration by a recipient covered entity or business associate do not require an additional authorization, provided it is sufficiently clear to the individual in the original authorization that the recipient covered entity or business associate will further disclose the individual's protected health information in exchange for remuneration. In response to the commenter that argued that the original authorization form should indicate whether the recipient of the protected health information will further exchange the information for remuneration, as explained above we believe the language included in Section 13405 of the HITECH Act was to alert the individual as to whether the disclosures he or she was authorizing at the time involved remuneration. Where the recipient of protected health information pursuant to an authorization is a third party that is not a covered entity or business associate, we do not have authority to require that entity to disclose to the disclosing covered entity or business associate whether it plans to further exchange the protected health information for remuneration for purposes of including such information on the authorization form. However, covered entities that are informed of such information may include it on the authorization form if they wish to. In any event, the Privacy Rule retains the requirement that an authorization inform the individual of the potential for information disclosed pursuant to the authorization to be subject to redisclosure by the recipient and to no longer be subject to the Privacy Rule.

Comment: Several commenters asked for clarification on the effect the final rule will have on existing research efforts and some suggested that HHS should grandfather in all Privacy Rule authorizations for research obtained under existing law before the effective date of the final rule. These commenters believed addressing current research would be necessary to ensure the rule would not frustrate ongoing research efforts.

Response: We agree that ongoing research studies that are based on a prior permission under the Privacy Rule for the research use or disclosure of protected health information should be grandfathered so as not to disrupt these ongoing studies. We have added a reference to the authorization requirements that apply to the sale of protected health information at § 164.508(a)(4) to make clear that the transition provisions in § 164.532 apply to permissions existing prior to the applicable compliance date of the Rule. Thus, a covered entity may continue to rely on an authorization obtained from an individual prior to the compliance date even if remuneration is involved but the authorization does not indicate that the disclosure is in exchange for remuneration. This would apply to authorizations for any permissible purpose under the Rule and not just for research purposes. Further, in the research context, where a covered entity obtained documentation of a waiver of authorization from an Institutional Review Board or Privacy Board prior to the compliance date for this final rule, the covered entity may continue to rely on that documentation to release protected health information to a researcher, even if the covered entity receives remuneration in the form of more than a reasonable, cost based fee to prepare and transmit the data. Finally, we also provide at new § 164.532(f) that a covered entity may continue to use or disclose a limited data set in accordance with an existing data use agreement that meets the requirements of § 164.514(e), including for research purposes, until the data use agreement is renewed or modified or until one year from the compliance date of this final rule, whichever is earlier, even if such disclosure would otherwise constitute a sale of protected health information upon the effective date of this rule.

Comment: Some commenters were concerned that the sale prohibition would apply to a covered entity's sale of accounts receivable including protected health information to a collection agency, arguing that such disclosures should remain permissible without authorization as a payment disclosure.

Response: Disclosures of protected health information for payment collection activities are permitted without authorization as a payment disclosure under the Privacy Rule (see §§ 164.501 and 164.506(a)) and thus, are excepted from the remuneration prohibition at § 164.502(a)(5)(ii)(B)(*2*)(*iii*).

Comment: A few commenters asked that the final rule clarify that transfers of value among entities under common control does not implicate the authorization requirements. Similarly, some commenters sought clarification on whether business transfers on the books for internal reorganization would also be excluded under the transfer, merger, and consolidation exception to the final rule.

Response: First, we clarify that uses of protected health information within a covered entity that is a single legal entity are not implicated by the remuneration prohibition as the prohibition applies only to disclosures outside of a covered entity. Second, the use of protected health information among legally separate covered entities under common ownership or control that have designated themselves as an affiliated covered entity (i.e., a single covered entity for purposes of compliance with the HIPAA Rules) is not implicated. See the requirements for affiliated covered entities at § 164.105(b). Thus, to the extent that what the commenters contemplate is an otherwise permissible use of protected health information within a single legal entity that is a covered entity or an affiliated covered entity, such use of data is not impacted by these provisions. Third, disclosures of protected health information for the sale, transfer, merger, or consolidation of all or part of a covered entity with another covered entity, or with an entity that following such activity will become a covered entity and due diligence related to such activity are excepted from the definition of sale of protected health information at § 164.502(a)(5)(ii)(B)(*2*)(*iv*).

Comment: Some commenters expressed concern over the role the

Institutional Review Board will play in determining reasonable costs, and several commenters asked that the final rule clarify that the Institutional Review Board is not responsible for making a determination regarding the permissibility of the fees paid in exchange for a disclosure of protected health information for research purposes.

Response: We clarify that a covered entity, or business associate if applicable, is responsible for determining whether any fees paid to the entity in exchange for protected health information covers the covered entity's or business associate's costs to prepare and transmit protected health information for research.

Comment: A few commenters sought clarification on how to differentiate access to protected health information from access to statistical data, particularly when remuneration is provided for access to a database but the party is solely interested in a population study, not an individual's protected health information.

Response: Disclosures of health information that has been de-identified in accordance with the Privacy Rule at § 164.514(b)–(d) are not subject to the remuneration prohibition as such information is not protected health information under the Rule. However, a covered entity that allows a third party access to a database containing protected health information in exchange for remuneration is subject to these provisions unless an exception applies (e.g., the remuneration received is limited to a reasonable, cost-based fee to prepare and make available the data).

Comment: A number of commenters argued that limited data sets should be exempted entirely from the remuneration prohibition because they are not fully identifiable data sets and are subject to protections under data use agreements.

Response: We decline to completely exempt limited data sets from these provisions as, unlike de-identified data, they are still protected health information. However, disclosures of limited data sets for purposes permitted under the Rule would be exempt from the authorization requirements to the extent the only remuneration received in exchange for the data is a reasonable, cost-based fee to prepare and transmit the data or a fee otherwise expressly permitted by other law. We also provide at new § 164.532(f) that a covered entity may continue to use or disclose a limited data set in accordance with an existing data use agreement that meets the requirements of § 164.514(e), including for research purposes, until the data use agreement is renewed or modified or until one year from the compliance date of this final rule, whichever is earlier, even if such disclosure would otherwise constitute a sale of protected health information upon the effective date of this rule.

b. Research

i. Compound Authorizations

Proposed Rule

Section 164.508(b)(4) of the Privacy Rule prohibits covered entities from conditioning treatment, payment, enrollment in a health plan, or eligibility for benefits on the provision of an authorization. This limitation is intended to ensure that authorization from an individual for a use or disclosure of protected health information is voluntarily provided. However, there are exceptions to this general rule for certain circumstances, including in the research context, where a covered entity may condition the provision of research-related treatment, such as in a clinical trial, on obtaining the individual's authorization for the use or disclosure of protected health information for such research. Permitting the use of protected health information is part of the decision to receive care through a clinical trial, and health care providers conducting such trials are able to condition research-related treatment on the individual's willingness to authorize the use or disclosure of protected health information for research associated with the trial.

Section 164.508(b)(3) generally prohibits what are termed ''compound authorizations,'' i.e., where an authorization for the use and disclosure of protected health information is combined with any other legal permission. However, § 164.508(b)(3)(i) carves out an exception to this general prohibition, permitting the combining of an authorization for a research study with any other written permission for the same study, including another authorization or informed consent to participate in the research. Nonetheless, § 164.508(b)(3)(iii) prohibits combining an authorization that conditions treatment, payment, enrollment in a health plan, or eligibility for benefits (conditioned authorization) with an authorization for another purpose for which treatment, payment, enrollment, or eligibility may not be conditioned (unconditioned authorization). This limitation on certain compound authorizations was intended to help ensure that individuals understand that they may decline the activity described in the unconditioned authorization yet still receive treatment or other benefits or services by agreeing to the conditioned authorization.

The impact of these authorization requirements and limitations can be seen during clinical trials that are associated with a corollary research activity, such as when protected health information is used or disclosed to create or to contribute to a central research database or repository. For example, § 164.508(b)(3)(iii) prohibits covered entities from obtaining a single authorization for the use or disclosure of protected health information for a research study that includes both treatment as part of a clinical trial and tissue banking of specimens (and associated protected health information) collected, since the individual generally must sign the authorization for the use of his or her protected health information in the clinical trial in order to receive the research-related treatment (conditioned authorization) but whether the individual also signs the tissue banking authorization is completely voluntary and will not affect the individual receiving the research-related treatment (unconditioned authorization). Thus, covered entities must obtain separate authorizations from research participants for a clinical trial that also collects specimens with associated protected health information for a central repository.

As stated in the NPRM, various groups, including researchers and professional organizations, have expressed concern at this lack of integration. A number of persons in the research community have stated that requiring separate forms for these corollary research activities is inconsistent with current practice under the Common Rule (45 CFR Part 46) with respect to obtaining informed consent and creates unnecessary documentation burdens. Persons have also indicated that the multiple authorization forms are potentially confusing to research subjects and/or may dissuade them altogether from participating in a clinical trial, and that redundant information on the forms diverts an individual's attention from other content that describes how and why the personal health information may be used. In light of these concerns, the Secretary's Advisory Committee on Human Research Protections in 2004 (Recommendation V, in a letter to the Secretary of HHS, available at *http://www.hhs.gov/ohrp/sachrp/hipaalettertosecy090104.html*), as well as the Institute of Medicine in its 2009 Report, ''Beyond the HIPAA Privacy Rule: Enhancing Privacy, Improving Health Through Research''

(Recommendation II.B.2), made specific recommendations to allow combined authorizations for clinical trials and biospecimen storage.

To address these concerns and streamline the process in the Privacy Rule for obtaining an individual's authorization for research, we proposed to amend § 164.508(b)(3)(i) and (iii) to allow a covered entity to combine conditioned and unconditioned authorizations for research, provided that the authorization clearly differentiates between the conditioned and unconditioned research components and clearly allows the individual the option to opt in to the unconditioned research activities. These provisions would allow covered entities to combine authorizations for the use and disclosure of protected health information for clinical trials and related biospecimen banking activities, as well as other scenarios that often occur in research studies.

While we did not propose to alter the core elements or required statements integral to a valid authorization, we stated that covered entities would have some flexibility with respect to how they met the authorization requirements. For example, covered entities could facilitate an individual's understanding of a compound authorization by describing the unconditioned research activity on a separate page of a compound authorization and could also cross-reference relevant sections of a compound authorization to minimize the potential for redundant language. In addition, a covered entity could use a separate check-box for the unconditioned research activity to signify whether an individual has opted-in to the unconditioned research activity, while maintaining one signature line for the authorization, or alternatively provide a distinct signature line for the unconditioned authorization to signal that the individual is authorizing optional research that will not affect research-related treatment. We requested comment on additional methods that would clearly differentiate to the individual the conditioned and unconditioned research activities on the compound authorization.

Overview of Public Comments

Almost all commenters on this topic strongly supported the proposal to allow combined authorizations for conditioned and unconditioned research activities. Many commenters supported allowing flexibility for institutions to determine how best to differentiate the unconditioned authorization for the voluntary research activity, including whether to use a check box with a single signature line, or separate signature lines. Several commenters suggested that an opt out method should be permitted as an alternative to an opt in approach.

A few commenters opposed the proposal to allow compound authorizations for conditioned and unconditioned research activities. These commenters generally felt that separate authorizations are appropriate and that there is not sufficient evidence to suggest that combining the forms will be beneficial to individuals.

The Secretary's Advisory Committee on Human Research Protections, in its letter of comment on the Department's NPRM, indicated its support for the proposal to permit compound authorizations for conditioned and unconditioned research activities, and expressed particular appreciation for the goal of harmonization with the Common Rule. The Secretary's Advisory Committee on Human Research Protections also supported flexibility in the manner that the conditioned and unconditioned research activities are differentiated. The Secretary's Advisory Committee on Human Research Protections requested clarification that the compound authorizations permitted under this proposal would be permissible for any type of combined research studies, and not exclusively for clinical trials with a biospecimen banking component.

Final Rule

The final rule adopts the proposal to amend § 164.508(b)(3)(i) and (iii) to allow a covered entity to combine conditioned and unconditioned authorizations for research, provided that the authorization clearly differentiates between the conditioned and unconditioned research components and clearly allows the individual the option to opt in to the unconditioned research activities. We intend this provision to allow for the use of compound authorizations for any type of research activities, and not solely to clinical trials and biospecimen banking, except to the extent the research involves the use or disclosure of psychotherapy notes. For research that involves the use or disclosure of psychotherapy notes, an authorization for a use or disclosure of psychotherapy notes may only be combined with another authorization for a use or disclosure of psychotherapy notes. See § 164.508(b)(3)(ii). Thus, aside from the use of psychotherapy notes, combined authorizations could be obtained for the use of protected health information in a clinical trial and optional sub-studies, as well as for biospecimen banking that also permits future secondary use of the data (to the extent the future use authorization is aligned with the discussion in the following section regarding authorizations for future research). Also, this provision continues to allow for a covered entity to combine such authorizations with informed consent documents for the research studies.

The final rule provides covered entities, institutions, and Institutional Review Boards with flexibility to determine the best approach for clearly differentiating the conditioned and unconditioned research activities and giving research participants the option to opt in to the unconditioned research activities. We decline to permit a combined authorization that only allows the individual the option to opt out of the unconditioned research activities (e.g., ''check here if you do NOT want your data provided to the biospecimen bank'') because an opt out option does not provide individuals with a clear ability to authorize the optional research activity, and may be viewed as coercive by individuals. The final rule does not remove the requirement that an individual affirmatively authorize the unconditioned research activities; it merely provides flexibility to streamline the authorization process by combining the forms.

With respect to the commenters that believed there is insufficient evidence that combining conditioned and unconditioned research activities into a compound authorization would be beneficial, and that such compound authorizations may be confusing for patients, as indicated above, there have been anecdotal reports to the Department that the use of multiple authorization forms has caused confusion among research subjects. Further, we note that these modifications do not remove the required elements of an authorization that are necessary to inform the individual about the study (e.g., description of the information to be used or disclosed, description of the purpose, etc.); they merely introduce flexibility to avoid redundant language that would otherwise be necessary to include in the authorizations for the multiple research activities. In addition, these changes are intended to align the HIPAA Privacy Rule's authorization requirements with what has been common and ongoing practice in terms of the informed consent form under the Common Rule.

We note that covered entities are permitted but not required by the modifications adopted at

§ 164.508(b)(3)(i) and (iii) to create compound authorizations for conditioned and unconditioned research activities. Previously approved, ongoing studies may continue to rely on the separate authorization forms that were obtained under the prior provisions. For new studies, covered entities and researchers may continue to use separate authorizations for conditioned and unconditioned research activities, or may transition to compound authorizations as they deem appropriate, which can be used beginning on the effective date of this rule.

Response to Other Public Comments

Comment: The Secretary's Advisory Committee on Human Research Protections asked whether the following approaches for distinguishing between conditioned and unconditioned research activities would be acceptable: Using (1) a combined consent/authorization form for a clinical trial and optional banking component, with a check-box for the individual to have the choice to opt in to the optional banking component, and one signature; (2) a combined consent/authorization form for a clinical trial and optional banking component, with one signature for the clinical trial and another signature to indicate the individual agrees to the optional banking component; and (3) a combined consent/authorization form for a clinical trial and optional banking component, with a check box for the individual to have the choice to opt in to the banking component, and one signature, but with detailed information about the banking component presented in a separate brochure or information sheet that is referenced directly in the consent/authorization form.

Response: Covered entities and researchers have flexibility in the methods used to distinguish the conditioned and unconditioned research activities and to provide the individual with a clear opportunity to opt in to the unconditioned portion, and all of the above approaches would be acceptable provided, with respect to the third approach, that the brochure or information sheet is incorporated by reference into the authorization/consent form such that it is considered to be part of the form (even if not physically attached to the form). In addition, if the brochure or information sheet includes required elements of the authorization (or informed consent), and authorization/consent has not been altered by an Institutional Review Board, then the brochure or information sheet must be made available to potential research participants before they are asked to sign the authorization/consent document (unless the authorization form itself includes the required elements). Finally, in such cases, a covered entity must keep not only the signed authorization/consent form, but also a copy of the brochure or information sheet, in order to be in compliance with the documentation requirements at § 164.530(j).

Comment: The Secretary's Advisory Committee on Human Research Protections requested confirmation that the compound authorization proposal would not affect the waiver provisions currently existing in the Privacy Rule, such that such provisions could be used, if appropriate, for new studies distinct from both the original study and the banking activity.

Response: The new compound authorization provision does not affect the waiver of authorization provisions in the Privacy Rule. A covered entity may continue to use or disclose protected health information for research purposes based on documentation that meets the requirements at § 164.512(i), indicating that an Institutional Review Board or Privacy Board has waived the obtaining of individual authorization for such purposes, based on a determination that (1) the use or disclosure of protected health information involves no more than a minimal risk to the privacy of individuals; (2) the research could not practicably be conducted without the waiver; and (3) the research could not practicably be conducted without access to and use of the protected health information.

Comment: The Secretary's Advisory Committee on Human Research Protections requested clarification on the effect of revoking only one part of a compound authorization. For example, if an individual signs a combined authorization for conditioned and unconditioned research activities and later specifically revokes only the unconditioned research activity (e.g., the banking component), then the covered entity may continue to act in reliance on the authorization for the conditioned component (e.g., the clinical trial).

Response: Where it is clear that an individual is revoking only one part of a compound authorization, such revocation does not equate to a revocation of the entire authorization to include the other studies. However, where it is not clear exactly to which research activities the individual's revocation applies, written clarification must be obtained from the individual in order for the revocation to apply only to certain of the research activities identified in the authorization, or the entire authorization must be treated as revoked. Further, such revocations must be maintained and documented in a manner that will ensure uses and disclosures of protected health information for the activity to which the revocation applies discontinue, except to the extent the covered entity has already acted in reliance on the authorization, which would permit certain limited, continued use and disclosure, such as necessary to maintain the integrity of the research study.

ii. Authorizing Future Research Use or Disclosure

Prior Interpretation

Research often involves obtaining health information and biological specimens to create a research database or repository for future research. For example, this frequently occurs where clinical trials are paired with corollary research activities, such as the creation of a research database or repository where information and specimens obtained from a research participant during the trial are transferred and maintained for future research. It is our understanding that Institutional Review Boards in some cases may approve an informed consent document for a clinical trial that also asks research participants to permit future research on their identifiable information or specimens obtained during the course of the trial. It is also our understanding that an Institutional Review Board may in some cases review an informed consent for a prior clinical trial to determine whether a subsequent research use is encompassed within the original consent.

The Department has previously interpreted the Privacy Rule, however, to require that authorizations for research be study specific for purposes of complying with the Rule's requirement at § 164.508(c)(1)(iv) that an authorization must include a description of each purpose of the requested use or disclosure. See 67 FR 53182, 53226, Aug. 14, 2002. In part, the Department's interpretation was based on a concern that patients could lack necessary information in the authorization to make an informed decision about the future research. In addition, it was recognized that not all uses and disclosures of protected health information for a future research purpose would require a covered entity to re-contact the individual to obtain another authorization (e.g., uses or disclosures with a waiver of

authorization from an Institutional Review Board or Privacy Board as provided under § 164.512(i) or of a limited data set pursuant to a data use agreement under § 164.514(e) for the future research purpose).

Subsequent to issuing this interpretation, the Department heard concerns from covered entities and researchers that the Department's interpretation encumbers secondary research, and limits an individual's ability to agree to the use or disclosure of their protected health information for future research. In addition, many commenters noted that the Department's interpretation limiting the scope of a HIPAA authorization for research appeared to diverge from the current practice under the Common Rule with respect to the ability of a researcher to seek subjects' informed consent to future research so long as the future research uses are described in sufficient detail to allow an informed consent. These commenters, as well as the Secretary's Advisory Committee on Human Research Protections in 2004 (Recommendation IV, in a letter to the Secretary of HHS, available at *http://www.hhs.gov/ohrp/sachrp/hipaalettertosecy090104.html*) and the Institute of Medicine in its 2009 Report entitled ''Beyond the HIPAA Privacy Rule: Enhancing Privacy, Improving Health Through Research'' (Recommendation II.B.1), had urged the Department to allow the HIPAA authorization to permit future research use and disclosure of protected health information.

Given these concerns, the Department explained in the NPRM that it was considering a number of options regarding authorizations for future research, including whether the Privacy Rule should: permit an authorization for uses and disclosures of protected health information for future research purposes to the extent such purposes are adequately described in the authorization such that it would be reasonable for the individual to expect that his or her protected health information could be used or disclosed for such future research; or permit an authorization for future research but require certain specific elements or statements with respect to the future research, particularly where the future research may encompass certain types of sensitive research activities, such as research involving genetic analyses or mental health research, that may alter an individual's willingness to participate in the research. We requested comment on these options and on how a revocation would operate with respect to future downstream research studies.

Overview of Public Comments

Almost all commenters on this topic supported the proposal to allow authorizations for future research. Many commenters indicated this flexibility to be important, particularly considering evolving technologies and discoveries.

About half of these commenters specifically advocated for providing investigators and Institutional Review Boards with the maximum flexibility to determine the appropriateness of the descriptions for future research and felt that this would best align with the Common Rule. These commenters were thus against requiring specific statements in the Privacy Rule about the future research, including for sensitive research. Other commenters were in favor of requiring the additional statements about sensitive categories of research, stating that this would better inform individuals and give them greater choice in determining their willingness to participate in certain types of future research. A couple of these commenters recommended working with National Committee on Vital and Health Statistics on the categories of sensitive research, however no further examples of specific types of research were given beyond the examples provided in the proposed rule (genetic analyses or mental health research). Several commenters specifically advised against requiring specific statements for sensitive research, citing concerns of variability in what is considered sensitive information and practicality challenges due to the changing nature of the concept over time.

A few commenters opposed the proposal to allow authorizations for future research altogether. Some of these commenters felt strongly that study-specific authorizations are critical to protect patients, and are the only way that individuals can make a truly informed decision. These commenters suggested that outreach to patients and potential research participants to solicit feedback, as well as a study on the potential burdens that enhanced authorizations may have on stakeholders, were necessary before any changes were made.

In its comment letter on the NPRM, the Secretary's Advisory Committee on Human Research Protections supported the proposal to harmonize HIPAA authorizations with the Common Rule informed consent requirements, and also requested consultation with the FDA to ensure that authorizations for future research align not only with the Common Rule standards but also FDA standards for informed consent. They indicated that the authorization should be reasonably specific such that individuals are aware of the types of research that may be conducted. However, the Secretary's Advisory Committee on Human Research Protections emphasized the need for flexibility to rely on Institutional Review Board judgment and recommended against requiring prescribed statements about certain types of ''sensitive'' research, since these concepts change over time and requiring prescribed authorization statements may conflict with Institutional Review Boards' judgments about how to appropriately describe the research in the informed consent.

Modified Interpretation

We modify the prior Departmental interpretation that research authorizations must be study specific. This modification does not make any changes to the authorization requirements at § 164.508. A HIPAA authorization for future research must still address each of the core elements and statements required at § 164.508(c). However, the Department no longer interprets the ''purpose'' provision at § 164.508(c)(1)(iv) as requiring that an authorization for the use or disclosure of protected health information for research purposes be study specific. In order to satisfy the requirement that an authorization include a description of each purpose of the requested use or disclosure, an authorization for uses and disclosures of protected health information for future research purposes must adequately describe such purposes such that it would be reasonable for the individual to expect that his or her protected health information could be used or disclosed for such future research. This could include specific statements with respect to sensitive research to the extent such research is contemplated. However, we do not prescribe specific statements in the Rule. We agree that it is difficult to define what is sensitive and that this concept changes over time. We also agree with commenters that this approach best harmonizes with practice under the Common Rule regarding informed consent for future research, and allows covered entities, researchers and Institutional Review Boards to have flexibility in determining what adequately describes a future research purpose depending on the circumstances. We have consulted with Office for Human Research Protections (OHRP) and the FDA on this approach to ensure consistency and

harmonization with the HHS and FDA human subjects protections regulations, where appropriate.

With respect to commenters that stated it is impossible for individuals to be truly informed about future research, we note that we are aligning with existing practice under the Common Rule in regard to informed consent and still require that all required elements of authorization be included in an authorization for future research, even if they are to be described in a more general manner than is done for specific studies.

Pursuant to this modified interpretation, covered entities that wish to obtain individual authorization for the use or disclosure of protected health information for future research may do so at any time after the effective date of this final rule. Alternatively, covered entities may continue to use only study-specific authorizations for research if they choose.

Response to Other Public Comments

Comment: The Secretary's Advisory Committee on Human Research Protections requested flexibility regarding the description in the authorization of the information to be used or disclosed for future research as well as to whom the covered entity may make the requested use or disclosure as there may be some uncertainty of the identity of future researchers. The Secretary's Advisory Committee on Human Research Protections also suggested that the description of information to be collected be allowed to reference information beyond the time of the original study, for example ''your future medical records [at Hospital]'' or ''your future medical records [relating to diseases/conditions].''

Response: Covered entities and researchers have flexibility to describe the information to be used or disclosed for the future research, so long as it is reasonable from such description to believe that the individual would expect the information to be used or disclosed for the future research. We also clarify that a description of the protected health information to be used for the future research may include information collected beyond the time of the original study. Further, the Privacy Rule authorization requirements allow a ''class of persons'' to be described for purposes of identifying in the authorization the recipients of the protected health information. Thus, covered entities and researchers have flexibility in the manner in which they describe the recipients of the protected health information for the future research, so long as it is reasonable from such description to believe that the individual would expect his or her protected health information to be shared with such persons for the future research.

Comment: The Secretary's Advisory Committee on Human Research Protections requested that the Department allow for grandfathering of existing, ongoing studies that involve the possibility of future/secondary research, if an Institutional Review Board-approved consent reasonably informed the individuals of the future research. In these situations, researchers would have needed to obtain a study-specific authorization or waiver of authorization before commencing the future/secondary research that was encompassed in the original informed consent.

Response: Covered entities and researchers may rely on an Institutional Review Board-approved consent obtained prior to the effective date of this final rule that reasonably informed individuals of the future research, provided the informed consent was combined with a HIPAA authorization (even though the authorization itself was specific to the original study or creation and maintenance of a repository).

Comment: One commenter advocated for the use of time-limited authorizations for future research.

Response: This modification in Departmental interpretation does not change the requirement at § 164.508(c)(1)(v), which states that an authorization must contain an expiration date or an expiration event that relates to the individual or the purpose of the use or disclosure. This statement may be a specific time limit, or be ''end of the research study,'' ''none,'' or similar language for a research study.

Comment: Several commenters suggested that revocation of authorizations should continue to be permitted in the same manner that it is currently allowed under the Privacy Rule. The Secretary's Advisory Committee on Human Research Protections recommended that revocations of authorization for future research be permitted orally, rather than in writing, as is currently required for all authorizations under §§ 164.508(b)(5) and (c)(2)(i) of the Rule.

Response: Covered entities may continue to rely on existing guidance regarding how revocations of authorizations operate in the research context. Such guidance is published in several materials available at *http://www.hhs.gov/ocr/privacy/hipaa/understanding/special/research/index.html* (see, e.g., the fact sheet entitled, ''Health Services Research and the HIPAA Privacy Rule''). The Department may issue additional guidance in the future with respect to revocation policies in the context of authorizations that specify, and under which protected health information has been disclosed for, future research uses.

In response to the Secretary's Advisory Committee on Human Research Protections recommendation, we also clarify that while the Privacy Rule requires that a revocation of authorization from an individual be in writing, uses and disclosures pursuant to an authorization are permissive and not required, and thus, a covered entity may cease using or disclosing protected health information pursuant to an authorization based on an individual's oral request if it chooses to do so.

5. Protected Health Information About Decedents

a. Section 164.502(f)—Period of Protection for Decedent Information

Proposed Rule

Section 164.502(f) requires covered entities to protect the privacy of a decedent's protected health information generally in the same manner and to the same extent that is required for the protected health information of living individuals. Thus, if an authorization is required for a particular use or disclosure of protected health information, a covered entity may use or disclose a decedent's protected health information in that situation only if the covered entity obtains an authorization from the decedent's personal representative. The personal representative for a decedent is the executor, administrator, or other person who has authority under applicable law to act on behalf of the decedent or the decedent's estate. The Department heard a number of concerns since the publication of the Privacy Rule that it can be difficult to locate a personal representative to authorize the use or disclosure of the decedent's protected health information, particularly after an estate is closed. Furthermore, archivists, biographers, and historians had expressed frustration regarding the lack of access to ancient or old records of historical value held by covered entities, even when there are likely few surviving individuals concerned with the privacy of such information. Archives and libraries may hold medical records, as well as correspondence files, physician diaries and casebooks, and photograph collections containing fragments of

identifiable health information, that are centuries old. Currently, to the extent such information is maintained by a covered entity, it is subject to the Privacy Rule.

Accordingly, we proposed to amend § 164.502(f) to require a covered entity to comply with the requirements of the Privacy Rule with regard to the protected health information of a deceased individual for a period of 50 years following the date of death. We also proposed to modify the definition of ''protected health information'' at § 160.103 to make clear that the individually identifiable health information of a person who has been deceased for more than 50 years is not protected health information under the Privacy Rule. We proposed 50 years to balance the privacy interests of living relatives or other affected individuals with a relationship to the decedent, with the difficulty of obtaining authorizations from personal representatives as time passes. A 50-year period of protection had also been suggested at a National Committee for Vital and Health Statistics (the public advisory committee which advises the Secretary on the implementation of the Administrative Simplification provisions of HIPAA, among other issues) meeting, at which committee members heard testimony from archivists regarding the problems associated with applying the Privacy Rule to very old records. See *http://ncvhs.hhs.gov/050111mn.htm*. We requested public comment on the appropriateness of this time period.

Overview of Public Comments

The majority of public comment on this proposal was in favor of limiting the period of protection for decedent health information to 50 years past the date of death. Some of these commenters specifically cited the potential benefits to research. A few commenters stated that the 50-year period was too long and should be shortened to, for example, 25 years. Some supporters of limiting privacy protection for decedent information indicated that the date of death is often difficult to determine, and thus suggested an alternative time period (e.g., 75, 100, 120, 125 years) starting from the last date in the medical record, if the date of death is unknown.

Some commenters were opposed to limiting the period of protection for decedent health information due to the continued privacy interests of living relatives as well as the decedent, particularly when highly sensitive information is involved, including HIV/AIDS status, or psychiatric or substance abuse treatment. A couple of commenters recommended that there should be no time limit on the protection of psychotherapy notes. One commenter expressed concern that this modification may encourage covered entities to retain records that they would not have otherwise in order to profit from the data after the 50-year period. One commenter suggested that the period of protection should be extended to 100 years, if protections are to be limited at all. A few commenters were opposed to the 50-year period of protection because they interpreted this provision to be a proposed record retention requirement.

Final Rule

After considering the public comments, the final rule adopts the proposal. We believe 50 years is an appropriate period of protection for decedent health information, taking into account the remaining privacy interests of living individuals after the span of approximately two generations have passed, and the difficulty of obtaining authorizations from a personal representative of a decedent as the same amount of time passes. For the same reason, we decline to shorten the period of protection as suggested by some commenters or to adopt a 100-year period of protection for decedent information. We also believe the 50-year period of protection to be long enough so as not to provide an incentive for covered entities to change their record retention policies in order to profit from the data about a decedent once 50 years has elapsed.

With respect to commenters' concerns regarding protected health information about decedents that is sensitive, such as HIV/AIDS, substance abuse, or mental health information, or that involves psychotherapy notes, we emphasize that the 50-year period of protection for decedent health information under the Privacy Rule does not override or interfere with State or other laws that provide greater protection for such information, or the professional responsibilities of mental health or other providers. Covered entities may continue to provide privacy protections to decedent information beyond the 50-year period, and may be required to do so under other applicable laws or as part of their professional responsibility. Alternatively, covered entities may choose to destroy decedent information although other applicable law may prescribe or limit such destruction.

We also decline to limit protections under the Privacy Rule to a certain period beyond the last date in the medical record. While we appreciate the challenges that may be present in determining the date of death of an individual in cases in which it is not sufficiently clear from the age of the record whether the individual is deceased, we believe that this determination is necessary in closer cases to protect the individual, as well as living relatives and others, who may be affected by disclosure of the information. Further, as we stated in the NPRM, this modification has no impact on a covered entity's disclosures permitted under other provisions of the Privacy Rule. For example, a covered entity is permitted to disclose protected health information of decedents for research that is solely on the information of decedents in accordance with § 164.512(i)(1)(iii), without regard to how long the individual has been deceased.

Finally, we clarify that the 50-year period of protection is not a record retention requirement. The HIPAA Privacy Rule does not include medical record retention requirements and covered entities may destroy such records at the time permitted by State or other applicable law. (We note that covered entities are subject to the accounting requirements at § 164.528 and, thus, would need to retain or record certain information regarding their disclosures of protected health information.) However, if a covered entity does maintain decedent health information for longer than 50 years following the date of death of the individual, this information will no longer be subject to the Privacy Rule.

b. Section 164.510(b)—Disclosures About a Decedent to Family Members and Others Involved in Care

Proposed Rule

Section 164.510(b) describes how a covered entity may use or disclose protected health information to persons, such as family members or others, who are involved in an individual's care or payment related to the individual's health care. The Department had received a number of questions about the scope of the section, specifically with regard to disclosing protected health information when the individual who is the subject of the information was deceased. We had additionally heard concerns that family members, relatives, and others, many of whom may have had access to the health information of the deceased individual prior to death, have had difficulty obtaining access to such information after the death of the individual, because many do not qualify as a

''personal representative'' of the decedent under the Privacy Rule at § 164.502(g)(4).

As such, we proposed to amend § 164.510(b) to add a new paragraph (5), which would permit covered entities to disclose a decedent's information to family members and others who were involved in the care or payment for care of the decedent prior to death, unless doing so is inconsistent with any prior expressed preference of the individual that is known to the covered entity. We emphasized that these modifications would not change the authority of a decedent's personal representative with regard to the decedent's protected health information. Thus, a personal representative would continue to have a right to access the decedent's protected health information relevant to such personal representation, and have authority to authorize uses and disclosures of the decedent's protected health information that are not otherwise permitted or required by the Privacy Rule. We requested comment on any unintended consequences that this proposed disclosure provision might cause.

Overview of Public Comments

Most commenters supported the proposal to permit disclosures to family members and others involved in the care or payment for care of the decedent prior to death, unless doing so is inconsistent with any prior expressed preference of the individual that is known to the covered entity. These commenters felt that such permissive disclosures would help facilitate important and appropriate communications with family members and others who had been involved in the individual's care or payment for health care prior to the individual's death but who may not rise to the level of personal representative. Some commenters stated that the provision recognizes the legitimate interest that family members may have in a decedent's health information as it affects their own health care.

A few commenters opposed the proposal to expressly permit communications with family members and other persons who had been involved with the individual's care or payment for care prior to death. Two commenters felt it would be a large burden on covered entities to determine the legitimacy of a requestor as a family member or individual involved in the care or payment for care. One commenter questioned the need for family members to have access to decedent health information and the likelihood of anyone other than the personal representative to have been meaningfully involved in the care or payment for care of the decedent.

Final Rule

The final rule adopts the proposal to amend § 164.510(b) to permit covered entities to disclose a decedent's protected health information to family members and others who were involved in the care or payment for care of the decedent prior to death, unless doing so is inconsistent with any prior expressed preference of the individual that is known to the covered entity.

In response to commenters who opposed this provision, we believe the provision strikes the appropriate balance in allowing communications with family members and other persons who were involved in the individual's care or payment for care prior to death, unless doing so is inconsistent with the prior expressed wishes of the individual. This will ensure family members and others can find out about the circumstances surrounding the death of their loved ones, unless the individual prior to his or her death objected to the covered entity making such communications. Further, the Privacy Rule limits such disclosures, similar to the other disclosures permitted under § 164.510(b), to the protected health information relevant to the family member or other person's involvement in the individual's health care or payment for health care. For example, a covered health care provider could describe the circumstances that led to an individual's passing with the decedent's sister who is asking about her sibling's death. In addition, a covered health care provider could disclose billing information to a family member of a decedent who is assisting with wrapping up the decedent's estate. However, in both of these cases, the provider generally should not share information about past, unrelated medical problems. Finally, these disclosures are permitted and not required, and thus, a covered entity that questions the relationship of the person to the decedent or otherwise believes, based on the circumstances, that disclosure of the decedent's protected health information would not be appropriate, is not required to make the disclosure.

Response to Other Public Comments

Comment: Commenters requested guidance on what it means for a person to have been ''involved in the care'' of the decedent prior to death. One commenter suggested including language in the final rule that would put the burden of proof of ''involvement in the individual's care'' on the requestor and not the covered entity, and would hold the covered entity harmless when disclosing decedent information in good faith in accordance with this new permission.

Response: We interpret this phrase in the same manner as we have with respect to disclosures of protected health information of living individuals under § 164.510(b). See the Department's existing guidance at *http://www.hhs.gov/ocr/privacy/hipaa/understanding/coveredentities/provider_ffg.pdf*. Subject to the specified conditions, disclosures may be made under this provision to family members, as well as to other persons provided the covered entity has reasonable assurance the individual prior to death was involved in the individual's care or payment for care. Depending on the circumstances, this could include disclosures to spouses, parents, children, domestic partners, other relatives, or friends of a decedent. As with similar disclosures concerning living individuals under § 164.510(b)(1)(i), this provision does not generally apply to disclosures to health care providers, health plans, public health authorities, law enforcement officials, and others whose access to protected health information is governed by other provisions of the Privacy Rule.

We decline to include language in the final rule placing the burden of proof on the requestor to demonstrate they were involved in the individual's care. In some cases, it will be readily apparent to the covered entity that a person is a family member or was involved in the individual's care prior to death because the person would have made themselves known to the covered entity prior to the individual's death by either visiting with or inquiring about the individual, or the individual would have identified such person as being involved in their care or payment for care to a member of the covered entity's workforce. In other cases, the covered entity need just have reasonable assurance that the person is a family member of the decedent or other person who was involved in the individual's care or payment for care prior to death. For example, the person may indicate to the covered entity how he or she is related to the decedent or offer sufficient details about the decedent's circumstances prior to death to indicate involvement in the decedent's care prior to death. As stated above, a covered entity that is uncomfortable disclosing protected health information under this provision because of questions about the person's

relationship to the decedent is not required to do so.

Comment: Several commenters requested and offered suggested clarifications on the scope of the terms ''personal representative'' and ''family member.''

Response: The Privacy Rule already identifies the persons who qualify as a personal representative of a decedent at § 164.502(g)(4). Further, this final rule includes a definition of ''family member'' at § 160.103.

Comment: A few commenters suggested extending this provision to allow disclosures to the decedent's health care ''proxy,'' ''medical power of attorney,'' ''power of attorney,'' and ''estate executor.''

Response: We decline to expand the provision as suggested. Under the Privacy Rule, a person with authority under applicable law to act on behalf of the decedent or the decedent's estate is the personal representative of the decedent. Thus, certain of these persons, such as the executor of the estate, already have a right of access to the decedent's protected health information. In cases where a person does not rise to the level of a personal representative, the final rule at § 164.510(b) permits, subject to any prior expressed preference of the individual, a covered entity to disclose relevant protected health information of the decedent to family members of the decedent or persons who otherwise were involved in the individual's care or payment for care prior to the individual's death, which may include persons who held a health care proxy for the individual or a medical power of attorney.

6. Section 164.512(b)—Disclosure of Student Immunizations to Schools

Proposed Rule

The Privacy Rule, at § 164.512(b), recognizes that covered entities must balance protecting the privacy of health information with sharing health information with those responsible for ensuring public health and safety, and permits covered entities to disclose the minimum necessary protected health information to public health authorities or other designated persons or entities without an authorization for public health purposes specified by the Rule.

Schools play an important role in preventing the spread of communicable diseases among students by ensuring that students entering classes have been immunized. Most States have ''school entry laws'' which prohibit a child from attending school unless the school has proof that the child has been appropriately immunized. Some States allow a child to enter school provisionally for a certain period of time while the school waits for the necessary immunization information. Typically, schools ensure compliance with those requirements by requesting the immunization records from parents (rather than directly from a health care provider). However, where a covered health care provider is requested to send the immunization records directly to a school, the Privacy Rule generally requires written authorization by the child's parent before a covered health care provider may do so.

Since the Privacy Rule went into effect, we had heard concerns that the requirement for covered entities to obtain authorization before disclosing student immunization information may make it more difficult for parents to provide, and for schools to obtain, the necessary immunization documentation for students, which may prevent students' admittance to school. The National Committee on Vital and Health Statistics submitted these concerns to the HHS Secretary and recommended that HHS regard disclosure of immunization records to schools to be a public health disclosure, thus eliminating the requirement for authorization. See *http://www.ncvhs.hhs.gov/04061712.html*. As such, we proposed to amend § 164.512(b)(1) by adding a new paragraph that permits covered entities to disclose proof of immunization to schools in States that have school entry or similar laws.[10] While written authorization that complies with § 164.508 would no longer have been required for disclosure of such information under the proposal, the covered entity would still have been required to obtain agreement, which may have been oral, from a parent, guardian or other person acting *in loco parentis* for the individual, or from the individual him- or herself, if the individual is an adult or emancipated minor. Because the proposed provision would have permitted a provider to accept a parent's oral agreement to disclose immunization results to a school—as opposed to a written agreement—the NPRM acknowledged a potential for a miscommunication and later objection by the parent. We, therefore, requested comment on whether the Privacy Rule should require that a provider document any oral agreement under this provision to help avoid such problems, or whether a requirement for written documentation would be overly cumbersome, on balance. We also requested comment on whether the rule should mandate that the disclosures go to a particular school official and if so, who that should be.

In addition, the Privacy Rule does not define the term ''school'' and the types of schools subject to the school entry laws may vary by State. For example, depending on the State, such laws may apply to public and private elementary or primary schools and secondary schools (kindergarten through 12th grade), as well as daycare and preschool facilities, and post-secondary institutions. Thus, we requested comment on the scope of the term ''school'' for the purposes of this section and whether we should include a specific definition of ''school'' within the regulation itself. In addition, we requested comment on the extent to which schools that may not be subject to these school entry laws but that may also require proof of immunization have experienced problems that would warrant their being included in this category of public health disclosures.

Overview of Public Comments

Most commenters were generally in favor of permitting covered entities to disclose student immunization records based on obtaining agreement, which may be oral, from a parent, guardian or other person acting *in loco parentis* for the individual, or from the individual himself or herself, if the individual is an adult or emancipated minor, rather than written authorization. Commenters supported the intent to facilitate the transmission of immunization records to ease the burden on parents, schools and covered entities, and to minimize the amount of school missed by students.

Some commenters opposed the proposal to require oral or written agreement, claiming that a new form of ''agreement'' would introduce unnecessary complexity and confusion, and would not help to reduce burden. These commenters asserted that covered entities would document the verbal agreements for their own liability purposes, even if not required by the Privacy Rule. In this manner, the documentation burden would still be

[10] We note that once a student's immunization records are obtained and maintained by an educational institution or agency to which the Family Educational Rights and Privacy Act (FERPA) applies, the records are protected by FERPA, rather than the HIPAA Privacy Rule. See paragraphs (2)(i) and (2)(ii) of the definition of ''protected health information'' at § 160.103, which exclude from coverage under the Privacy Rule student records protected by FERPA. In addition, for more information on the intersection of FERPA and HIPAA, readers are encouraged to consult the Joint HHS/ED Guidance on the Application of FERPA and HIPAA to Student Health Records, available at *http://www.hhs.gov/ocr/privacy/hipaa/understanding/coveredentities/hipaaferpajointguide.pdf*.

present. Some commenters recommended that instead of an oral agreement or authorization requirement, disclosure of immunization records to schools should be considered an exempt public health disclosure. A small minority of commenters felt that the current authorization system should be maintained as it is the best way to ensure patient safety and privacy while avoiding miscommunications and misunderstandings.

Commenters were divided on the issue of requiring written documentation of the agreement. Some commenters were in favor of documenting oral agreements, citing that the documentation would be less cumbersome than obtaining written authorizations while also helping to avoid miscommunications. On the other hand, some commenters felt that requiring written documentation would be burdensome and would eliminate the benefits introduced by permitting oral agreements. Some commenters also requested flexibility for covered entities to determine whether or not written documentation is appropriate and necessary for their purposes.

The majority of commenters requested that a designated recipient of the student immunization records not be defined, and that schools be allowed flexibility to identify the appropriate individual(s) that can act as the school official permitted to receive the records. Commenters indicated that while the disclosures would ideally be made to a nurse or licensed health professional at the school, such a health professional may not always be present. In such instances, it should be permissible that the immunization records be disclosed to another official designated by the school as a suitable representative. One commenter recommended that the school nurse be designated as the recipient and custodian of the records.

Most commenters recommended that the definition of ''school'' be interpreted broadly in order to best support public health efforts. Commenters provided suggestions on the types of schools that should be included, for example, K–12 schools, public and private schools, and post-secondary schools. Many commenters also suggested that daycare, preschool and nursery school facilities be encompassed in the definition of school. One commenter expressly recommended that child care facilities or day care programs not be included in the definition of school, despite acknowledging the need to protect the health of these children, due to the fact that many States have different laws for these settings and are separate from school systems. Two commenters suggested defining schools as being open to children up to age 18, since students become adults at age 18 and can authorize the disclosure of their own information. A few commenters suggested that the definition include all schools that require immunization documentation as a prerequisite to enrollment, not just those that are subject to State entry laws, in order to protect public health in all school settings, since the threat of un-immunized children exists regardless of State school entry laws. Additionally, some commenters recommended that the term ''school'' not be defined in the Privacy Rule due to the variation across States in the types of schools that are subject to the entry laws.

Final Rule

The final rule adopts the proposal to amend § 164.512(b)(1) by adding a new paragraph that permits a covered entity to disclose proof of immunization to a school where State or other law requires the school to have such information prior to admitting the student. While written authorization will no longer be required to permit this disclosure, covered entities will still be required to obtain agreement, which may be oral, from a parent, guardian or other person acting *in loco parentis* for the individual, or from the individual himself or herself, if the individual is an adult or emancipated minor. We believe that the option to provide oral agreement for the disclosure of student immunization records will relieve burden on parents, schools, and covered entities, and greatly facilitate the role that schools play in public health, while still giving parents the opportunity to consider whether to agree to the disclosure of this information.

The final rule additionally requires that covered entities document the agreement obtained under this provision. The final rule does not prescribe the nature of the documentation and does not require signature by the parent, allowing covered entities the flexibility to determine what is appropriate for their purposes. The documentation must only make clear that agreement was obtained as permitted under this provision. For example, if a parent or guardian submits a written or email request to a covered entity to disclose his or her child's immunization records to the child's school, a copy of the request would suffice as documentation of the agreement. Likewise, if a parent or guardian calls the covered entity and requests over the phone that his or her child's immunization records be disclosed to the child's school, a notation in the child's medical record or elsewhere of the phone call would suffice as documentation of the agreement. We emphasize that the agreement is not equivalent to a HIPAA-compliant authorization, and covered entities are not required to document a signature as part of this requirement. We disagree with comments that documentation would be as burdensome on covered entities as written authorization, since an authorization form contains many required statements and elements, including a signature by the appropriate individual, which are not required for the agreement and documentation contemplated here. Furthermore, we believe that documentation of oral agreements will help to prevent miscommunications and potential future objections by parents or individuals, and the concerns that covered entities may have regarding liability, penalty or other enforcement actions for disclosures made pursuant to an oral agreement.

Several commenters recommended that in lieu of an oral agreement, disclosure of immunization records to schools are presumed to be permitted, while giving individuals the option to opt out of this presumption or request a restriction to the disclosure. One commenter advocated for this public health exemption for disclosure of immunization records as being particularly critical for children who may be, for example, homeless, living with someone other than a parent or legal guardian, or living with a parent that does not speak English. We remove the written authorization requirement to help facilitate these disclosures with as much flexibility as possible. However, we do not intend this provision to change the current practice of parents, guardians, or other persons acting *in loco parentis* contacting a child's health care provider to request proof of immunization be sent to the child's school. Therefore, we still require active agreement from the appropriate individual, and a health care provider may not disclose immunization records to a school under this provision without such agreement. The agreement must be an affirmative assent or request by a parent, guardian, or other person acting *in loco parentis* (or by an adult individual or emancipated minor, if applicable) to the covered entity, which may be oral and over the phone, to allow the disclosure of the immunization records. A mere request by a school to a health care provider for the immunization records of a student would not be sufficient to permit disclosure under this provision (and

such a request by a school might also raise implications under other laws, such as FERPA).

We decline to include definitions of ''school official'' and ''school'' in the final rule. The motivation for this new permissive disclosure is to promote public health by reducing the burden associated with providing schools with student immunization records and we do not wish to create additional difficulties or confusion in doing so. We therefore agree with commenters that schools are best equipped to determine the appropriate individual to receive student immunization records at their location and will benefit from having this flexibility. We also agree with commenters that ''school'' should remain undefined in the Privacy Rule due to the variation across States in the types of schools that are subject to the entry laws. We believe that this will best align with State law and cause the least amount of confusion. We did not receive sufficient comment regarding the breadth of schools that are not subject to school entry laws or the burden that these institutions face to justify expanding this provision to allow disclosure of proof of immunization to such schools without an authorization.

Response to Other Public Comments

Comment: Several commenters raised concerns about the dynamic between the Privacy Rule requirements and State law requirements regarding immunization disclosures. Commenters indicated that some State laws require providers to directly share immunization records with schools and provide parents with the opportunity to opt out of this direct sharing. Commenters also indicated the use of State immunization registries in many States, to which schools are permitted direct access. One commenter suggested that the Privacy Rule permit State law to determine what is the minimum necessary for proof of immunization.

Response: We take this opportunity to clarify that the Privacy Rule at § 164.512(a) permits a covered entity to use or disclose protected health information to the extent that such use or disclosure is required by law and the use or disclosure complies with and is limited to the relevant requirements of such law. As such, the Privacy Rule does not prohibit immunization disclosures that are mandated by State law, nor does it require authorization for such disclosures. With regard to State laws that require covered entities to disclose immunization records to schools and allow parents to opt out, this is not in any way prohibited by the Privacy Rule. However, with regard to State laws that permit but do not require covered entities to disclose immunization records to schools, this does not meet the requirements of the provisions at § 164.512(a), and disclosures of immunization records are subject to the Privacy Rule agreement and documentation requirements described in this part. We also note that the Privacy Rule at § 164.512(b) permits a covered entity to disclose protected health information for public health activities. Disclosures of protected health information to State immunization registries are therefore permitted by the Privacy Rule and also do not require authorization. The Privacy Rule at § 164.514(d)(3)(iii)(A) provides that a covered entity, when making a permitted disclosure pursuant to § 164.512 to a public official, may determine, if such a determination is reasonable under the circumstances, that information requested by a public official is the minimum necessary information for the stated purpose, if the public official represents that the information requested is the minimum necessary for the stated purpose(s). Under this provision, a covered entity may rely on State law or a State official's determination of the minimum necessary information required for proof of immunization, unless such determination is unreasonable.

Comment: Commenters requested guidance on when and how often to obtain agreement for immunization disclosures.

Response: We anticipate that covered entities will obtain agreement for the disclosure of immunization records on a case-by-case basis as needed. For example, a parent may call and request that a covered entity provide his or her child's immunization records before the child begins elementary school, if required by State school entry laws. If that child moves to a different school and is unable to transfer their immunization records to the new school, the parent may need to request that the covered entity provide his or her child's immunization records to the new school, if required by State school entry laws. A parent might also generally indicate to a covered entity that he or she affirmatively agrees to the immediate or future disclosure of his or her child's immunization records to the child's school as necessary, or the continued disclosure of such information if, for example, updates are required by the school when a series of vaccinations have been completed.

Comment: Commenters requested clarification on the length of time an agreement may be relied upon.

Response: An agreement to permit the disclosure of immunization records is considered effective until revoked by the parent, guardian or other person acting *in loco parentis* for the individual, or by the individual himself or herself, if the individual is an adult or emancipated minor.

Comment: Commenters requested clarification regarding any requirement for schools to maintain the immunization records.

Response: The Privacy Rule does not require schools to keep student immunization records; however individual State or other laws may require this.

7. Section 164.514(f)—Fundraising

Proposed Rule

Section 164.514(f)(1) of the Privacy Rule permits a covered entity to use, or disclose to a business associate or an institutionally related foundation, the following protected health information about an individual for the covered entity's fundraising from that individual without the individual's authorization: (1) Demographic information relating to an individual; and (2) the dates of health care provided to an individual. Section 164.514(f)(2) of the Privacy Rule requires a covered entity that plans to use or disclose protected health information for fundraising under this paragraph to inform individuals in its notice of privacy practices that it may contact them to raise funds for the covered entity. In addition, § 164.514(f)(2) requires that a covered entity include in any fundraising materials it sends to an individual a description of how the individual may opt out of receiving future fundraising communications and that a covered entity must make reasonable efforts to ensure that individuals who do opt out are not sent future fundraising communications.

Section 13406(b) of the HITECH Act requires the Secretary to provide by rule that a covered entity provide the recipient of any fundraising communication with a clear and conspicuous opportunity to opt out of receiving any further fundraising communications. Additionally, section 13406(b) states that if an individual does opt out of receiving further fundraising communications, the individual's choice to opt out must be treated as a revocation of authorization under § 164.508 of the Privacy Rule.

In the NPRM, we proposed a number of changes to the Privacy Rule's fundraising requirements to implement the statutory provisions. First, we proposed to strengthen the opt out by

requiring that a covered entity provide, with each fundraising communication sent to an individual under these provisions, a clear and conspicuous opportunity for the individual to elect not to receive further fundraising communications. To satisfy this requirement, we also proposed to require that the method for an individual to elect not to receive further fundraising communications may not cause the individual to incur an undue burden or more than nominal cost. We encouraged covered entities to consider the use of a toll-free phone number, an email address, or similar opt out mechanism that would provide individuals with a simple, quick, and inexpensive way to opt out of receiving future communications. We noted that we considered requiring individuals to write a letter to opt out to constitute an undue burden on the individual.

We also proposed to provide that a covered entity may not condition treatment or payment on an individual's choice with respect to receiving fundraising communications. We believed this modification would implement the language in section 13406(b) of the HITECH Act that provides that an election by an individual not to receive further fundraising communications shall be treated as a revocation of authorization under the Privacy Rule.

Further, we proposed to provide that a covered entity may not send fundraising communications to an individual who has elected not to receive such communications. This would strengthen the current requirement at § 164.514(f)(2)(iii) that a covered entity make ''reasonable efforts'' to ensure that those individuals who have opted out of receiving fundraising communications are not sent such communications. The NPRM proposed stronger language to make clear the expectation that covered entities abide by an individual's decision not to receive fundraising communications, as well as to make the fundraising opt out operate more like a revocation of authorization, consistent with the statutory language and legislative history of section 13406(b) of the HITECH Act discussed above.

With respect to the operation of the opt out, we requested comment regarding to what fundraising communications the opt out should apply (i.e., should the opt out apply to all future fundraising communications or should and can the opt out be structured in a way to apply only to the particular fundraising campaign described in the letter). We also requested comment on whether the Rule should allow a similar method, short of the individual signing an authorization, by which an individual who has previously opted out can put his or her name back on an institution's fundraising list.

We proposed to retain the requirement that a covered entity that intends to contact the individual to raise funds under these provisions include a statement to that effect in its notice of privacy practices. However, we proposed that the required statement also inform individuals that they have a right to opt out of receiving such communications.

In addition to the above modifications, we requested public comment on the requirement at § 164.514(f)(1) which limits the information a covered entity may use or disclose for fundraising to demographic information about and dates of health care service provided to an individual. Since the promulgation of the Privacy Rule, we acknowledged that certain covered entities have raised concerns regarding this limitation, maintaining that the Privacy Rule's prohibition on the use or disclosure of certain treatment information without an authorization, such as the department of service where care was received and outcomes information, impedes their ability to raise funds from often willing and grateful patients because they are unable to target their fundraising efforts and avoid inappropriate solicitations to individuals who may have had a bad treatment outcome. Such entities have argued that obtaining an individual's authorization for fundraising as the individual enters or leaves the hospital for treatment is often impracticable or inappropriate. The proposed rule also discussed the fact that the National Committee on Vital and Health Statistics held a hearing and heard public testimony on this issue in July 2004 and recommended to the Secretary that the Privacy Rule should allow covered entities to use or disclose information related to the patient's department of service (broad designations, such as surgery or oncology, but not narrower designations or information relating to diagnosis or treating physician) for fundraising activities without patient authorization. The National Committee on Vital and Health Statistics also recommended that a covered entity's notice of privacy practices inform patients that their department of service information may be used in fundraising, and that patients should be afforded the opportunity to opt out of the use of their department of service information for fundraising or all fundraising contacts altogether. See *http://www.ncvhs.hhs.gov/040902lt1.htm*.

In light of these concerns and the prior recommendation of the National Committee on Vital and Health Statistics, we asked for public comment on whether and how the current restriction on what information may be used and disclosed should be modified to allow covered entities to more effectively target fundraising and avoid inappropriate solicitations to individuals, as well as to reduce the need to send solicitations to all patients. In particular, we solicited comment on: (1) Whether the Privacy Rule should allow additional categories of protected health information to be used or disclosed for fundraising, such as department of service or similar information, and if so, what those categories should be; (2) the adequacy of the minimum necessary standard to appropriately limit the amount of protected health information that may be used or disclosed for fundraising purposes; or (3) whether the current limitation should remain unchanged. We also solicited comment on whether, if additional information is permitted to be used or disclosed for fundraising absent an authorization, covered entities should be required to provide individuals with an opportunity to opt out of receiving any fundraising communications before making the first fundraising solicitation, in addition to the opportunity to opt out with every subsequent communication. We invited public comment on whether such a pre-solicitation opt out would be workable for covered entities and individuals and what mechanisms could be put into place to implement the requirement.

Overview of Public Comments

In general, the public comments received in response to the NPRM were supportive of the proposed modifications but many asked that the final rule give covered entities flexibility with respect to operationalizing these requirements. Several commenters provided examples of routine communications and expressed the need for guidance and clarification about what constitutes a fundraising communication.

Generally, most commenters supported the NPRM's proposed requirement that the method through which the covered entity permits individuals to opt out of receiving future fundraising communications not cause individuals to incur an undue burden or more than a nominal cost. Many commenters stated that the final rule should give covered entities the flexibility to determine which opt out

methods will work best given their circumstances, instead of requiring all covered entities to employ specific opt out methods. These commenters noted that depending on the size of the covered entity and type of population it serves, certain opt out methods might not be feasible, such as one that requires the establishment of a toll-free number, which may be cost prohibitive for some small entities. Similarly, some commenters noted that because not all individuals have access to a computer and the Internet, providing individuals with the opportunity to opt out via email alone may not be sufficient.

With respect to the scope of the opt out, the commenters were generally split on whether the opt out should apply to communications related to a specific fundraising campaign or to all future fundraising communications. The commenters in support of applying the opt out to a specific fundraising campaign stated that it would be too difficult for individuals to make a meaningful decision about whether they wanted to opt out of all future fundraising communications, and allowing individuals to opt out of all futurefundraising communications would greatly hinder a covered entity's ability to raise funds. Those commenters in favor of implementing an all or nothing opt out stated that it would be too difficult for covered entities, especially large facilities, to track campaign-specific opt outs for each individual, so applying the opt out universally would make it much easier for covered entities to implement. Other commenters asked that the final rule take a flexible approach and permit covered entities to decide the scope of the opt out, while others stated that the final rule should require covered entities to include both opt out options on each fundraising communication leaving the decision to individuals.

Additionally, while most commenters supported the prohibition on conditioning treatment or payment on an individual's choice regarding the receipt of fundraising communications, most commenters opposed the NPRM's proposal that prohibited covered entities from sending future fundraising communications to those individuals who had opted out and stated that it was too strict. The majority of these commenters suggested that the final rule retain the Privacy Rule's original ''reasonable efforts'' language and stated that while covered entities have every incentive not to send fundraising communications to those individuals who have opted out of receiving them, it is very difficult for covered entities to ensure 100 percent accuracy with this policy. Several commenters stated that there are lag times between the period of time in which a fundraising mailing list is compiled and the time in which a fundraising communication is sent out, so if an individual has opted out during the interim time period, covered entities may not be able to prevent the prepared fundraising communication from being sent. Other commenters stated that it may be difficult to implement an opt out across all records belonging to that individual where complications, such as name changes and variation, address changes, and multiple addresses are involved.

For those individuals who have opted out of receiving fundraising communications, commenters generally supported allowing those individuals to opt back in to receiving such communications. Some suggested that individuals be able to opt back in using the same methods they used to opt out, while others suggested that any communication indicating a willingness to resume receiving fundraising communications, such as making a donation to the covered entity, should function as an opt in. Other commenters suggested that the final rule limit the amount of time that an individual can opt out, such that after this period of time the individual automatically begins receiving fundraising communications again. A few commenters were opposed to permitting individuals to opt back in to receive fundraising communications, stating that this would be too costly and burdensome for covered entities to track.

With respect to the requests for public comments regarding the potential use or disclosure of additional protected health information to provide more targeted fundraising communications, the vast majority of commenters supported allowing the use or disclosure of additional protected health information for fundraising. These commenters stated that the use of additional protected health information would streamline their fundraising efforts and ensure that individuals were sent communications about campaigns that would be meaningful to their experiences. These commenters also stated that it would eliminate the concern of sending a communication to an individual or family that suffered a negative outcome. Commenters suggested several categories of protected health information that covered entities should be able to use to target their fundraising efforts, including department or site of service, generic area of treatment, department where last seen, outcome information, treating physician, diagnosis, whether the individual was a pediatric or adult patient, medical record number, Social Security number, or other unique identifier, and any other information that reflects the fact that the individual was served by the covered entity.

With respect to the minimum necessary standard, a few commenters supported its use to limit any additional categories of protected health information that can be used to target a covered entity's fundraising efforts. These commenters supported the use of the standard because of how familiar and comfortable most covered entities are at applying the minimum necessary standard. However, another commenter was opposed to the use of the minimum necessary standard, stating that it is not uniformly applied across covered entities.

Despite the general support for the use of additional protected health information, a small minority of commenters opposed allowing the use of additional protected health information to target fundraising efforts, citing privacy concerns with doing so. One commenter opposed expanding the information that could be used for fundraising in cases where outside fundraising entities are used, including those with whom the covered entity has executed business associate agreements.

All commenters were opposed to requiring covered entities to provide a pre-solicitation opt out to individuals and stated that permitting individuals to opt out in the first fundraising communication is sufficient. Several commenters noted that the proposed revision to the notice of privacy practices to require a covered entity to inform individuals of their right to opt out of receiving fundraising communications effectively functions as a pre-solicitation opt out, so individuals who wish to opt out of receiving such communications immediately can do so upon receipt of the notice.

Final Rule

We generally adopt the proposals in the final rule, as well as allow certain additional types of protected health information to be used or disclosed for fundraising purposes.

With respect to the commenters who expressed confusion over what constitutes a fundraising communication, we emphasize that the final rule does nothing to modify the types of communications that are currently considered to be for fundraising purposes. A communication to an individual that is made by a covered entity, an institutionally related foundation, or a business associate on behalf of the covered entity for the

purpose of raising funds for the covered entity is a fundraising communication for purposes of § 164.514(f). The Department has stated that ''[p]ermissible fundraising activities include appeals for money, sponsorship of events, etc. They do not include royalties or remittances for the sale of products of third parties (except auctions, rummage sales, etc.).'' See 65 FR 82718. Additionally, the Privacy Rule has always required that such communications contain a description of how the individual may opt out of receiving further fundraising communications (§ 164.514(f)(2)(ii)).

With respect to the proposed requirement that the method for an individual to elect not to receive further fundraising communications should not cause the individual to incur an undue burden or more than a nominal cost, we generally agree with the commenters who suggested that the final rule be flexible and not prescriptive. Under the final rule, covered entities are free to decide what methods individuals can use to opt out of receiving further fundraising communications, as long as the chosen methods do not impose an undue burden or more than a nominal cost on individuals. Covered entities should consider the use of a toll-free phone number, an email address, or similar opt out mechanisms that provide individuals with simple, quick, and inexpensive ways to opt out of receiving further fundraising communications. Covered entities may employ multiple opt out methods, allowing individuals to determine which opt out method is the simplest and most convenient for them, or a single method that is reasonably accessible to all individuals wishing to opt out.

In response to commenters who expressed concern about the cost of setting up a toll-free phone number, we clarify that covered entities may require individuals who wish to opt out of further fundraising communications to do so through other methods, (e.g., through the use of a local phone number), where appropriate, as long as the method or methods adopted do not impose an undue burden or cost on the individual. We encourage covered entities to consider the size of the population to which they are sending the communications, the geographic distribution, and any other factors that may help determine which opt out method(s) is most appropriate and least burdensome to individuals.

We continue to consider requiring individuals to write and send a letter to the covered entity asking not to receive further fundraising communications to constitute an undue burden. However, requiring that individuals opt out of further fundraising communications by simply mailing a pre-printed, pre-paid postcard would not constitute an undue burden under the final rule and is an appropriate alternative to the use of a phone number or email address.

Regarding the scope of the opt out, the commenters were split on whether the opt out should apply to all future fundraising communications or to a specific fundraising campaign. The final rule leaves the scope of the opt out to the discretion of covered entities. For those covered entities that expressed concern about the ability to track campaign-specific opt outs, they have the discretion to apply the opt out to all future fundraising communications. Likewise, those covered entities that prefer, and have the ability to track, campaign-specific opt outs are free to apply the opt out to specific fundraising campaigns only. Covered entities are also free to provide individuals with the choice of opting out of all future fundraising communications or just campaign-specific communications. Whatever method is employed, the communication should clearly inform individuals of their options and any consequences of electing to opt out of further fundraising communications.

Despite the commenters who did not support the strengthened language in the NPRM prohibiting covered entities from sending further fundraising communications to those individuals who have already opted out, the final rule adopts this provision without modification. While many commenters supported the current ''reasonable efforts'' standard and cited several reasons that may make it difficult to attain the proposed standard, we adopt the proposed standard because it is consistent with the statute and more protective of an individual's right to elect not to receive further fundraising communications. For example, some commenters cited lag times between the creation of mailing lists and the receipt or update of opt out lists and difficulty in accurately identifying individuals on the fundraising lists due to name changes or variations and multiple addresses. These issues are common to the management of the medical or billing records and effectuating revocations of authorization, requests for access, and other general communications between the entity and the individual. We expect the same care and attention to the handling of protected health information in fundraising communications as is necessary for the proper handling of this information in all other health care operations performed by the covered entity. Covered entities voluntarily choosing to send fundraising communications to individuals must have data management systems and processes in place to timely track and flag those individuals who have opted out of receiving fundraising communications to ensure that they are not sent additional fundraising communications.

The majority of commenters supported allowing a process for individuals who have opted out of receiving further fundraising communications to opt back in and the final rule at § 164.514(f)(2)(v) permits covered entities have one. Like the discretion given to covered entities regarding the methods through which an individual can opt out, the final rule gives covered entities the discretion to determine how individuals should be able to opt back in. For example, a covered entity could include as a part of a routine newsletter sent to all patients a phone number individuals can call to be put on a fundraising list.

While some commenters suggested that opt outs should be time limited such that an individual automatically opts back in after a certain period of time, we do not believe that an individual's election not to receive further fundraising communications is something that should automatically lapse. Because the individual has actively chosen to opt out, only a similar active decision by the individual to opt back in will suffice. Additionally, where an individual who has opted out of fundraising communications makes a donation to a covered entity, it does not serve, absent a separate election to opt back in, to automatically add the individual back onto the mailing list for fundraising communications.

The Privacy Rule currently permits covered entities to use or disclose only demographic information relating to the individual and dates of health care provided to the individual for fundraising communications. In response to several commenters who asked for clarification regarding the scope of demographic information, the final rule, at § 164.514(f)(1)(i), clarifies that demographic information relating to an individual includes names, addresses, other contact information, age, gender, and dates of birth. Although much of this information was listed in the preamble to the 2000 final rule (65 FR 82718) as being demographic information with respect to the fundraising provisions, we have added this information to the regulatory text for clarity. Additionally, we have included date of birth as demographic information, instead of merely age. We

believe that date of birth may be useful to covered entities because they are more likely to maintain a record of an individual's date of birth, rather than his or her static age. We also note that the 2000 preamble identifies insurance status as falling within the category of demographic information. The final rule continues to allow covered entities to use or disclose information about an individual's health insurance status for fundraising purposes; however, we list this category of information separately in the regulatory text, as we do not believe this information truly constitutes demographic information.

In addition to demographic information, health insurance status, and dates of health care provided to the individual (which is currently permitted under the Rule), this final rule also allows covered entities to use and disclose department of service information, treating physician information, and outcome information for fundraising purposes. These three categories of information were most frequently identified by commenters as the most needed for covered entities to further target fundraising communications to appropriate individuals. Although we do not define these terms, we clarify that department of service information includes information about the general department of treatment, such as cardiology, oncology, or pediatrics. Additionally, we clarify that outcome information includes information regarding the death of the patient or any sub-optimal result of treatment or services. In permitting its use for fundraising purposes, we intend for it to be used by the covered entity itself to screen and eliminate from fundraising solicitations those individuals experiencing a sub-optimum outcome, and for its disclosure to a business associate or institutionally related foundation only where such screening function is done by those parties. We also emphasize that as with any use or disclosure under the Privacy Rule, a covered entity must apply the minimum necessary standard at § 164.502(b) to ensure that only the minimum amount of protected health information necessary to accomplish the intended purpose is used or disclosed.

We adopt in the final rule the provision prohibiting the conditioning of treatment or payment on an individual's choice with respect to the receipt of fundraising communications. We also adopt at § 164.520(b)(1)(iii)(A) the requirement that the notice of privacy practices inform individuals that a covered entity may contact them to raise funds for the covered entity and an individual has a right to opt out of receiving such communications. The final rule does not require covered entities to send pre-solicitation opt outs to individuals prior to the first fundraising communication. We believe that because the individual will be on notice of the opportunity to opt out of receiving fundraising communications through the notice of privacy practices and the first fundraising communication itself will contain a clear and conspicuous opportunity to opt out, there is no need to require covered entities to incur the additional burden and cost of sending pre-solicitation opt outs.

Under the Privacy Rule fundraising communications can take many forms, including communications made over the phone. Despite the fact that the HITECH Act refers only to written fundraising communications, because the Privacy Rule applies to communications made over the phone, we believe it would be counterintuitive to apply the strengthened opt out requirement to only written fundraising communications. Therefore, like fundraising communications made in writing, covered entities that make fundraising communications over the phone must clearly inform individuals that they have a right to opt out of further solicitations. Accordingly, to make clear that the opt out requirement applies to fundraising solicitations made over the phone, the final rule provides that the opt out requirement applies to each fundraising communication ''made'' rather than ''sent'' to an individual.

We also emphasize that the notice and opt out requirements for fundraising communications apply only where the covered entity is using or disclosing protected health information to target the fundraising communication. If the covered entity does not use protected health information to send fundraising materials, then the notice and opt out requirements do not apply. For example, if a covered entity uses a public directory to mail fundraising communications to all residents in a particular geographic service area, the notice and opt out requirements are not applicable.

Response to Other Public Comments

Comment: A few commenters suggested that, to better protect an individual's privacy, particularly where sensitive health information may be used to target solicitations, the final rule should require an opt in process rather than an opt out process for consenting to fundraising communications.

Response: We decline to require an opt in process. The HITECH Act did not replace the right to opt out of fundraising communications with an opt in process. Further, we continue to believe that the opt out process, particularly as it has been strengthened by the HITECH Act and this final rule, provides individuals with appropriate control over the use of their information for these purposes.

Comment: One commenter asked that if an individual opts out of receiving further fundraising communications through a mailed communication, must the covered entity also remove the individual's name from the list through which the covered entity sends email fundraising communications, or must the individual opt out of receiving such email communications separately.

Response: A covered entity may choose to provide individuals with the opportunity to select their preferred method for receiving fundraising communications. If an individual elects to opt out of future fundraising communications, then the opt out is effective for all forms of fundraising communications. Thus, the individual must be removed from all such lists.

8. Section 164.520—Notice of Privacy Practices for Protected Health Information

Proposed Rule

Section 164.520 of the Privacy Rule sets out the requirements for most covered entities to have and distribute a notice of privacy practices (NPP). The NPP must describe the uses and disclosures of protected health information a covered entity is permitted to make, the covered entity's legal duties and privacy practices with respect to protected health information, and the individual's rights concerning protected health information.

Section 164.520(b)(1)(ii) requires a covered entity to include separate statements about permitted uses and disclosures that the covered entity intends to make, including uses and disclosures for certain treatment, payment, or health care operations purposes. Further, § 164.520(b)(1)(ii)(E) currently requires that the NPP contain a statement that any uses and disclosures other than those permitted by the Privacy Rule will be made only with the written authorization of the individual, and that the individual has the right to revoke an authorization pursuant to § 164.508(b)(5).

We proposed to amend § 164.520(b)(1)(ii)(E) to require that the NPP describe the uses and disclosures of protected health information that

require an authorization under § 164.508(a)(2) through (a)(4) (i.e., including a statement that most uses and disclosures of psychotherapy notes and of protected health information for marketing purposes and the sale of protected health information require an authorization), and provide that other uses and disclosures not described in the notice will be made only with the individual's authorization.

Section 164.520(b)(1)(iii) requires a covered entity to include in its NPP separate statements about certain activities if the covered entity intends to engage in any of the activities. In particular, § 164.520(b)(1)(iii) requires a separate statement in the notice if the covered entity intends to contact the individual to provide appointment reminders or information about treatment alternatives or other health-related benefits or services; to contact the individual to fundraise for the covered entity; or, with respect to a group health plan, to disclose protected health information to the plan sponsor.

First, with respect to this provision, the NPRM proposed to modify § 164.520(b)(1)(iii)(A) to align the required statement with the proposed modifications related to marketing and subsidized treatment communications. The provision would have required a covered health care provider that intends to send treatment communications to individuals and has received financial remuneration in exchange for making the communication to, in its NPP, notify individuals of this intention and to inform them that they can opt out of receiving such communications. Second, at § 164.520(b)(1)(iii)(B) we proposed to require that if a covered entity intends to contact the individual to raise funds for the entity as permitted under § 164.514(f)(1), the covered entity must not only inform the individual in the NPP of this intention but also must inform the individual that he or she has the right to opt out of receiving such communications.

Section 164.520(b)(1)(iv) requires that the NPP contain statements regarding the rights of individuals with respect to their protected health information and a brief description of how individuals may exercise such rights. Section 164.520(b)(1)(iv)(A) currently requires a statement and a brief description addressing an individual's right to request restrictions on the uses and disclosures of protected health information pursuant to § 164.522(a), including the fact that the covered entity is not required to agree to this request.

The NPRM proposed to modify § 164.520(b)(1)(iv)(A) to require a statement explaining that the covered entity is required to agree to a request to restrict disclosure of protected health information to a health plan if the disclosure is for payment or health care operations and pertains to a health care item or service for which the individual has paid out of pocket in full, as provided at § 164.522(a)(1)(vi).

Under Subpart D of Part 164, covered entities now have new breach notification obligations. We requested comment on whether the Privacy Rule should require a specific statement regarding this new legal duty and what particular aspects of this new duty would be important for individuals to be notified of in the NPP.

The NPRM stated that modifications to § 164.520 would represent material changes to covered entities' NPPs. Section 164.520(b)(3) requires that when there is a material change to the NPP, covered entities must promptly revise and distribute the NPP as outlined at § 164.520(c). Section 164.520(c)(1)(i)(C) requires that health plans provide notice to individuals covered by the plan within 60 days of any material revision to the NPP. Because we acknowledged that revising and redistributing a NPP may be costly for health plans, we requested comment on ways to inform individuals of this change to privacy practices without unduly burdening health plans. We requested comment on options for informing individuals in a timely manner of this proposed or other material changes to the NPP. We also requested comment on this issue in the proposed changes to the Privacy Rule pursuant to the Genetic Information Nondiscrimination Act (GINA), as discussed below in Section VI. In particular, the Department requested comment on the following options: (1) Replace the 60-day requirement with a requirement for health plans to revise their NPPs and redistribute them (or at least notify members of the material change to the NPP and how to obtain the revised NPP) in their next annual mailing to members after a material revision to the NPP, such as at the beginning of the plan year or during the open enrollment period; (2) provide a specified delay or extension of the 60-day timeframe for health plans (3) retain the provision generally to require health plans to provide notice within 60 days of a material revision but provide that the Secretary will waive the 60-day timeframe in cases where the timing or substance of modifications to the Privacy Rule call for such a waiver; or (4) make no change and thus, require that health plans that perform underwriting provide notice to individuals within 60 days of the material change to the NPP that would be required by this proposed rule. The Department requested comment on these options, as well as any other options for informing individuals in a timely manner of material changes to the NPP.

Section 164.520(c)(2)(iv) requires that when a health care provider with a direct treatment relationship with an individual revises the NPP, the health care provider must make the NPP available upon request on or after the effective date of the revision and must comply with the requirements of § 164.520(c)(2)(iii) to have the NPP available at the delivery site and to post the notice in a clear and prominent location. We did not propose changes to these provisions because we did not believe these requirements to be overly burdensome but we requested comment on the issue.

Overview of Public Comments

We received several comments expressing support for the proposed requirement that the NPP include a statement about the uses and disclosures that require authorization. However, other commenters opposed this requirement, arguing that because not all uses and disclosures will apply to every individual, the statement will cause confusion and unnecessary concern. Additionally, these commenters argued that the cost of listing all of the situations requiring authorization would be significant.

We received several comments in support of the proposed requirement that the NPP include a specific statement about authorization for uses and disclosures of psychotherapy notes. Some of these commenters requested that the final rule require covered providers to describe in their NPPs their recordkeeping practices with regard to psychotherapy notes and how those practices affect what information can be used and disclosed. Several commenters argued that only covered entities that record psychotherapy notes should be required to include a statement about the authorization requirement for psychotherapy notes in their NPPs.

We also received several comments expressing concern regarding the proposed requirement to include information in the NPP about the individual's right to opt out of receiving certain communications. These commenters argued that information notifying individuals that they could opt out of receiving further subsidized treatment or fundraising communications would provide little

value to individuals at a significant cost to covered entities. These commenters felt that including this information would be unnecessary because all subsidized treatment and fundraising communications themselves will include an opt-out mechanism, and as such, including the information in the NPP may cause unnecessary concern for consumers.

We received one comment in support of the requirement to include in the NPP a statement about an individual's right to restrict certain uses and disclosures of protected health information if the individual pays for treatment or services out-of-pocket in full. We also received one comment suggesting that only health care providers should be required to include such a statement in their NPP.

We received a number of comments supporting a requirement to include a statement in the NPP about the right to be notified following a breach of unsecured protected health information. One commenter suggested that explaining breach notification requirements in the NPP would help entities handle customer service issues that arise when customers become upset upon receipt of such a breach notification. However, a number of other commenters expressed opposition to this proposal due to concern that such a statement would cause unnecessary concern and fear among individuals who may believe that covered entities cannot appropriately secure their protected health information. Finally, we received one comment requesting that HHS specify the required elements of a breach notification statement for a NPP.

We also received several comments arguing that the proposed changes should not constitute material changes to privacy practices requiring a new NPP, particularly where covered entities have already revised their NPPs to comply with the HITECH Act or State law requirements. Two additional commenters argued that each covered entity should determine whether a change is material or not, depending on its existing privacy practices.

We received a number of comments regarding the appropriate timing and manner for distributing new NPPs. The majority of the comments received generally fell into three categories: (1) Support for a requirement to revise and distribute notices within 60 days of a material change; (2) a recommendation for HHS to require that covered entities promptly post a revised NPP on their Web site in conjunction with a requirement to send a notice of the change by mail within a specified period; and (3) a request for HHS to extend the compliance deadline and permit the distribution of the revised NPP through a quarterly newsletter, annual mailing, after 18 months of transition, or in a triennial mailing. In addition, many commenters supported electronic distribution of an NPP or a notice of material changes to the NPP.

While not proposed, some commenters suggested eliminating or alternatives to the current requirements for health care providers with direct treatment relationships to hand the NPP to every individual patient and make a good faith attempt to obtain acknowledgement of receipt.

A few commenters also expressed concern regarding the cost burden associated with revising and distributing a new NPP. One commenter argued that considerations of cost do not justify a delay in distributing a revised NPP.

Final Rule

First, the final rule adopts the modification to § 164.520(b)(1)(ii)(E), which requires certain statements in the NPP regarding uses and disclosures that require authorization. We note that, contrary to some commenter concerns, the final rule does not require the NPP to include a list of all situations requiring authorization. Instead, the NPP must contain a statement indicating that most uses and disclosures of psychotherapy notes (where appropriate), uses and disclosures of protected health information for marketing purposes, and disclosures that constitute a sale of protected health information require authorization, as well as a statement that other uses and disclosures not described in the NPP will be made only with authorization from the individual.

The final rule does not require the NPP to include a description of a covered entity's recordkeeping practices with respect to psychotherapy notes; however, covered entities are free to include such additional information in their NPP if they choose. Additionally, in response to requests by some commenters, we clarify that covered entities that do not record or maintain psychotherapy notes are not required to include a statement in their NPPs about the authorization requirement for uses and disclosures of psychotherapy notes.

Second, because the final rule treats all subsidized treatment communications as marketing communications, we have not adopted the proposal to require a statement in the NPP about such communications and the ability of an individual to opt out. For further discussion on the decision to treat all subsidized treatment communications as marketing communications requiring an authorization, please see the above discussion regarding § 164.501.

The final rule, however, adopts the proposed requirement for a statement in the NPP regarding fundraising communications and an individual's right to opt out of receiving such communications, if a covered entity intends to contact an individual to raise funds for the covered entity. Because individuals will be provided the opportunity to opt out of fundraising communications with each solicitation, the final rule does not require the NPP to include the mechanism for individuals to opt out of receiving fundraising communications, although covered entities are free to include such information if they choose to do so.

The final rule also adopts the proposal that the NPP inform individuals of their new right to restrict certain disclosures of protected health information to a health plan where the individual pays out of pocket in full for the health care item or service. Only health care providers are required to include such a statement in the NPP; other covered entities may retain the existing language indicating that a covered entity is not required to agree to a requested restriction.

The final rule also requires covered entities to include in their NPP a statement of the right of affected individuals to be notified following a breach of unsecured protected health information. We believe that individuals should be informed of their right to receive and the obligations of covered entities to provide notification following a breach. We disagree with the commenters who argued that such a statement would cause individuals unnecessary concern and would create unfounded fear that covered entities cannot appropriately secure protected health information. Such advance notice of their rights should provide helpful context for individuals should they later receive a breach notification. In response to comments, we also clarify that a simple statement in the NPP that an individual has a right to or will receive notifications of breaches of his or her unsecured protected health information will suffice for purposes of this requirement. We do not intend for this requirement to add undue complexity or length to a covered entity's NPP. Thus, the statement need not be entity-specific, such as by describing how the covered entity will conduct a risk assessment, include the regulatory descriptions of ''breach'' or ''unsecured PHI,'' or describe the types

of information to be provided in the actual breach notification to the individual. However, covered entities that wish to include additional or more detailed information may do so.

These changes represent material changes to the NPP of covered entities. We disagree with the few commenters who argued that such modifications to § 164.520 do not constitute material changes of privacy practices requiring the distribution of new NPPs. The modifications to § 164.520 are significant and are important to ensure that individuals are aware of the HITECH Act changes that affect privacy protections and individual rights regarding protected health information.

Section 164.520(c)(1) of the final rule requires a health plan that currently posts its NPP on its Web site in accordance with § 164.520(c)(3)(i) to: (1) Prominently post the material change or its revised notice on its web site by the effective date of the material change to the notice (e.g., the compliance date of this final rule) and (2) provide the revised notice, or information about the material change and how to obtain the revised notice, in its next annual mailing to individuals then covered by the plan, such as at the beginning of the plan year or during the open enrollment period. Health plans that do not have customer service web sites are required to provide the revised NPP, or information about the material change and how to obtain the revised notice, to individuals covered by the plan within 60 days of the material revision to the notice. These requirements apply to all material changes including, where applicable, the rule change adopted pursuant to GINA to prohibit most health plans from using or disclosing genetic information for underwriting purposes.

We believe these distribution requirements best balance the right of individuals to be informed of their privacy rights with the burden on health plans to provide the revised NPP. We also note that health plans should provide both paper- and web-based notices in a way accessible to all beneficiaries, including those individuals with disabilities. These modifications provide an avenue for an individual to be informed of material changes upon their effective date while better aligning the NPP distribution with health plans' normal mailings to individuals.

For health care providers, the final rule does not modify the current requirements to distribute revisions to the NPP. As such, § 164.520(c)(2)(iv) requires that when a health care provider with a direct treatment relationship with an individual revises the NPP, the health care provider must make the NPP available upon request on or after the effective date of the revision and must comply with the requirements of § 164.520(c)(2)(iii) to have the NPP available at the delivery site and to post the notice in a clear and prominent location. In response to several comments expressing concern about printing costs for new NPPs, we clarify that providers are not required to print and hand out a revised NPP to all individuals seeking treatment; providers must post the revised NPP in a clear and prominent location and have copies of the NPP at the delivery site for individuals to request to take with them. Providers are only required to give a copy of the NPP to, and obtain a good faith acknowledgment of receipt from, new patients. As a result, we do not believe that the current requirement is overly burdensome to providers, nor is it overly costly. We also clarify that while health care providers are required to post the NPP in a clear and prominent location at the delivery site, providers may post a summary of the notice in such a location as long as the full notice is immediately available (such as on a table directly under the posted summary) for individuals to pick up without any additional burden on their part. It would not be appropriate, however, to require the individual to have to ask the receptionist for a copy of the full NPP.

To the extent that some covered entities have already revised their NPPs in response to the enactment of the HITECH Act or State law requirements, we clarify that as long as a covered entity's current NPP is consistent with this final rule and individuals have been informed of all material revisions made to the NPP, the covered entity is not required to revise and distribute another NPP upon publication of this final rule. Finally, we note that to the extent a covered entity is required to comply with Section 504 of the Rehabilitation Act of 1973 or the Americans with Disabilities Act of 1990, the covered entity has an obligation to take steps that may be necessary to ensure effective communication with individuals with disabilities, which could include making the revised NPP or notice of material changes to the NPP available in alternate formats, such as Braille, large print, or audio.

Response to Other Public Comments

Comment: One commenter expressed concern about the addition of more information to the NPP when it is already very long and complex, while several commenters recommended that the final rule require NPPs to be shortened, simplified, and written in a clear, easily understandable manner. In addition, while a few commenters suggested that HHS provide a sample or standard NPP, many more commenters requested flexibility in developing the content of their respective NPPs.

Response: We believe that the additions to the NPP required by the final rule are necessary to fully inform individuals of the covered entity's privacy practices and their rights. The NPP should be provided in a clear, concise, and easy to understand manner, and we clarify that covered entities may use a ''layered notice'' to implement the Rule's provisions, so long as the elements required at § 164.520(b) are included in the document that is provided for the individual. For example, a covered entity may satisfy the NPP provisions by providing the individual with both a short notice that briefly summarizes the individual's rights, as well as other information, and a longer notice, layered beneath the short notice that contains all the elements required by the Rule. Additionally, the Privacy Rule requires that the NPP be written in plain language, and we note that some covered entities may have obligations under other laws with respect to their communication with affected individuals. For example, to the extent a covered entity is obligated to comply with Title VI of the Civil Rights Act of 1964, the covered entity must take reasonable steps to ensure meaningful access for Limited English Proficient persons to the services of the covered entity, which could include translating the NPP into frequently encountered languages. In addition, we agree with the commenters who suggested that covered entities have flexibility and discretion to determine how to draft and prepare their NPPs. Because each NPP will vary based on the functions of the individual covered entity, there is no ''one size fits all'' approach. However, we continue to explore options for making model or best practice language available.

Comment: One commenter requested elimination of the requirement that covered entities obtain agreement from individuals (an opt in) before electronic distribution while another commenter requested that HHS clarify that a covered entity may obtain an electronic agreement from an individual to receive an NPP electronically.

Response: The Privacy Rule permits covered entities to distribute their NPPs or notices of material changes by email, provided the individual has agreed to receive an electronic copy. Although

internet access is a convenience of daily life for many individuals, maintaining the opt-in requirement ensures that individuals who are not able to or choose not to receive information electronically are fully informed of how their protected health information is being used and disclosed and of their individual rights with respect to this information. We clarify that agreement to receive electronic notice can be obtained electronically pursuant to the requirements at § 164.520(c)(3).

9. Section 164.522(a)—Right To Request a Restriction of Uses and Disclosures

Section 164.522(a) of the Privacy Rule requires covered entities to permit individuals to request that a covered entity restrict uses or disclosures of their protected health information for treatment, payment, and health care operations purposes, as well as for disclosures to family members and certain others permitted under § 164.510(b). While covered entities are not required to agree to such requests for restrictions, if a covered entity does agree to restrict the use or disclosure of an individual's protected health information, the covered entity must abide by that restriction, except in emergency circumstances when the information is required for the treatment of the individual. Section 164.522 also includes provisions for the termination of such a restriction and requires that covered entities that have agreed to a restriction document the restriction in writing.

Proposed Rule

Section 13405(a) of the HITECH Act sets forth certain circumstances in which a covered entity now must comply with an individual's request for restriction of disclosure of his or her protected health information. Specifically, section 13405(a) of the HITECH Act requires that when an individual requests a restriction on disclosure pursuant to § 164.522, the covered entity must agree to the requested restriction unless the disclosure is otherwise required by law, if the request for restriction is on disclosures of protected health information to a health plan for the purpose of carrying out payment or health care operations and if the restriction applies to protected health information that pertains solely to a health care item or service for which the health care provider has been paid out of pocket in full.

To implement section 13405(a) of the HITECH Act, we proposed a number of changes to the Privacy Rule's provisions regarding an individual's right to request restrictions of certain uses and disclosures. First, we proposed at § 164.522(a)(1)(vi) to require a covered entity to agree to a request by an individual to restrict the disclosure of protected health information about the individual to a health plan if: (A) the disclosure is for the purposes of carrying out payment or health care operations and is not otherwise required by law; and (B) the protected health information pertains solely to a health care item or service for which the individual, or person on behalf of the individual other than the health plan, has paid the covered entity in full. In recognition that there are many situations in which family members or other persons may pay for the individual's treatment, we proposed to include language to the provision to ensure that this requirement not be limited to solely the individual paying for the health care item or service but would also include payment made by another person, other than the health plan, on behalf of the individual.

We proposed to modify § 164.522(a)(1)(ii), which states that a covered entity is not required to agree to a restriction, to refer to this exception to that general rule. We noted in the NPRM that in cases where an individual has exercised his or her right to restrict disclosure to a health plan under the above circumstances, the covered entity is also prohibited from making such disclosures to a business associate of the health plan, because a covered entity may only disclose protected health information to a business associate of another covered entity if the disclosure would be permitted directly to the other covered entity. We also proposed conforming modifications to § 164.522(a)(2) and (3) regarding terminating restrictions and documentation of restrictions to reflect these new requirements, and to make clear that, unlike other agreed to restrictions, a covered entity may not unilaterally terminate a required restriction to a health plan under § 164.522(a)(1)(ii).

We provided a number of clarifications, and solicited public comment on a number of issues, regarding these proposed provisions, as follows. We stated that we interpret section 13405(a) as giving the individual a right to determine for which health care items or services the individual wishes to pay out of pocket and restrict. Thus, section 13405(a) would not permit a covered entity to require individuals who wish to restrict disclosures about only certain health care items or services to a health plan to restrict disclosures of protected health information regarding all health care to the health plan. We requested comment on the types of treatment interactions between individuals and covered entities that would make implementing a restriction more difficult and ways to address such difficult situations, such as where an individual wishes to restrict a disclosure regarding a prescription to a health plan but because the provider electronically sends prescriptions to the pharmacy to be filled, the pharmacy may have already billed the health plan by the time the patient arrives at the pharmacy. We requested comment generally on whether covered health care providers that know of a restriction should inform other health care providers downstream of such restriction, including pharmacies, and whether technology could facilitate such notification. We requested comment on examples of the types of disclosures that may fall under this ''required by law'' exception. With respect to an individual, or someone on behalf of the individual, paying out of pocket for the health care item or service, we noted that the individual should not expect that this payment would count towards the individual's out of pocket threshold with respect to his or her health plan benefits. We requested comment on how this provision will function with respect to HMOs, given our understanding that under most current HMO contracts with providers an individual could not pay the provider in full for the treatment or service received. We clarified in the NPRM that if an individual's out of pocket payment for a health care item or service is not honored (e.g., the individual's check bounces), the covered entity is not obligated to continue to abide by the requested restriction because the individual has not fulfilled the requirements necessary to obtain the restriction. Additionally, we stated our expectation in such cases that covered entities make some attempt to resolve any payment issues with the individual prior to sending the protected health information to the health plan, such as by notifying the individual that his or her payment did not go through and giving the individual an opportunity to submit payment and requesting comment on the extent to which covered entities must make reasonable efforts to secure payment from the individual prior to billing the health plan. We requested comment on the scope of a restriction and in what circumstances it should apply to a subsequent, but related, treatment

encounter, such as follow-up care for treatment of a particular condition.

Overview of Public Comments

We received many comments on these proposed provisions and our questions as to how they should apply. A number of commenters generally supported the provisions as being an important right for health care consumers. However, many commenters expressed concerns with these new requirements. Many commenters raised concerns with, and requested guidance on, how to operationalize a restriction. Several commenters were concerned with having to create separate records to ensure that restricted data is not inadvertently sent to or accessible by the health plan or to manually redact information from the medical record prior to disclosure to a health plan. Commenters argued that having to segregate restricted and unrestricted information or redact restricted information prior to disclosure would be burdensome as such a process would generally have to occur manually, and may result in difficulties with ensuring that treating providers continue to have access to the entire medical record. Some commenters were concerned specifically with having to manually redact or create separate records prior to a health plan audit, or otherwise with withholding information from a plan during an audit, to ensure a health plan would not see restricted information.

With respect to the exception to a restriction for disclosures that are required by law, several commenters supported this exception but requested clarification on how such an exception would affect providers' existing legal obligations. Many commenters suggested that providers would be prohibited from receiving cash payment from individuals for items or services otherwise covered by State or Federally funded programs, such as Medicare and Medicaid, and thus, requested that disclosures to such State or Federally funded programs not be eligible for restriction. Similarly, some commenters sought clarification on the effect of this provision where certain State laws prohibit ''balance billing,'' making it illegal for the provider to bill the patient for any covered services over and above any permissible copayment, coinsurance or deductible amounts. Some commenters asked that we clarify that the ''required by law'' exception allows providers to disclose protected health information subject to a restriction for Medicare and Medicaid audits, because those insurers require complete, accurate records for audits.

Other commenters were concerned with applying a restriction to only certain health care items or services provided during a single patient encounter or visit. Commenters argued that split billing is not possible for most providers or that it may be obvious to a health plan if one item or service out of a bundle is restricted and that unbundling services may be costly. One commenter suggested that individuals should only be able to restrict certain types of services/treatment (e.g., cosmetic surgery and family planning services) as such services are more easily segregable from other health care services.

In response to our question regarding available electronic methods through which a prescribing provider could alert a pharmacy that an individual intends to pay out of pocket for a prescription and restrict disclosure to a health plan, commenters indicated they were generally unaware of any system that would alert a pharmacy of restrictions electronically, and many agreed that the cost and burden of flagging records manually would not be feasible for all covered entities. In general, commenters agreed that paper prescriptions would provide individuals with an opportunity to request a restriction when they arrive at the pharmacy. However, commenters also noted that returning to the use of paper prescriptions over electronic prescribing would be a step in the wrong direction, as there are many benefits to electronic prescribing, and it is important not to limit these benefits.

Almost all of the comments we received regarding the obligation generally of health care providers that know of a restriction to inform downstream health care providers of the restriction argued that it should be the individual's and not the provider's responsibility to inform downstream providers of any requested restriction. While a few commenters stated that the provider should bear this responsibility, the majority believed that this obligation would be difficult and burdensome for a provider. Some commenters acknowledged that in time, more advanced electronic and automated systems may allow providers to notify other providers downstream of a restriction, but these commenters stressed that such systems are not widely available at this time.

With respect to the requirement's application to health care providers providing care within an HMO context, many commenters expressed support for the suggestion that HMO patients would have to use an out-of-network provider for treatment to ensure that the restricted information would not be disclosed to the HMO. Some commenters indicated that State laws and/or provider contracts with an HMO may prohibit the provider from receiving a cash payment from an HMO patient above the patient's cost-sharing amount for the health care item or service. Conversely, some commenters stated that individuals should not have to go out-of-network when requesting a restriction and instead, providers could and should treat the services as non-covered services and accept payment directly from the patient. Several commenters also suggested that managed care contracts would have to be revised or renegotiated in order to comply with this provision and as such, ample time for renegotiation should be provided.

Commenters generally supported the language in the proposed rule making clear that a restriction would apply where an individual requests a restriction, but someone other than the individual (other than the health plan), such as a family member, pays for the individual's care on behalf of the individual. One commenter asked for clarification that payment by any health plan would not constitute payment out of pocket by the individual. The commenter stated that such clarification was necessary to avoid the situation where an individual has coverage under multiple plans, pays for care with a secondary plan, requests a restriction on disclosure to the primary plan, and then the secondary plan proceeds to obtain reimbursement from the primary plan disclosing the protected health information at issue. Another commenter asked that we clarify that a clinical research participant whose health care services are paid for by a research grant can still qualify for a restriction to the individual's health plan.

Most commenters supported not having to abide by a requested restriction in cases where the individual's method of payment is returned or otherwise does not go through. A few commenters suggested that a covered entity should include information to this effect in its notice of privacy practices. A number of commenters expressed concern with the ability of a provider to bill a health plan for services following an individual's inability to pay. For example, a provider may find it difficult to be reimbursed for services if the provider did not obtain the plan's required pre-certification for services because the individual initially agreed to pay out of pocket for the services.

Several commenters asked for guidance on what constitutes a

''reasonable effort'' to obtain payment from an individual prior to billing a health plan for health care services where an individual's original form of payment fails, and argued that the effort required should not be too burdensome on providers. A number of commenters suggested various alternatives. A few commenters suggested that providers should be able to set a deadline for payment and then bill the plan if the patient fails to pay; others requested that the regulation set a specific timeframe in which providers must be paid or the requested restriction is terminated. Some commenters suggested that a ''reasonable effort'' should be based upon a covered entity making one or two attempts to contact the patient and obtain payment. Another commenter recommended that reasonable efforts should require the provider to make a good faith effort to obtain payment based on their usual debt collection practices. Other commenters requested clarification that reasonable efforts would not require a provider sending a bill to a collection agency. Some commenters were generally concerned with requiring a provider to wait too long for payment, as the provider could risk the plan not paying for the treatment if it is billed too late. Certain commenters argued that providers should not have to engage in any attempts to resolve payment issues if an individual's payment fails prior to billing the health plan for the services. Finally, a number of commenters asked whether a provider could require payment in full at the time of the request for a restriction to avoid payment issues altogether.

Finally, many commenters responded to the NPRM's approach to follow-up care. The majority of commenters supported the idea that if an individual does not request a restriction and pay out of pocket for follow up care, then the covered entity may disclose the protected health information necessary to obtain payment from the health plan for such follow up care, recognizing that some of the protected health information may relate to and/or indicate that the individual received the underlying health care item or service to which a restriction applied. A few commenters asked whether individual authorization would be required to disclose previously restricted protected health information to a health plan if the individual does not want to restrict the follow up care. A number of commenters expressed support for providers counseling patients on the consequences of not restricting follow-up care. A few commenters were concerned as to how a provider would know when such counseling was needed and what it should include, and asked whether giving the individual a written statement explaining the consequences would suffice.

Final Rule

We adopt the modifications to § 164.522 as proposed in the NPRM to implement section 13405(a) of the HITECH Act. In response to questions and comments regarding how to operationalize these requirements, we provide the following clarifications. We clarify that these provisions do not require that covered health care providers create separate medical records or otherwise segregate protected health information subject to a restricted health care item or service. Covered health care providers will, however, need to employ some method to flag or make a notation in the record with respect to the protected health information that has been restricted to ensure that such information is not inadvertently sent to or made accessible to the health plan for payment or health care operations purposes, such as audits by the health plan. Covered entities should already have in place, and thus be familiar with applying, minimum necessary policies and procedures, which require limiting the protected health information disclosed to a health plan to the amount reasonably necessary to achieve the purpose of the disclosure. Thus, covered entities should already have mechanisms in place to appropriately limit the protected health information that is disclosed to a health plan.

With respect to commenters who were concerned about providers being able to continue to meet their legal obligations, such as disclosing protected health information to Medicare or Medicaid for required audits, we note that the statute and final rule continue to allow disclosures that are otherwise required by law, notwithstanding that an individual has requested a restriction on such disclosures. Thus, a covered entity may disclose the protected health information necessary to meet the requirements of the law. Under the Privacy Rule, ''required by law'' is defined at § 164.103 as a mandate contained in law that compels a covered entity to make a use or disclosure of protected health information and that is enforceable in a court of law. For purposes of this definition, ''required by law'' includes Medicare conditions of participation with respect to health care providers participating in the program, and statutes and regulations that require the production of information if payment is sought under a government program providing public benefits. Therefore, if a covered entity is required by law to submit protected health information to a Federal health plan, it may continue to do so as necessary to comply with that legal mandate. With respect to commenters' concerns with prohibitions in State law and under Medicare and Medicaid that prevent providers from billing, and receiving cash payment from, an individual for covered services over and above any permissible cost sharing amounts, we provide the following guidance. If a provider is required by State or other law to submit a claim to a health plan for a covered service provided to the individual, and there is no exception or procedure for individuals wishing to pay out of pocket for the service, then the disclosure is required by law and is an exception to an individual's right to request a restriction to the health plan pursuant to § 154.522(a)(1)(vi)(A) of the Rule. With respect to Medicare, it is our understanding that when a physician or supplier furnishes a service that is covered by Medicare, then it is subject to the mandatory claim submission provisions of section 1848(g)(4) of the Social Security Act (the Act), which requires that if a physician or supplier charges or attempts to charge a beneficiary any remuneration for a service that is covered by Medicare, then the physician or supplier must submit a claim to Medicare. However, there is an exception to this rule where a beneficiary (or the beneficiary's legal representative) refuses, of his/her own free will, to authorize the submission of a bill to Medicare. In such cases, a Medicare provider is not required to submit a claim to Medicare for the covered service and may accept an out of pocket payment for the service from the beneficiary. The limits on what the provider may collect from the beneficiary continue to apply to charges for the covered service, notwithstanding the absence of a claim to Medicare. See the Medicare Benefit Policy Manual, Internet only Manual pub. 100–2, ch. 15, sect. 40, available at *http://www.cms.gov/manuals/Downloads/bp102c15.pdf*. Thus, if a Medicare beneficiary requests a restriction on the disclosure of protected health information to Medicare for a covered service and pays out of pocket for the service (i.e., refuses to authorize the submission of a bill to Medicare for the service), the provider must restrict the disclosure of protected health information regarding the service to Medicare in accordance with § 164.522(a)(1)(vi).

Certain commenters raised concerns with an individual requesting a restriction with respect to only one of several health care items or services provided in a single patient encounter, and a provider being prohibited from unbundling, or it being more costly to unbundle, the services for purposes of billing a health plan. In such cases, we expect providers to counsel patients on the ability of the provider to unbundle the items or services and the impact of doing so (e.g., the health plan still may be able to determine that the restricted item or service was performed based on the context). If a provider is able to unbundle the items or services and accommodate the individual's wishes after counseling the individual on the impact of unbundling, it should do so. If a provider is not able to unbundle a group of items or services, the provider should inform the individual and give the individual the opportunity to restrict and pay out of pocket for the entire bundle of items or services. Where a provider is not able to unbundle a group of bundled items or services, we view such group of bundled items or services as one item or service for the purpose of applying § 164.522(a)(1)(v). However, we would expect a provider to accommodate an individual's request for a restriction for separable and unbundled health care items or services, even if part of the same treatment encounter, such as in the prior example with respect to the patient receiving both treatment for asthma and diabetes. Thus, we decline to provide as a general rule that an individual may only restrict either all or none of the health care items or services that are part of one treatment encounter.

In response to the question we posed in the NPRM regarding methods through which a provider could electronically (such as through an e-prescribing tool) notify a pharmacist of an individual's restriction request, the majority of commenters indicated that there currently is not a widely available method for electronically notifying a pharmacy that a patient has requested a restriction. Further, commenters generally argued that it would be costly, burdensome, and unworkable for a provider to attempt to notify all subsequent providers of an individual's restriction request, particularly given the lack of automated tools to make such notifications, and thus, it should remain the obligation of the individual to notify downstream providers if the individual wants to restrict protected health information to a health plan. We agree that it would be unworkable at this point, given the lack of automated technologies to support such a requirement, to require health care providers to notify downstream providers of the fact that an individual has requested a restriction to a health plan. However, we do encourage providers to counsel patients that they would need to request a restriction and pay out of pocket with other providers for the restriction to apply to the disclosures by such providers. In the case of an individual who wants to restrict disclosures to a health plan concerning a prescribed medication, the prescribing provider can provide the patient with a paper prescription to allow the individual an opportunity to request a restriction and pay for the prescription with the pharmacy before the pharmacy has submitted a bill to the health plan. However, while we do not require it, providers are permitted and encouraged to assist individuals as feasible in alerting downstream providers of the individual's desire to request a restriction and pay out of pocket for a particular health care item or service.

For example, consider an individual who is meeting with her primary physician and requests a restriction on tests that are being administered to determine if she has a heart condition. If, after conducting the tests, the patient's primary physician refers the patient to a cardiologist, it is the patient's obligation to request a restriction from the subsequent provider, the cardiologist, if she wishes to pay out of pocket rather than have her health plan billed for the visit. Although the primary physician in this example would not be required to alert the cardiologist of the patient's potential desire to request a restriction, we encourage providers to do so if feasible or in the very least, to engage in a dialogue with the patient to ensure that he or she is aware that it is the patient's obligation to request restrictions from subsequent providers. In response to commenters who were confused about whether the individual or the provider would have the obligation of notifying subsequent providers when a Health Information Exchange is involved, we clarify that the responsibility to notify downstream providers of a restriction request in this situation also remains with the individual, and not the provider.

With respect to HMOs, we clarify that a provider providing care in such a setting should abide by an individual's requested restriction unless doing so would be inconsistent with State or other law. Thus, if a provider within an HMO is prohibited by law from accepting payment from an individual above the individual's cost-sharing amount (i.e., the provider cannot accept an out of pocket payment from the individual for the service), then the provider may counsel the individual that he or she will have to use an out-of-network provider for the health care item or service in order to restrict the disclosure of protected health information to the HMO for the health care. Providers operating within an HMO context and who are able under law to treat the health care services to which the restriction would apply as out-of-network services should do so in order to abide by the requested restriction. We would not consider a contractual requirement to submit a claim or otherwise disclose protected health information to an HMO to exempt the provider from his or her obligations under this provision. Further, the final rule provides a 180-day compliance period beyond the effective date of these revisions to the Privacy Rule, during which provider contracts with HMOs can be updated as needed to be consistent with these new requirements.

As proposed in the NPRM, under the final rule, a covered entity must apply a restriction not only where an individual pays in full for the healthcare item or service, but also where a family member or other person pays for the item or service on behalf of the individual. We decline to modify the regulation, as suggested by one commenter, to provide that payment from ''any'' health plan, rather than the one to which the disclosure is restricted, should not constitute payment on behalf of the individual. In response to the commenter's concern about difficulties in coordination of benefits for individuals with coverage under multiple plans, we note that this provision does not impede a health plan's ability to disclose protected health information as necessary to another health plan for coordination of benefits. Thus, health plans may continue to make such disclosures.

Many commenters supported the discussion in the NPRM regarding not abiding by a restriction if an individual's payment is dishonored. In such cases, we continue to expect that providers will make a reasonable effort to contact the individual and obtain payment prior to billing a health plan. We do not prescribe the efforts a health care provider must make but leave that up to the provider's policies and individual circumstances. While we require the provider to make a reasonable effort to secure payment from the individual, this requirement is not intended to place an additional

burden on the provider but is instead intended to align with its current policies for contacting individuals to obtain an alternative form of payment to one that was dishonored. We do not require that the individual's debt be placed in collection before a provider is permitted to bill a health plan for the health care services. Further, a provider may choose to require payment in full at the time of the request for a restriction to avoid payment issues altogether. Similarly, where precertification is required for a health plan to pay for services, a provider may require the individual to settle payments for the care prior to providing the service and implementing a restriction to avoid the situation where the provider is unable to be reimbursed by either the individual or the health plan.

We also recognize that a provider may not be able to implement a restriction where an individual waits until care has been initiated to make such a request, such as in the case of a hospital stay, in which case the individual's protected health information may have already been disclosed to the health plan.

With respect to restrictions and follow-up care, we continue to maintain the approach discussed in the NPRM. If an individual has a restriction in place with respect to a health care service but does not pay out of pocket and request a restriction with regard to follow-up treatment, and the provider needs to include information that was previously restricted in the bill to the health plan in order to have the service deemed medically necessary or appropriate, then the provider is permitted to disclose such information so long as doing so is consistent with the provider's minimum necessary policies and procedures. We also clarify that such a disclosure would continue to be permitted for payment purposes and thus, would not require the individual's written authorization. However, as we did in the NPRM, we highly encourage covered entities to engage in open dialogue with individuals to ensure that they are aware that previously restricted protected health information may be disclosed to the health plan unless they request an additional restriction and pay out of pocket for the follow-up care.

Response to Other Public Comments

Comment: Several commenters asked that the provision be limited to just providers and not to covered entities in general. Commenters also asked for clarification on whether the restriction prohibits providers from giving protected health information to health plans solely for payment or health care operations purposes in such cases or all entities that may receive protected health information for payment or health care operations.

Response: We clarify that this provision, in effect, will apply only to covered health care providers. However, the provisions of § 164.522(a) apply to covered entities generally and thus, we decline to alter the regulatory text. In response to commenters' concerns regarding disclosure for payment or health care operations purposes to entities other than the health plan, we clarify that this provision does not affect disclosures to these other entities as permitted by the Privacy Rule.

Comment: Commenters asked what the liability is for a provider who discloses restricted protected health information to a plan.

Response: A provider who discloses restricted protected health information to the health plan is making a disclosure in violation of the Privacy Rule and the HITECH Act, which, as with other impermissible disclosures is subject to the imposition of possible criminal penalties, civil money penalties, or corrective action.

Comment: Several commenters asked that we clarify that the ''required by law'' exception allows providers to respond to subpoenas, court orders, and judicial proceedings.

Response: The ''required by law'' exception in § 164.522(a)(1)(vi) does allow health care providers to respond to court orders and subpoenas issued by a court requiring disclosure of protected health information to a health plan. See the definition of ''required by law'' at § 164.103. Further, § 164.522(a)(1)(vi) does not affect the disclosure of protected health information to entities that are not health plans and thus, disclosures to these other entities made as required by law, for judicial and administrative proceedings, or for law enforcement activities in accordance with §§ 164.512(a), 164.512(e), and 164.512(f), respectively, continue to be permitted.

Comment: Several commenters suggested that the final rule be written to ensure that there are no conflicts with the Fair Debt Collection Practices Act and similar State laws regarding the legal obligation to validate a debt that is disputed by a debtor. Commenters sought clarification on whether the provider can still disclose protected health information for the recovery of debts.

Response: The final rule does not impact a provider's ability to disclose protected health information for payment purposes to a collection agency or otherwise for collection activities related to an individual's debt to the provider. Section 164.522(a) restricts disclosures to a health plan for payment purposes where the individual has paid out of pocket for the health care item or service that is the subject of the disclosure and requests such a restriction.

Comment: Commenters asked that we clarify whether payment with a Flexible Spending Account (FSA) or Health Savings Account (HSA) is considered a payment by a person on behalf of the individual.

Response: An individual may use an FSA or HSA to pay for the health care items or services that the individual wishes to have restricted from another plan; however, in doing so the individual may not restrict a disclosure to the FSA or HSA necessary to effectuate that payment.

Comment: When a restriction is requested, the provider is also prohibited from making disclosures of the restricted protected health information to the business associate of the health plan. One commenter suggested that the final rule make it the priority of the business associate to inform the provider that they are acting as the business associate of the health plan to ensure provider compliance with the rule. Other comments misconstrued the preamble statements on this issue and commented that a provider should be allowed to provide restricted protected health information to its own business associates.

Response: A provider that is prohibited from disclosing protected health information to a health plan may not disclose such information to the health plan's business associate. We do not include a requirement that the business associate inform the provider that they are acting as a business associate of the health plan as it is the provider's responsibility to know to whom and for what purposes it is making a disclosure. We also clarify that a provider is not prohibited from disclosing protected health information restricted from a health plan to its own business associates for the provider's own purposes.

Comment: One commenter expressed concern about the number of workforce members who must know about the restriction and indicated that this may create a risk for potential error with regard to the information.

Response: Covered entities must identify those workforce members or class of persons who need access to particular protected health information, and appropriately train their workforce members as necessary to comply with these new requirements.

10. Section 164.524—Access of Individuals to Protected Health Information

Proposed Rule

Section 164.524 of the Privacy Rule currently establishes, with limited exceptions, an enforceable means by which individuals have a right to review or obtain copies of their protected health information to the extent such information is maintained in the designated record set(s) of a covered entity. An individual's right of access exists regardless of the format of the protected health information, and the standards and implementation specifications that address individuals' requests for access and timely action by the covered entity (i.e., provision of access, denial of access, and documentation) apply to an electronic environment in a similar manner as they do to a paper-based environment. See The HIPAA Privacy Rule's Right of Access and Health Information Technology (providing guidance with respect to how § 164.524 applies in an electronic environment and how health information technology can facilitate providing individuals with this important privacy right), available at: *http://www.hhs.gov/ocr/privacy/hipaa/understanding/special/healthit/eaccess.pdf*.

Section 13405(e) of the HITECH Act strengthens the Privacy Rule's right of access with respect to covered entities that use or maintain an electronic health record (EHR) on an individual. Section 13405(e) provides that when a covered entity uses or maintains an EHR with respect to protected health information of an individual, the individual shall have a right to obtain from the covered entity a copy of such information in an electronic format and the individual may direct the covered entity to transmit such copy directly to the individual's designee, provided that any such choice is clear, conspicuous, and specific. Section 13405(e) also provides that any fee imposed by the covered entity for providing such an electronic copy shall not be greater than the entity's labor costs in responding to the request for the copy.

Section 13405(e) applies by its terms only to protected health information in EHRs. However, incorporating these new provisions in such a limited manner in the Privacy Rule could result in a complex set of disparate requirements for access to protected health information in EHR systems versus other types of electronic records systems. As such, the Department proposed to use its authority under section 264(c) of HIPAA to prescribe the rights individuals should have with respect to their individually identifiable health information to strengthen the right of access as provided under section 13405(e) of the HITECH Act more uniformly to all protected health information maintained in one or more designated record sets electronically, regardless of whether the designated record set is an EHR. The public comments and final regulation on the scope are discussed here. The proposed amendments to each provision implicated by section 13405(e), together with the public comments and final regulation, are discussed more specifically in separate sections below.

Overview of Public Comments

Most commenters were opposed to the proposal to expand the scope of the individual access provision to include all electronic designated record sets and favored limiting the requirement to EHRs. These commenters felt that limiting the access provision to EHRs was consistent with congressional intent and questioned the authority of the Department to expand the scope. Commenters also argued that having disparate requirements for different systems would not be confusing, and requiring electronic access to electronic designated record sets that are not EHRs would be highly burdensome for covered entities. Specifically, commenters stated that the proposed requirement for electronic access would include numerous types of legacy systems, many of which are incapable of producing reports in easily readable formats that can be transmitted electronically. These commenters indicated that a significant amount of information technology development and investment would be needed to comply with this requirement if it applies to all electronic designated record sets.

A number of consumer advocates supported the expanded scope to include all electronic designated records sets in addition to EHRs. These commenters felt that this would provide complete transparency for consumers, help individuals gain access to their medical records and make better-informed decisions about their health care, and promote consistent and uniform practices.

Final Rule

The final rule adopts the proposal to amend the Privacy Rule at § 164.524(c)(2)(ii) to require that if an individual requests an electronic copy of protected health information that is maintained electronically in one or more designated record sets, the covered entity must provide the individual with access to the electronic information in the electronic form and format requested by the individual, if it is readily producible, or, if not, in a readable electronic form and format as agreed to by the covered entity and the individual. In such cases, to the extent possible, we expect covered entities to provide the individual with a machine readable copy of the individual's protected health information. The Department considers machine readable data to mean digital information stored in a standard format enabling the information to be processed and analyzed by computer. For example, this would include providing the individual with an electronic copy of the protected health information in the format of MS Word or Excel, text, HTML, or text-based PDF, among other formats.

We disagree with commenters that questioned the Department's authority to extend the strengthened electronic access right to all protected health information maintained electronically in designated record sets, and believe that this extended electronic right of access is important for individuals as covered entities increasingly transition from paper to electronic records. With regard to the additional burdens on covered entities, we note that providing access to protected health information held in electronic designated record sets was already required under the Privacy Rule at § 164.524, which applies to protected health information in both paper and electronic designated record sets, and which requires providing the copy in the form and format requested by the individual, including electronically, if it is readily producible in such form and format. We anticipate the additional burden to be small due to the flexibility permitted in satisfying this new requirement, as discussed in the section on Form and Format.

Response to Other Public Comments

Comment: Some commenters worried that giving individuals access to administrative systems (in contrast to clinical systems) would present a security concern to covered entities.

Response: Covered entities are not required by this provision to provide individuals with direct access to their systems. They must only provide individuals with an electronic copy of their protected health information.

Comment: Commenters requested clarification on what constitutes an EHR.

Response: Under this final rule, the requirement to provide individuals with access to an electronic copy includes all

protected health information maintained in an electronic designated record set held by a covered entity. Because we are not limiting the right of electronic access to EHRs, we do not believe there is a need to define or further clarify the term at this time.

Comment: One commenter requested clarification that this electronic access requirement preempts State laws that diminish, block, or limit individual access to their records.

Response: We clarify that this HIPAA electronic right of access requirement does preempt contrary State law unless such law is more stringent. In the case of right of access, more stringent means that such State law permits greater rights of access to the individual.

Comment: Several commenters sought clarification of how the new e-access provisions would apply to business associates. One commenter asked whether business associates could continue to provide patients access to records when permitted and acting on behalf of a covered entity. Another commenter asked whether business associates are required to provide information to covered entities and not to individuals directly. One commenter was opposed to direct access from a business associate because of security concerns and increased burden on business associates if corrections are needed.

Response: How and to what extent a business associate is to support or fulfill a covered entity's obligation to provide individuals with electronic access to their records will be governed by the business associate agreement between the covered entity and the business associate. For example, the business associate agreement may provide for the business associate to give copies of the requested information directly to the individual, or to the covered entity for the covered entity to provide the copies to the individual. There is no separate requirement on business associates to provide individuals with direct access to their health records, if that is not what has been agreed to between the covered entity and the business associate in the business associate agreement.

a. Form and Format

Proposed Rule

Section 164.524(c)(2) of the Privacy Rule currently requires a covered entity to provide the individual with access to the protected health information in the form or format requested by the individual, if it is readily producible in such form or format, or, if not, in a readable hard copy form or such other form or format as agreed to by the covered entity and the individual. Section 13405(e) of the HITECH Act expands this requirement by explicitly requiring a covered entity that uses or maintains an EHR with respect to protected health information to provide the individual with a copy of such information in an electronic format.

We proposed to implement this statutory provision, in conjunction with our broader authority under section 264(c) of HIPAA, by requiring, in proposed § 164.524(c)(2)(ii), that if the protected health information requested is maintained electronically in one or more designated record sets, the covered entity must provide the individual with access to the electronic information in the electronic form and format requested by the individual, if it is readily producible, or, if not, in a readable electronic form and format as agreed to by the covered entity and the individual. This provision would require any covered entity that electronically maintains the protected health information about an individual, in one or more designated record sets, to provide the individual with an electronic copy of such information (or summary or explanation if agreed to by the individual in accordance with proposed § 164.524(c)(2)(iii)) in the electronic form and format requested or in an otherwise agreed upon electronic form and format. While an individual's right of access to an electronic copy of protected health information is currently limited under the Privacy Rule by whether the form or format requested is readily producible, covered entities that maintain such information electronically in a designated record set would be required under these proposed modifications to provide some type of electronic copy, if requested by an individual.

Because we did not want to bind covered entities to standards that may not yet be technologically mature, we proposed to permit covered entities to make some other agreement with individuals as to an alternative means by which they may provide a readable electronic copy to the extent the requested means is not readily producible. If, for example, a covered entity received a request to provide electronic access via a secure web-based portal, but the only readily producible version of the protected health information was in portable document format (PDF), proposed § 164.524(c)(2)(ii) would require the covered entity to provide the individual with a PDF copy of the protected health information, if agreed to by the covered entity and the individual. We noted that while a covered entity may provide individuals with limited access rights to their EHR, such as through a secure web-based portal, nothing under the current Rule or proposed modifications would require a covered entity to have this capability.

We noted that the option of arriving at an alternative agreement that satisfies both parties is already part of the requirement to provide access under § 164.524(c)(2)(i), so extension of such a requirement to electronic access should present few implementation difficulties. Further, as with other disclosures of protected health information, in providing the individual with an electronic copy of protected health information through a web-based portal, email, on portable electronic media, or other means, covered entities should ensure that reasonable safeguards are in place to protect the information. We also noted that the proposed modification presumes that covered entities have the capability of providing an electronic copy of protected health information maintained in their designated record set(s) electronically through a secure web-based portal, via email, on portable electronic media, or other manner. We invited public comment on this presumption.

Overview of Public Comments

We received many comments and requests for clarification and guidance regarding the permitted methods for offering protected health information on electronic media, and the acceptable form and format of the electronic copy. Several commenters suggested that covered entities be permitted flexibility in determining available electronic formats and requested clarification on what is considered ''readily producible.'' These commenters expressed concerns that a limited number of permissible electronic formats may result in a situation where protected health information could not be converted from a particular electronic system. Other commenters indicated that there should be minimum standards and clearly defined media that are permissible to meet this requirement. One commenter felt that this requirement is important but should be deferred until covered entities have improved their technological capabilities.

Many commenters requested guidance on how to proceed if a covered entity and an individual are unable to come to an agreement on the medium of choice and what is expected in terms of accommodating the individual's medium of choice. Some commenters suggested various alternate solutions if

an agreement cannot be reached, including any readily producible format, PDF, or hard copy protected health information. Some covered entities felt that individuals should not have an unlimited choice in terms of the electronic media they are willing to accept, and should only be permitted to confine their choices of electronic media to a couple of options that the covered entity has available.

Final Rule

The final rule adopts the proposal to require covered entities to provide electronic information to an individual in the electronic form and format requested by the individual, if it is readily producible, or, if not, in a readable electronic form and format as agreed to by the covered entity and the individual. We recognize that what is available in a readable electronic form and format will vary by system and that covered entities will continue to improve their technological capabilities over time. We therefore allow covered entities the flexibility to provide readily producible electronic copies of protected health information that are currently available on their various systems. A covered entity is not required to purchase new software or systems in order to accommodate an electronic copy request for a specific form that is not readily producible by the covered entity at the time of the request, provided that the covered entity is able to provide some form of electronic copy. We note that some legacy or other systems may not be capable of providing any form of electronic copy at present and anticipate that some covered entities may need to make some investment in order to meet the basic requirement to provide some form of electronic copy.

We agree with covered entities that individuals should not have an unlimited choice in the form of electronic copy requested. However, covered entities must still provide individuals with some kind of readable electronic copy. If an individual requests a form of electronic copy that the covered entity is unable to produce, the covered entity must offer other electronic formats that are available on their systems. If the individual declines to accept any of the electronic formats that are readily producible by the covered entity, the covered entity must provide a hard copy as an option to fulfill the access request. While we remain neutral on the type of technology that covered entities may adopt, a PDF is a widely recognized format that would satisfy the electronic access requirement if it is the individual's requested format or if the individual agrees to accept a PDF instead of the individual's requested format. Alternatively, there may be circumstances where an individual prefers a simple text or rich text file and the covered entity is able to accommodate this preference. A hard copy of the individual's protected health information would not satisfy the electronic access requirement. However, a hard copy may be provided if the individual decides not to accept any of the electronic formats offered by the covered entity.

Response to Other Public Comments

Comment: Several covered entities commented on the form of a request for access to electronic protected health information. Some expressed appreciation for permitting an electronic request process, including e-signatures and authentication. Some expressed opposition to the requirement for a signed request in writing, as it would be highly burdensome and cause delays. Covered entities sought guidance on elements that would be required or permitted in a request form for individuals.

Response: We clarify that the requirement at § 164.524(b)(1), which states that the covered entity may require individuals to make requests for access in writing, provided that it informs individuals of such a requirement, remains unchanged. Therefore, covered entities may at their option require individuals to make requests for electronic copies of their protected health information in writing. We note that the Privacy Rule allows for electronic documents to qualify as written documents, as well as electronic signatures to satisfy any requirements for a signature, to the extent the signature is valid under applicable law. If the covered entity chooses to require a written request, it has flexibility in determining what information to put into the request form. However, the request form may not be in any way designed to discourage an individual from exercising his or her right. A covered entity may also choose to accept an individual's oral request for an electronic copy of their protected health information without written signature or documentation.

Comment: We received several comments on the content that covered entities are required to provide in response to an electronic access request. Some commenters felt that there should be a defined minimum set of data elements to satisfy this requirement, particularly for non-EHR data. Covered entities also requested clarification on how to handle links to images or other data.

Response: We clarify that just as is currently required for hard copy protected health information access requests, covered entities must provide an electronic copy of all protected health information about the individual in an electronically maintained designated record set, except as otherwise provided at § 164.524(a). If the designated record set includes electronic links to images or other data, the images or other data that is linked to the designated record set must also be included in the electronic copy provided to the individual. The electronic copy must contain all protected health information electronically maintained in the designated record set at the time the request is fulfilled. The individual may request, however, only a portion of the protected health information electronically maintained in the designated record set, in which case the covered entity is only required to provide the requested information.

Comment: One commenter asserted that the request for protected health information should only apply to protected health information the covered entity has at the time of the request, not any additional protected health information that it obtains while processing the request.

Response: We clarify that the electronic copy must reflect all electronic protected health information held by the covered entity in a designated record set, or the subset of electronic protected health information specifically requested by the individual, at the time the request is fulfilled.

Comment: One commenter asked for confirmation that the new electronic requirement does not include a requirement to scan paper and provide electronic copies of records held in paper form.

Response: We clarify that covered entities are not required to scan paper documents to provide electronic copies of records maintained in hard copy. We note that for covered entities that have mixed media, it may in some cases be easier to scan and provide all records in electronic form rather than provide a combination of electronic and hard copies, however this is in no way required.

Comment: Many commenters expressed security concerns related to this new requirement. Covered entities felt that they should not have to use portable devices brought by individuals (particularly flash drives), due to the security risks that this would introduce to their systems. Some covered entities

additionally asserted that requiring the use of individually-supplied media is prohibited by the Security Rule, based on the risk analysis determination of an unacceptable risk to the confidentiality, integrity and availability of the covered entity's electronic protected health information.

Response: We acknowledge these security concerns and agree with commenters that it may not be appropriate for covered entities to accept the use of external portable media on their systems. Covered entities are required by the Security Rule to perform a risk analysis related to the potential use of external portable media, and are not required to accept the external media if they determine there is an unacceptable level of risk. However, covered entities are not then permitted to require individuals to purchase a portable media device from the covered entity if the individual does not wish to do so. The individual may in such cases opt to receive an alternative form of the electronic copy of the protected health information, such as through email.

Comment: Several commenters specifically commented on the option to provide electronic protected health information via unencrypted email. Covered entities requested clarification that they are permitted to send individuals unencrypted emails if they have advised the individual of the risk, and the individual still prefers the unencrypted email. Some felt that the ''duty to warn'' individuals of risks associated with unencrypted email would be unduly burdensome on covered entities. Covered entities also requested clarification that they would not be responsible for breach notification in the event that unauthorized access of protected health information occurred as a result of sending an unencrypted email based on an individual's request. Finally, one commenter emphasized the importance that individuals are allowed to decide if they want to receive unencrypted emails.

Response: We clarify that covered entities are permitted to send individuals unencrypted emails if they have advised the individual of the risk, and the individual still prefers the unencrypted email. We disagree that the ''duty to warn'' individuals of risks associated with unencrypted email would be unduly burdensome on covered entities and believe this is a necessary step in protecting the protected health information. We do not expect covered entities to educate individuals about encryption technology and the information security. Rather, we merely expect the covered entity to notify the individual that there may be some level of risk that the information in the email could be read by a third party. If individuals are notified of the risks and still prefer unencrypted email, the individual has the right to receive protected health information in that way, and covered entities are not responsible for unauthorized access of protected health information while in transmission to the individual based on the individual's request. Further, covered entities are not responsible for safeguarding information once delivered to the individual.

b. Third Parties

Proposed Rule

Section 164.524(c)(3) of the Privacy Rule currently requires the covered entity to provide the access requested by the individual in a timely manner, which includes arranging with the individual for a convenient time and place to inspect or obtain a copy of the protected health information, or mailing the copy of protected health information at the individual's request. The Department had previously interpreted this provision as requiring a covered entity to mail the copy of protected health information to an alternative address requested by the individual, provided the request was clearly made by the individual and not a third party. Section 13405(e)(1) of the HITECH Act provides that if the individual chooses, he or she has a right to direct the covered entity to transmit an electronic copy of protected health information in an EHR directly to an entity or person designated by the individual, provided that such choice is clear, conspicuous, and specific.

Based on section 13405(e)(1) of the HITECH Act and our authority under section 264(c) of HIPAA, we proposed to expand § 164.524(c)(3) to expressly provide that, if requested by an individual, a covered entity must transmit the copy of protected health information directly to another person designated by the individual. This proposed amendment is consistent with the Department's prior interpretation on this issue and would apply without regard to whether the protected health information is in electronic or paper form. We proposed to implement the requirement of section 13405(e)(1) that the individual's ''choice [be] clear, conspicuous, and specific'' by requiring that the individual's request be ''in writing, signed by the individual, and clearly identify the designated person and where to send the copy of protected health information.'' We noted that the Privacy Rule allows for electronic documents to qualify as written documents for purposes of meeting the Rule's requirements, as well as electronic signatures to satisfy any requirements for a signature, to the extent the signature is valid under applicable law. Thus, a covered entity could employ an electronic process for receiving an individual's request to transmit a copy of protected health information to his or her designee under this proposed provision. Whether the process is electronic or paper-based, a covered entity must implement reasonable policies and procedures under § 164.514(h) to verify the identity of any person who requests protected health information, as well as implement reasonable safeguards under § 164.530(c) to protect the information that is used or disclosed.

Overview of Public Comments

Commenters requested clarification regarding the proposal to transmit an electronic copy of protected health information to another person designated by the individual. In particular, covered entities sought clarification on whether or not an authorization is required prior to transmitting the requested electronic protected health information to a third party designated by the individual. Some commenters supported the ability to provide electronic protected health information access to third parties without individual authorization, while others felt that authorization should be required. Covered entities requested clarification that they are not liable when making reasonable efforts to verify the identity of a third party recipient identified by the individual.

Final Rule

The final rule adopts the proposed amendment § 164.524(c)(3) to expressly provide that, if requested by an individual, a covered entity must transmit the copy of protected health information directly to another person designated by the individual. In contrast to other requests under § 164.524, when an individual directs the covered entity to send the copy of protected health information to another designated person, the request must be made in writing, signed by the individual, and clearly identify the designated person and where to send the copy of the protected health information. If a covered entity has decided to require all access requests in writing, the third party recipient information and signature by the individual can be included in the same written request; no additional or separate written request is

required. This written request for protected health information to be sent to a designated person is distinct from an authorization form, which contains many additional required statements and elements (see § 164.508(c)). Covered entities may rely on the information provided in writing by the individual when providing protected health information to a third party recipient identified by the individual, but must also implement reasonable policies and procedures under § 164.514(h) to verify the identity of any person who requests protected health information, as well as implement reasonable safeguards under § 164.530(c) to protect the information that is used or disclosed. For example, reasonable safeguards would not require the covered entity to confirm that the individual provided the correct email address of the third party, but would require reasonable procedures to ensure that the covered entity correctly enters the email address into its system.

c. Fees

Proposed Rule

Section 164.524(c)(4) of the Privacy Rule currently permits a covered entity to impose a reasonable, cost-based fee for a copy of protected health information (or a summary or explanation of such information). However, such a fee may only include the cost of: (1) The supplies for, and labor of, copying the protected health information; (2) the postage associated with mailing the protected health information, if applicable; and (3) the preparation of an explanation or summary of the protected health information, if agreed to by the individual. With respect to providing a copy (or summary or explanation) of protected health information from an EHR in electronic form, however, section 13405(e)(2) of the HITECH Act provides that a covered entity may not charge more than its labor costs in responding to the request for the copy.

In response to section 13405(e)(2) of the HITECH Act, we proposed to amend § 164.524(c)(4)(i) to identify separately the labor for copying protected health information, whether in paper or electronic form, as one factor that may be included in a reasonable cost-based fee. While we did not propose more detailed considerations for this factor within the regulatory text, we retained all prior interpretations of labor with respect to paper copies—that is, that the labor cost of copying may not include the costs associated with searching for and retrieving the requested information. With respect to electronic copies, we asserted that a reasonable cost-based fee includes costs attributable to the labor involved to review the access request and to produce the electronic copy, which we expected would be negligible. However, we did not consider a reasonable cost-based fee to include a standard ''retrieval fee'' that does not reflect the actual labor costs associated with the retrieval of the electronic information or that reflects charges that are unrelated to the individual's request (e.g., the additional labor resulting from technical problems or a workforce member's lack of adequate training). We invited public comment on this aspect of our rulemaking, specifically with respect to what types of activities related to managing electronic access requests should be compensable aspects of labor.

We also proposed to amend § 164.524(c)(4)(ii) to provide separately for the cost of supplies for creating the paper copy or electronic media (i.e., physical media such as a compact disc (CD) or universal serial bus (USB) flash drive), if the individual requests that the electronic copy be provided on portable media. This reorganization and the addition of the phrase ''electronic media'' reflected our understanding that since section 13405(e)(2) of the HITECH Act permits only the inclusion of labor costs in the charge for electronic copies, it by implication excludes charging for the supplies that are used to create an electronic copy of the individual's protected health information, such as the hardware (computers, scanners, etc.) or software that is used to generate an electronic copy of an individual's protected health information in response to an access request. We noted that this limitation is in contrast to a covered entity's ability to charge for supplies for hard copies of protected health information (e.g., the cost of paper, the prorated cost of toner and wear and tear on the printer). See 65 FR 82462, 82735, Dec. 28, 2000 (responding to a comment seeking clarification on ''capital cost for copying'' and other supply costs by indicating that a covered entity was free to recoup all of their reasonable costs for copying). We asserted that this interpretation was consistent with the fact that, unlike a hard copy, which generally exists on paper, an electronic copy exists independent of media, and can be transmitted securely via multiple methods (e.g., email, a secure web-based portal, or an individual's own electronic media) without accruing any ancillary supply costs. We also noted, however, that our interpretation of the statute would permit a covered entity to charge a reasonable and cost-based fee for any electronic media it provided, as requested or agreed to by an individual.

While we proposed to renumber the remaining factors at § 164.524(c)(4), we did not propose to amend their substance. With respect to § 164.524(c)(4)(iii), however, we noted that our interpretation of the statute would permit a covered entity to charge for postage if an individual requests that the covered entity transmit portable media containing an electronic copy through mail or courier (e.g., if the individual requests that the covered entity save protected health information to a CD and then mail the CD to a designee).

Overview of Public Comments

Commenters generally supported and appreciated the inclusion of a reasonable, cost-based fee that includes both labor and, in some cases, supply costs to support the new electronic access requirement. Several commenters disagreed that the cost related to reviewing and responding to requests would be negligible, particularly if the scope includes information in designated record sets and not only EHRs, since more technically trained staff would be necessary to perform this function.

Commenters provided many suggestions of costs that should be permitted in the fees, including those associated with labor, materials, systems, retrieval (particularly for old data maintained in archives, backup media or legacy systems), copying, transmission, and capital to recoup the significant investments made for data access, storage and infrastructure. Commenters offered additional suggestions on labor-related costs, including: skilled technical staff time; time spent recovering, compiling, extracting, scanning and burning protected health information to media, and distributing the media; and preparation of an explanation or summary if appropriate. Suggestions of materials-related costs included: CDs, flash drives, tapes or other portable media; new types of technology needed to comply with individual requests; office supplies; and mail copies. Systems-related costs included: software necessary to conduct protected health information searches; and implementation and maintenance of security systems and secure connectivity.

Final Rule

The final rule adopts the proposed amendment at § 164.524(c)(4)(i) to identify separately the labor for copying protected health information, whether

in paper or electronic form, as one factor that may be included in a reasonable cost-based fee. We acknowledge commenters' assertions that the cost related to searching for and retrieving electronic protected health information in response to requests would be not be negligible, as opposed to what we had anticipated, particularly in regards to designated record set access that will require more technically trained staff to perform this function. We clarify that labor costs included in a reasonable cost-based fee could include skilled technical staff time spent to create and copy the electronic file, such as compiling, extracting, scanning and burning protected health information to media, and distributing the media. This could also include the time spent preparing an explanation or summary of the protected health information, if appropriate.

The final rule also adopts the proposed amendment at § 164.524(c)(4)(ii) to provide separately for the cost of supplies for creating the paper copy or electronic media (i.e., physical media such as a compact disc (CD) or universal serial bus (USB) flash drive), if the individual requests that the electronic copy be provided on portable media. We do not require that covered entities obtain new types of technology needed to comply with specific individual requests, and therefore the cost of obtaining such new technologies is not a permissible fee to include in the supply costs.

With respect to § 164.524(c)(4)(iii), we clarify that a covered entity is permitted to charge for postage if an individual requests that the covered entity transmit portable media containing an electronic copy through mail or courier (e.g., if the individual requests that the covered entity save protected health information to a CD and then mail the CD to a designee).

Fees associated with maintaining systems and recouping capital for data access, storage and infrastructure are not considered reasonable, cost-based fees, and are not permissible to include under this provision. Covered entities are not required to adopt or purchase new systems under this provision, and thus any costs associated with maintaining them are present regardless of the new electronic access right. Additionally, although the proposed rule indicated that a covered entity could charge for the actual labor costs associated with the retrieval of electronic information, in this final rule we clarify that a covered entity may not charge a retrieval fee (whether it be a standard retrieval fee or one based on actual retrieval costs). This interpretation will ensure that the fee requirements for electronic access are consistent with the requirements for hard copies, which do not allow retrieval fees for locating the data.

Response to Other Public Comments

Comment: Commenters requested clarification on how to proceed when State laws designate fees.

Response: When a State law provides a limit on the fee that a covered entity may charge for a copy of protected health information, this is relevant in determining whether a covered entity's fee is ''reasonable'' under § 164.524(c)(4). A covered entity's fee must be both reasonable and cost-based. For example, if a State permits a charge of 25 cents per page, but a covered entity is able to provide an electronic copy at a cost of five cents per page, then the covered entity may not charge more than five cents per page (since that is the reasonable and cost-based amount). Similarly, if a covered entity's cost is 30 cents per page but the State law limits the covered entity's charge to 25 cents per page, then the covered entity may not charge more than 25 cents per page (since charging 30 cents per page would be the cost-based amount, but would not be reasonable in light of the State law).

Comment: One commenter suggested that labor-related costs should include preparation of an affidavit certifying that the information is a true and correct copy of the records.

Response: We do not consider the cost to prepare an affidavit to be a copying cost. Thus, where an individual requests that an affidavit accompany the copy of protected health information requested by the individual for litigation purposes or otherwise, a covered entity may charge the individual for the preparation of such affidavit and is not subject to the reasonable, cost-based fee limitations of § 164.524(c)(4). However, a covered entity may not withhold an individual's copy of his or her protected health information for failure by the individual to pay any fees for services above and beyond the copying, such as for preparing an affidavit.

Comment: Some commenters recommended defining the following terms: ''preparing,'' ''producing,'' and ''transmitting.''

Response: We decline to define the terms ''preparing,'' ''producing,'' and ''transmitting,'' as we believe the terms have been adequately understood and utilized in the context of hard copy access to protected health information.

d. Timeliness

Proposed Rule

We requested comment on one aspect of the right to access and obtain a copy of protected health information which the HITECH Act did not amend. In particular, the HITECH Act did not change the timeliness requirements for provision of access at § 164.524(b). Under the current requirements, a request for access must be approved or denied, and if approved, access or a copy of the information provided, within 30 days of the request. In cases where the records requested are only accessible from an off-site location, the covered entity has an additional 30 days to respond to the request. In extenuating circumstances where access cannot be provided within these timeframes, the covered entity may have a one-time 30-day extension if the individual is notified of the need for the extension within the original timeframes.

With regard to the timeliness of the provision of access, we recognized that with the advance of EHRs, there is an increasing expectation and capacity to provide individuals with almost instantaneous electronic access to the protected health information in those records through personal health records or similar electronic means. On the other hand, we did not propose to limit the right to electronic access of protected health information to certified EHRs, and the variety of electronic systems that are subject to this proposed requirement would not all be able to comply with a timeliness standard based on personal health record capabilities. It was our assumption that a single timeliness standard that would address a variety of electronic systems, rather than having a multitude of standards based on system capacity, would be the preferred approach to avoid workability issues for covered entities. Even under a single standard, nothing would prevent users of EHR systems from exceeding the Privacy Rule's timeliness requirements for providing access to individuals. Additionally, the Medicare and Medicaid EHR Incentive Programs (the ''meaningful use'' programs) require users of Certified EHR Technology to provide individuals with expedited access to information. Based on the assumption that a single standard would be the preferred approach under the Privacy Rule, we requested public comment on an appropriate, common timeliness standard for the provision of access by covered entities with electronic designated record sets generally. We specifically requested comment on aspects of existing systems

that would create efficiencies in processing of requests for electronic information, as well as those aspects of electronic systems that would provide little change from the time required for processing a paper record. Alternatively, we requested comment on whether the current standard could be altered for all systems, paper and electronic, such that all requests for access should be responded to without unreasonable delay and not later than 30 days.

We also requested public comment on whether, contrary to our assumption, a variety of timeliness standards based on the type of electronic designated record set is the preferred approach and if so, how such an approach should be implemented.

Finally, we requested comment on the time necessary for covered entities to review access requests and make necessary determinations, such as whether the granting of access would endanger the individual or other persons so as to better understand how the time needed for these reviews relates to the overall time needed to provide the individual with access. Further, we requested comment generally on whether the provision which allows a covered entity an additional 30 days to provide access to the individual if the protected health information is maintained off-site should be eliminated altogether for both paper and electronic records, or at least for protected health information maintained or archived electronically because the physical location of electronic data storage is not relevant to its accessibility.

Overview of Public Comments

Commenters generally supported maintaining the same timeframe for response for both paper and electronic records and not modifying the existing timeframes for response. Commenters espoused many rationales for maintaining a single standard and the existing response standards, including that off-site electronic storage with back-up tapes will require time to obtain the electronic media, multiple electronic systems may need to be accessed, some systems may not have data stored in useable formats requiring time to convert data, and time may be required to obtain data from business associates and subcontractors.

Some commenters acknowledged that electronic records may be easier to access, but review of records and verification processes would still require time that cannot be shortcut because a record is electronic. One commenter acknowledged that shorter times may be achievable when specific data set standards are established and covered entities have electronic records in place. One commenter believed that electronic records could be furnished in a much shorter timeframe, such as two business days.

Several commenters suggested responses be done in much shorter timeframes, such as instantly, within one day or three days. One commenter noted that meaningful use standards required access within three days for 50 percent of patients. These commenters suggested alternative timeframes for adoption, such as allowing 60 days for response due to off-site storage issues and potential for multiple requests. One commenter suggested 30 and 60 day times were unworkable and another commenter suggested eliminating the 30 day extension for off-site record storage. One commenter suggested 30 days may be longer than is necessary, but cautioned against mandates that would unreasonably divert provider resources (e.g., five days would be unreasonable when a provider must take time to include explanatory notes).

Final Rule

The final rule modifies the timeliness requirements for right to access and to obtain a copy of protected health information at § 164.524(b). We remove the provision at § 164.524(b)(2)(ii) that permits 60 days for timely action when protected health information for access is not maintained or accessible to the covered entity on-site. We retain and renumber as necessary the provision at § 164.524(b)(2)(iii) that permits a covered entity a one-time extension of 30 days to respond to the individual's request (with written notice to the individual of the reasons for delay and the expected date by which the entity will complete action on the request).

We believe the 30 day timeframe for access is appropriate and achievable by covered entities given the increasing expectation and capacity to provide individuals with almost instantaneous electronic access to the protected health information in those records through personal health records or similar electronic means. While a covered entity is permitted 30 days to provide access (with a 30-day extension when necessary), we encourage covered entities to provide individuals with access to their information sooner, and to take advantage of technologies that provide individuals with immediate access to their health information. Nevertheless, for covered entities that continue to make use of off-site storage or have additional time constraints to providing access, the 30 day extension remains available for a covered entity to exercise. This means, for example, that a covered entity must provide an individual with access to off-site records within 30 days of the individual's request when possible, with a 30-day extension available (for a total of 60 days, in contrast to the current law that permits up to 90 days to provide the individual with access to such records).

We decline to establish separate timeframes for timely access based upon whether the protected health information to be accessed is paper or electronic. Commenters generally supported adoption of a single standard rather than differing standards based upon whether a record is paper or electronic and no comments provided compelling reasons to establish differing standards.

Response to Other Public Comments

Comment: One commenter asked for clarification as to when the time period for responding to a response begins if the parties spend significant time attempting to reach agreement on the format of the electronic copy.

Response: We confirm that the time period for responding to a request for access begins on the date of the request. Covered entities that spend significant time before reaching agreement on the electronic format for a response are using part of the 30 days permitted for response.

Comment: One commenter suggested there should be a transition period for those covered entities that do not currently have the capability to meet the electronic access requirement.

Response: We decline to implement a transition period for access to electronic copies of protected health information. Covered entities are already subject to the hard copy access requirement for all information held in designated record sets, including electronic designated record sets, and the new requirement for electronic copies gives covered entities the flexibility to provide an electronic copy in a form that is readily producible. We do not believe additional time is needed to provide electronic copies of protected health information that are readily producible.

11. Other Technical Changes and Conforming Changes

Proposed Rule

We proposed to make a number of technical and conforming changes to the Privacy Rule to fix minor problems, such as incorrect cross-references, mistakes of grammar, and typographical errors. These changes are shown in Table 3 below.

TABLE 3—TECHNICAL AND CONFORMING CHANGES

Regulation section	Current language	Proposed change	Reason for change
164.510(b)(2)(iii)	''based the exercise of professional Judgment''.	Insert ''on'' after ''based''	Correct typographical error.
164.512(b)(1)	''Permitted disclosures'' and ''may disclose''.	Insert ''uses and'' and ''use or'' before ''disclosures'' and ''disclose,'' respectively.	Correct inadvertent omission.
164.512(e)(1)(iii)	''seeking protecting health information''.	Change ''protecting'' to ''protected''	Correct typographical error.
164.512(e)(1)(vi)	''paragraph (e)(1)(iv) of this section''	Change ''(e)(1)(iv)'' to ''(e)(1)(v)''	Correct cross-reference.
164.512(k)(3)	''authorized by 18 U.S.C. 3056, or to foreign heads of state, or to for the conduct of investigations''.	Remove the comma after ''U.S.C. 3056'' and the ''to'' before ''for''.	Correct typographical errors.

In addition to the above technical changes, we proposed to make a few clarifications to existing text in various provisions of the regulation not otherwise addressed in the above preamble. These are as follows.

1. Section 164.506(c)(5) permits a covered entity to disclose protected health information ''to another covered entity that participates in the organized health care arrangement.'' We proposed to change the words ''another covered entity that participates'' to ''other participants'' because not all participants in an organized health care arrangement may be covered entities; for example, some physicians with staff privileges at a hospital may not be covered entities.

2. Section 164.510(a)(1)(ii) permits the disclosure of directory information to members of the clergy and other persons who ask for the individual by name. We proposed to add the words ''use or'' to this permission, to cover the provision of such information to clergy who are part of a facility's workforce.

3. Section 164.510(b)(3) covers uses and disclosures of protected health information when the individual is not present to agree or object to the use or disclosure, and, as pertinent here, permits disclosure to persons only of ''the protected health information that is directly relevant to the person's involvement with the individual's health care.'' We proposed to delete the last two quoted words and substitute the following: ''care or payment related to the individual's health care or needed for notification purposes.'' This change aligns the text of paragraph (b)(3) with the permissions provided for at paragraph (b)(1) of this section.

4. Where an employer needs protected health information to comply with workplace medical surveillance laws, such as the Occupational Safety and Health Administration or Mine Safety and Health Administration requirements, § 164.512(b)(1)(v)(A) permits a covered entity to disclose, subject to certain conditions, protected health information of an individual to the individual's employer if the covered entity is a covered health care provider ''who is a member of the workforce of such employer or who provides health care to the individual at the request of the employer.'' We proposed to amend the quoted language by removing the words ''who is a member of the workforce of such employer or,'' as the language is unnecessary.

5. At § 164.512(k)(1)(ii), we proposed to replace the word ''Transportation'' with ''Homeland Security.'' The language regarding a component of the Department of Transportation was included to refer to the Coast Guard; however, the Coast Guard was transferred to the Department of Homeland Security in 2003.

6. At § 164.512(k)(5), which permits a covered entity to disclose to a correctional institution or law enforcement official having lawful custody of an inmate or other individual protected health information about the inmate or individual in certain necessary situations, we proposed to replace the word ''and'' after the semicolon in paragraph (i)(E) with the word ''or.'' The intent of § 164.512(k)(5)(i) is not that the existence of all of the conditions is necessary to permit the disclosure, but rather that the existence of any would permit the disclosure.

Overview of Public Comments

One commenter requested clarification about whether business associates may participate in an organized health care arrangement (OHCA) under § 164.506(c)(5). Another commenter recommended against changing the language of § 164.506(c)(5), arguing that such a change could bring entities like employers and pharmaceutical companies into OHCAs that should not otherwise have access to protected health information, and suggested that the Department change the language to make clear that an OHCA may include only professional staff members.

Final Rule

The final rule implements the technical, conforming, and clarifying changes as proposed. In response to the comments regarding which entities may participate in an OHCA, we clarify that a covered entity participating in an OHCA or the OHCA itself may contract with a business associate to provide certain functions, activities, or services on its behalf that involve access to protected health information, provided the applicable requirements of §§ 164.502(e), 164.504(e), 164.308(b) and 164.314(a) are met. Further, the definition of an organized health care arrangement (OHCA) at § 160.103 includes a clinically integrated care setting in which individuals typically receive health care from more than one health care provider. We modified § 164.506(c)(5) as discussed above in recognition of the fact that not all participants in a clinically integrated care setting may be covered entities (e.g., hospital with physicians with staff privileges that are not workforce members). Such change does not permit employers and pharmaceutical representatives to receive access to protected health information from or through an OHCA in a manner they would otherwise be prohibited from now.

V. Modifications to the Breach Notification Rule Under the HITECH Act

A. Background

Section 13402 of the HITECH Act requires HIPAA covered entities to provide notification to affected individuals and to the Secretary of HHS following the discovery of a breach of unsecured protected health information. In some cases, the Act requires covered entities also to provide notification to the media of breaches. In the case of a breach of unsecured protected health

information at or by a business associate of a covered entity, the Act requires the business associate to notify the covered entity of the breach. Finally, the Act requires the Secretary to post on an HHS Web site a list of covered entities that experience breaches of unsecured protected health information involving more than 500 individuals.

Section 13400(1) of the Act defines ''breach'' to mean, generally, the unauthorized acquisition, access, use, or disclosure of protected health information which compromises the security or privacy of such information. The Act includes three exceptions to this definition to encompass situations Congress clearly intended not to constitute breaches: (1) Unintentional acquisition, access, or use of protected health information by an employee or other person acting under the authority of a covered entity or business associate if such acquisition, access, or use was made in good faith and within the course and scope of the employment or other professional relationship of such person with the covered entity or business associate and such information is not further acquired, accessed, used, or disclosed by any person (section 13400(1)(B)(i)); (2) inadvertent disclosure of protected health information from one person authorized to access protected health information at a facility operated by a covered entity or business associate to another person similarly situated at the same facility and the information received is not further acquired, accessed, used or disclosed without authorization by any person (section 13400(1)(B)(ii) and (iii)); and (3) unauthorized disclosures in which an unauthorized person to whom protected health information is disclosed would not reasonably have been able to retain the information (section 13400(1)(A)).

Further, section 13402(h) of the Act defines ''unsecured protected health information'' as ''protected health information that is not secured through the use of a technology or methodology specified by the Secretary in guidance'' and provides that the guidance specify the technologies and methodologies that render protected health information unusable, unreadable, or indecipherable to unauthorized individuals. Covered entities and business associates that implement the specified technologies and methodologies with respect to protected health information are not required to provide notifications in the event of a breach of such information—that is, the information is not considered ''unsecured'' in such cases. As required by the Act, the Secretary initially issued this guidance on April 17, 2009 (it was subsequently published at 74 FR 19006 on April 27, 2009). The guidance listed and described encryption and destruction as the two technologies and methodologies for rendering protected health information unusable, unreadable, or indecipherable to unauthorized individuals.

In cases in which notification is required, the Act at section 13402 prescribes the timeliness, content, and methods of providing the breach notifications.

Section 13402 required HHS to issue within 180 days of enactment interim final regulations to implement these breach notification requirements. The Department issued an interim final rule on August 24, 2009, with a 60-day public comment period (74 FR 42740). The interim final rule became effective on September 23, 2009. In the preamble to the interim final rule, the Department also re-issued without substantive change its Guidance Specifying the Technologies and Methodologies That Render Protected Health Information Unusable, Unreadable, or Indecipherable to Unauthorized Individuals that was initially issued on April 17, 2009. The Guidance continues to specify encryption and destruction as the two methods for rendering protected health information unusable, unreadable, or indecipherable to unauthorized individuals—or ''secured''—and thus, exempt from the breach notification obligations. See 74 FR 42741–43.

B. Overview of the Interim Final Rule

The interim final rule added a new subpart D to part 164 of title 45 of the Code of Federal Regulations (CFR) to implement the breach notification provisions of section 13402 of the HITECH Act. In developing the interim final rule, the Department consulted closely with the Federal Trade Commission (FTC), which administers similar breach notification requirements on vendors of personal health records (PHRs) and their third party service providers under section 13407 of the HITECH Act. The interim final rule and FTC's Health Breach Notification Rule (74 FR 42962, published August 25, 2009) made clear that entities operating as HIPAA covered entities and business associates are subject to HHS', and not the FTC's, breach notification rule. Second, to address those limited cases where an entity may be subject to both HHS' and the FTC's rules, such as a vendor that offers PHRs to customers of a HIPAA covered entity as a business associate and also offers PHRs directly to the public, both sets of regulations were harmonized by including the same or similar language, within the constraints of the statutory language.

The 60-day public comment period on the interim final rule closed on October 23, 2009. The Department received approximately 120 comments during the comment period from a variety of entities, including health care providers, hospital and medical associations, health plans, educational institutions, information technology companies, privacy and security advocates, consumer groups, state agencies, and several members of Congress. The provisions of the interim final rule are discussed in more detail below, along with the public comments received, and the provisions of this final rule.

C. Section-by-Section Description of Final Rule and Response to Comments

1. Section 164.402—Definitions

a. Definition of ''Breach''

Interim Final Rule

Section 13400(1)(A) of the Act defines ''breach'' as the ''unauthorized acquisition, access, use, or disclosure of protected health information which compromises the security or privacy of such information, except where an unauthorized person to whom such information is disclosed would not reasonably have been able to retain such information.'' Section 13400(1)(B) of the Act provides two additional exceptions to the definition of ''breach.'' The interim final rule at 45 CFR 164.402 defined a ''breach'' to mean generally ''the acquisition, access, use, or disclosure of protected health information in a manner not permitted [by the Privacy Rule] which compromises the security or privacy of the protected health information.'' The definition included the statutory exceptions to the definition (discussed below) and clarified that ''unauthorized'' for purposes of the statute meant in a manner not permitted by the Privacy Rule.

In addition, for purposes of this definition, the rule provided that ''compromises the security or privacy of the protected health information'' means poses a significant risk of financial, reputational, or other harm to the individual. The Department included this standard regarding a significant risk of harm to the individual (i.e., harm standard) after considering public comment received in response to the Department's request for information on the HITECH Act's breach notification provisions. See 74 FR 19006. The inclusion of the harm standard was intended to align the Department's rule with many State

breach notification laws, as well as existing obligations on Federal agencies pursuant to OMB Memorandum M–07–16, that have similar standards for triggering breach notification. In addition, the standard was intended to ensure that consumers were not flooded with breach notifications for inconsequential events, which could cause unnecessary anxiety and eventual apathy among consumers.

To determine whether an impermissible use or disclosure of protected health information constitutes a breach under this standard, covered entities and business associates were required to perform a risk assessment to determine if there is a significant risk of harm to the individual as a result of the impermissible use or disclosure. In conducting the risk assessment, covered entities and business associates were to consider a number or combination of factors, including who impermissibly used the information or to whom the information was impermissibly disclosed; whether the covered entity or business associate had taken steps to mitigate or eliminate the risk of harm; whether the protected health information was actually accessed; and what type or amount of protected health information was impermissibly used or disclosed.

The rule provided further that an impermissible use or disclosure of protected health information that qualifies as a limited data set but also excludes dates of birth and zip codes (both identifiers that may otherwise be included in a limited data set) does not compromise the security or privacy of the protected health information. The Department included this narrow exception in the belief that it would be very difficult to re-identify a limited data set that excludes dates of birth and zip codes. Thus, a breach of such information would pose a low level of risk of harm to an individual.

The interim final rule also included the three statutory exceptions to the definition of breach. To implement section 13400(1)(B)(i) of the Act, the first regulatory exception provided that a breach excludes any unintentional acquisition, access, or use of protected health information by a workforce member or person acting under the authority of a covered entity or business associate, if such acquisition, access, or use was made in good faith and within the scope of authority and does not result in further use or disclosure in a manner not permitted by the Privacy Rule. We substituted the term ''workforce members'' for the statutory term ''employees'' because ''workforce member'' is a defined term for purposes of the HIPAA Rules and means employees, volunteers, trainees, and other persons whose conduct, in the performance of work for a covered entity or business associate, is under the direct control of such covered entity or business associate.

In addition to unintentional, good faith access to protected health information by workforce members, this exception covers similar access by a business associate of a covered entity or subcontractor with respect to a business associate or other person acting on behalf of a covered entity or business associate. The exception does not, however, cover situations involving snooping employees, because access as a result of such snooping would be neither unintentional nor done in good faith.

To implement section 13400(1)(B)(ii) and (iii) of the Act, the second regulatory exception provided that a breach excludes inadvertent disclosures of protected health information from a person who is authorized to access protected health information at a covered entity or business associate to another person authorized to access protected health information at the same covered entity, business associate, or organized health care arrangement in which the covered entity participates. The regulatory exception includes reference to an ''organized health care arrangement'' to capture, among other things, clinically integrated care settings in which individuals typically receive health care from more than one health care provider, such as a hospital, and the health care providers who have staff privileges at the hospital.

In this regulatory exception, we also interpreted the statutory limitations that the disclosure be to ''another person similarly situated at the same facility'' to mean that the disclosure be to another person authorized to access protected health information (even if the two persons may not be authorized to access the same types of protected health information) at the same covered entity, business associate, or organized health care arrangement in which the covered entity participates (even if the covered entity, business associate, or organized health care arrangement has multiple facilities or locations across the country).

Finally, to implement section 13400(1)(A) of the Act, the interim final rule exempted disclosures of protected health information where a covered entity or a business associate has a good faith belief that an unauthorized person to whom the disclosure was made would not reasonably have been able to retain such information. For example, if a covered entity, due to a lack of reasonable safeguards, sends a number of explanations of benefits (EOBs) to the wrong individuals and a few of the EOBs are returned by the post office, unopened, as undeliverable, the covered entity can conclude that the improper addressees could not reasonably have retained the information. The EOBs that were not returned as undeliverable, however, and that the covered entity knows were sent to the wrong individuals, should be treated as potential breaches. As another example, if a nurse mistakenly hands a patient the discharge papers belonging to another patient, but she quickly realizes her mistake and recovers the protected health information from the patient, this would not constitute a breach if the nurse can reasonably conclude that the patient could not have read or otherwise retained the information.

With respect to any of the three exceptions discussed above, a covered entity or business associate has the burden of proof, pursuant to § 164.414(b) (discussed below), for showing why breach notification was not required. Accordingly, the covered entity or business associate must document why the impermissible use or disclosure falls under one of the above exceptions.

Overview of Public Comments

Of the approximately 85 public comments received on the interim final rule addressing the definition of breach, approximately 70 of those comments addressed the harm standard and risk assessment approach in the interim final rule. We received approximately 60 comments in support of the harm standard and the risk assessment approach. The commenters in support of this approach included providers, health plans, professional associations, and certain members of Congress. These commenters argued that the inclusion of the harm standard and accompanying risk assessment was consistent with the statutory language, aligned the interim final rule with many State breach notification laws and Federal policies, and appropriately placed the obligation to determine if a breach had occurred on covered entities and business associates since they had the requisite knowledge of the incident to best assess the likely impact of the impermissible use or disclosure.

The proponents of the harm standard and risk assessment approach also argued that its removal would increase the cost and burden of implementing the rule for covered entities, business associates, as well as HHS, and may cause unnecessary anxiety and eventual

apathy among consumers if notifications are sent when there is no risk of harm to the individual.

We also received approximately 10 comments opposed to the harm standard. Generally, the commenters opposed to this approach were members of Congress and consumer advocacy groups. Some opponents of the harm standard argued that its addition to the interim final rule set too high a bar for triggering breach notification, which was contrary to statutory intent. These commenters argued that the final rule should adopt a bright line standard for breach notification to ensure that individuals are aware of all impermissible uses and disclosures of their health information regardless of the potential risk and to make implementation and enforcement of the rule more uniform by removing the discretion and judgment given to covered entities in the interim final rule. These commenters argued that such transparency would better breed consumer trust and would allow individuals to assess the risk of harm themselves and take necessary measures to mitigate an impermissible use or disclosure of their health information.

Other commenters, while opposed to a harm standard to trigger breach notification, nonetheless agreed that breach notification should not be required following every impermissible use or disclosure of unsecured protected health information no matter how inconsequential the breach. These commenters argued that, rather than a subjective standard measuring the risk of harm to an individual, the final rule should include a more objective standard against which entities would be required to assess risk. These commenters suggested that the risk assessment should focus on the risk that the protected health information was compromised instead of on the risk of harm to the individual. Additionally, these commenters proposed four factors that should be considered to determine whether the information was compromised: (1) To whom the information was impermissibly disclosed; (2) whether the information was actually accessed or viewed; (3) the potential ability of the recipient to identify the subjects of the data; and (4) in cases where the recipient is the disclosing covered entity's business associate or is another covered entity, whether the recipient took appropriate mitigating action.

Some commenters stated that the default function of the rule was unclear. In particular, these commenters questioned whether the rule required notification of a breach unless it is determined that a significant risk of harm does not exist, or alternatively, required notification only in cases where significant risk of harm can be demonstrated. Other commenters suggested that we include in the definition an express presumption of a breach unless an entity can show otherwise.

Additionally, many commenters responded to the treatment of limited data sets in the interim final rule. Although many commenters expressed support for the assertion that limited data sets that do not contain dates of birth and zip codes do not compromise the security or privacy of protected health information, most of these commenters expressed concern that the interim final rule did not go far enough and should exempt even those limited data sets that contain dates of birth and/or zip codes from the breach notification requirements. These commenters argued that no impermissible use or disclosure of a limited data set should trigger breach notification obligations because without the 16 direct identifiers that the Privacy Rule requires to be stripped from the information, there is minimal risk of harm to the individual. Additionally, commenters indicated it would be costly and burdensome for entities to have to re-identify the information in a limited data set to provide notification and that re-identifying the information could also pose an additional risk of harm to the affected individuals. Finally, other commenters noted that because researchers commonly rely on limited data sets that contain dates of birth and zip codes, researchers would not be able to take advantage of the exception for certain limited data sets in the interim final rule, which may have the effect of deterring research.

In contrast, some commenters expressed concern regarding the inclusion of even the limited exception to the definition of breach for limited data sets that do not include dates of birth and zip codes. These commenters supported requiring entities to perform a risk assessment to determine whether an impermissible use or disclosure of such information compromised the security or privacy of the information, as there may be a risk of re-identification of this information depending on who received the information.

Final Rule

After considering the public comments on the definition, the Department in this final rule amends the definition of ''breach'' at 45 CFR 164.402. Based on the comments, we recognize that the language used in the interim final rule and its preamble could be construed and implemented in manners we had not intended. Accordingly, this final rule modifies and clarifies the definition of breach and the risk assessment approach outlined in the interim final rule.

First, we have added language to the definition of breach to clarify that an impermissible use or disclosure of protected health information is presumed to be a breach unless the covered entity or business associate, as applicable, demonstrates that there is a low probability that the protected health information has been compromised. We recognize that some persons may have interpreted the risk of harm standard in the interim final rule as setting a much higher threshold for breach notification than we intended to set. As a result, we have clarified our position that breach notification is necessary in all situations except those in which the covered entity or business associate, as applicable, demonstrates that there is a low probability that the protected health information has been compromised (or one of the other exceptions to the definition of breach applies). We believe that the express statement of this presumption in the final rule will help ensure that all covered entities and business associates interpret and apply the regulation in a uniform manner and also responds to commenters that indicated the default function of the rule was unclear. This new language is also consistent with § 164.414, which provides that covered entities and business associates have the burden of proof to demonstrate that all notifications were provided or that an impermissible use or disclosure did not constitute a breach (such as by demonstrating through a risk assessment that there was a low probability that the protected health information had been compromised) and must maintain documentation sufficient to meet that burden of proof.

Second, to further ensure that this provision is applied uniformly and objectively by covered entities and business associates, we have removed the harm standard and modified the risk assessment to focus more objectively on the risk that the protected health information has been compromised. Thus, breach notification is not required under the final rule if a covered entity or business associate, as applicable, demonstrates through a risk assessment that there is a low probability that the protected health information has been compromised, rather than demonstrate that there is no significant risk of harm to the individual as was provided under

the interim final rule. The final rule also identifies the more objective factors covered entities and business associates must consider when performing a risk assessment to determine if the protected health information has been compromised and breach notification is necessary.

Although some commenters urged us to implement a bright line standard, requiring notification for all impermissible uses and disclosures without any assessment of risk, we believe that a risk assessment is necessary. The statute acknowledges, by including a specific definition of breach and identifying exceptions to this definition, as well as by providing that an unauthorized acquisition, access, use, or disclosure of protected health information must compromise the security or privacy of such information to be a breach, that there are several situations in which unauthorized acquisition, access, use, or disclosure of protected health information is so inconsequential that it does not warrant notification. In addition to the statutory exceptions that have been included in both the interim final rule and this final rule, there may be other similar situations that do not warrant breach notification. We agree with commenters that providing notification in such cases may cause the individual unnecessary anxiety or even eventual apathy if notifications of these types of incidents are sent routinely. For example, if a covered entity misdirects a fax containing protected health information to the wrong physician practice, and upon receipt, the receiving physician calls the covered entity to say he has received the fax in error and has destroyed it, the covered entity may be able to demonstrate after performing a risk assessment that there is a low risk that the protected health information has been compromised. Although this scenario does not fit into any of the statutory or regulatory exceptions, we believe that, like the exceptions to breach, notification should not be required if the covered entity demonstrates a low probability that the data has been compromised.

Commenters argued that a rule containing a bright line standard for notification would be easier for both the regulated entities to implement and for HHS to enforce. We disagree. Although a rule that required notification following every impermissible use or disclosure may appear easier for covered entities and business associates to implement—as no determination of the risk that the protected health information has been compromised would be required—in effect, a bright line standard would be extremely burdensome and costly for entities to implement. With no risk assessment following an impermissible use or disclosure, entities may be required to provide many notices each year for incidents that did not compromise the security or privacy of an individual's protected health information.

Although we do not believe a bright line approach to breach notification is appropriate, we do agree with the commenters who expressed concern that the risk assessment focus on ''harm to an individual'' in the interim final rule was too subjective and would lead to inconsistent interpretations and results across covered entities and business associates. As a result, instead of assessing the risk of harm to the individual, covered entities and business associates must assess the probability that the protected health information has been compromised based on a risk assessment that considers at least the following factors: (1) The nature and extent of the protected health information involved, including the types of identifiers and the likelihood of re-identification; (2) the unauthorized person who used the protected health information or to whom the disclosure was made; (3) whether the protected health information was actually acquired or viewed; and (4) the extent to which the risk to the protected health information has been mitigated. We believe that the use of these factors, which are derived from the factors listed in the interim final rule as well as many of the factors suggested by commenters, will result in a more objective evaluation of the risk to the protected health information and a more uniform application of the rule.

As we have modified and incorporated the factors that must be considered when performing a risk assessment into the regulatory text, covered entities and business associates should examine their policies to ensure that when evaluating the risk of an impermissible use or disclosure they consider all of the required factors. In addition, given the circumstances of the impermissible use or disclosure, additional factors may need to be considered to appropriately assess the risk that the protected health information has been compromised. We note that, although we have included this risk assessment in the final rule, this type of assessment of risk should not be a new or different exercise for covered entities and business associates. Similar assessments of risk that data have been compromised must be performed routinely following security breaches and to comply with certain State breach notification laws.

The first factor requires covered entities and business associates to evaluate the nature and the extent of the protected health information involved, including the types of identifiers and the likelihood of re-identification of the information. To assess this factor, entities should consider the type of protected health information involved in the impermissible use or disclosure, such as whether the disclosure involved information that is of a more sensitive nature. For example, with respect to financial information, this includes credit card numbers, social security numbers, or other information that increases the risk of identity theft or financial fraud. With respect to clinical information, this may involve considering not only the nature of the services or other information [11] but also the amount of detailed clinical information involved (e.g., treatment plan, diagnosis, medication, medical history information, test results). Considering the type of protected health information involved in the impermissible use or disclosure will help entities determine the probability that the protected health information could be used by an unauthorized recipient in a manner adverse to the individual or otherwise used to further the unauthorized recipient's own interests. Additionally, in situations where there are few, if any, direct identifiers in the information impermissibly used or disclosed, entities should determine whether there is a likelihood that the protected health information released could be re-identified based on the context and the ability to link the information with other available information.[12] For example, if a covered entity impermissibly disclosed a list of patient names, addresses, and hospital identification numbers, the protected health information is obviously identifiable, and a risk assessment likely would determine that there is more than a low probability that the information has been compromised, dependent on an assessment of the other factors discussed below. Alternatively, if the covered entity disclosed a list of patient discharge dates and diagnoses, the

[11] We caution that many forms of health information, not just information about sexually transmitted diseases or mental health or substance abuse, are sensitive.

[12] Information that has been de-identified in accordance with 45 CFR 164.514(a)–(c) is not protected health information, and thus, any inadvertent or unauthorized use or disclosure of such information is not considered a breach for purposes of this rule.

entity would need to consider whether any of the individuals could be identified based on the specificity of the diagnosis, the size of the community served by the covered entity, or whether the unauthorized recipient of the information may have the ability to combine the information with other available information to re-identify the affected individuals (considering this factor in combination with the second factor discussed below). We emphasize, however, that the entity must evaluate all the factors, including those discussed below, before making a determination about the probability of risk that the protected health information has been compromised.

The second factor requires covered entities and business associates to consider the unauthorized person who impermissibly used the protected health information or to whom the impermissible disclosure was made. Entities should consider whether the unauthorized person who received the information has obligations to protect the privacy and security of the information. For example, as discussed in the interim final rule, if protected health information is impermissibly disclosed to another entity obligated to abide by the HIPAA Privacy and Security Rules or to a Federal agency obligated to comply with the Privacy Act of 1974 and the Federal Information Security Management Act of 2002, there may be a lower probability that the protected health information has been compromised since the recipient of the information is obligated to protect the privacy and security of the information in a similar manner as the disclosing entity. We also emphasize that this factor should be considered in combination with the factor discussed above regarding the risk of re-identification. If the information impermissibly used or disclosed is not immediately identifiable, entities should determine whether the unauthorized person who received the protected health information has the ability to re-identify the information. For example, if information containing dates of health care service and diagnoses of certain employees was impermissibly disclosed to their employer, the employer may be able to determine that the information pertains to specific employees based on other information available to the employer, such as dates of absence from work. In this case, there may be more than a low probability that the protected health information has been compromised.

Several commenters suggested that a risk assessment need be completed following only impermissible disclosures of protected health information, since information impermissibly ''used'' remains within the covered entity or business associate. We disagree. The final rule requires a risk assessment to be performed following both impermissible uses and disclosures (that do not otherwise fall within the other enumerated exceptions to breach). However, the fact that information only is impermissibly used within a covered entity or business associate and the impermissible use does not result in further impermissible disclosure outside the entity, is something that may be taken into account in conducting the risk assessment and may reduce the probability that the protected health information has been compromised.

The third factor requires covered entities and business associates to investigate an impermissible use or disclosure to determine if the protected health information was actually acquired or viewed or, alternatively, if only the opportunity existed for the information to be acquired or viewed. For example, as we discussed in the interim final rule, if a laptop computer was stolen and later recovered and a forensic analysis shows that the protected health information on the computer was never accessed, viewed, acquired, transferred, or otherwise compromised, the entity could determine that the information was not actually acquired by an unauthorized individual even though the opportunity existed. In contrast, however, if a covered entity mailed information to the wrong individual who opened the envelope and called the entity to say that she received the information in error, then, in this case, the unauthorized recipient viewed and acquired the information because she opened and read the information to the extent that she recognized it was mailed to her in error.

The final factor included in the final rule requires covered entities and business associates to consider the extent to which the risk to the protected health information has been mitigated. Covered entities and business associates should attempt to mitigate the risks to the protected health information following any impermissible use or disclosure, such as by obtaining the recipient's satisfactory assurances that the information will not be further used or disclosed (through a confidentiality agreement or similar means) or will be destroyed, and should consider the extent and efficacy of the mitigation when determining the probability that the protected health information has been compromised. We note that this factor, when considered in combination with the factor regarding the unauthorized recipient of the information discussed above, may lead to different results in terms of the risk to the protected health information. For example, a covered entity may be able to obtain and rely on the assurances of an employee, affiliated entity, business associate, or another covered entity that the entity or person destroyed information it received in error, while such assurances from certain third parties may not be sufficient. As described above, certain commenters suggested that mitigation should only be considered where the recipient of the information is a business associate of the covered entity or another covered entity. We do not in this rule limit this factor to those circumstances but, as discussed above, acknowledge that the recipient of the information will have an impact on whether the covered entity can conclude that an impermissible use or disclosure has been appropriately mitigated.

A covered entity's or business associate's analysis of the probability that protected health information has been compromised following an impermissible use or disclosure must address each factor discussed above. Other factors may also be considered where necessary. Covered entities and business associates must then evaluate the overall probability that the protected health information has been compromised by considering all the factors in combination, and we expect these risk assessments to be thorough, completed in good faith, and for the conclusions reached to be reasonable. If an evaluation of the factors discussed above fails to demonstrate that there is a low probability that the protected health information has been compromised, breach notification is required. We do note, however, that a covered entity or business associate has the discretion to provide the required notifications following an impermissible use or disclosure of protected health information without performing a risk assessment. Because the final rule clarifies the presumption that a breach has occurred following every impermissible use or disclosure of protected health information, entities may decide to notify without evaluation of the probability that the protected health information has been compromised. In the future, we will issue additional guidance to aid covered entities and business associates in performing risk assessments with respect to frequently occurring scenarios.

In addition to the removal of the harm standard and the creation of more objective factors to evaluate the probability that protected health information has been compromised, we have removed the exception for limited data sets that do not contain any dates of birth and zip codes. In the final rule, following the impermissible use or disclosure of any limited data set, a covered entity or business associate must perform a risk assessment that evaluates the factors discussed above to determine if breach notification is not required.

The vast majority of commenters were not supportive of the exception for certain limited data sets outlined in the interim final rule, either because they believed the exception did not go far enough and would chill research that needed access to birth dates and zip codes in limited data sets, or because of concerns regarding the re-identifiability of the limited information to which the exception applied. Based on the comments, we believe it is appropriate to require the impermissible use or disclosure of a limited data set, even those that do not contain dates of birth and zip codes, to be subject to a risk assessment to demonstrate that breach notification is not required. The final rule expressly includes a factor that would require consideration of the re-identifiability of the information, as well a factor that requires an assessment of the unauthorized person who used the protected health information or to whom the disclosure was made (i.e., whether this person has the ability to re-identify the affected individuals). Thus, the factors are particularly suited to address the probability that a data set without direct identifiers has been compromised following an impermissible use or disclosure. Further, we believe in most cases that the result would be the same under this final rule as under the interim final rule with respect to whether an impermissible use or disclosure of a limited data set that also excludes dates of birth and zip codes constitutes a breach for which notification is required. Due to the lack of identifiers present in the protected health information, entities may reasonably determine that there is a low probability of risk that the information has been compromised; however, we stress that this is a fact specific determination to be made based on the circumstances of the impermissible use or disclosure.

We encourage covered entities and business associates to take advantage of the safe harbor provision of the breach notification rule by encrypting limited data sets and other protected health information pursuant to the Guidance Specifying the Technologies and Methodologies that Render Protected Health Information Unusable, Unreadable, or Indecipherable to Unauthorized Individuals (74 FR 42740, 42742). If protected health information is encrypted pursuant to this guidance, then no breach notification is required following an impermissible use or disclosure of the information.

In addition to the comments discussed above, it was suggested that covered entities be required to include in their notice of privacy practices information about how a risk assessment will be conducted or their internal policies for determining whether a breach has occurred and notification is warranted. It was also suggested that the breach notice to the individual following discovery of a breach of unsecured protected health information contain information about the covered entity or business associate's risk assessment to help the individual better assess the level of threat posed by the breach and to better determine the appropriate steps, if any, to take.

We decline to require that the covered entity's notice of privacy practices include a description of how a risk assessment will be conducted, although covered entities may include such information in their notice of privacy practices if they choose. While each risk assessment will differ depending on the specific facts and circumstances surrounding the impermissible use or disclosure, we believe that the modifications in this final rule will help ensure that covered entities and business associates perform risk assessments more uniformly and objectively. We also note that the content requirements for the notice to the individual outlined in § 164.404(c) already require that the individual be notified of the circumstances of a breach, as well as what steps individuals should take to protect themselves from potential harm resulting from the breach.

One commenter suggested that we require a covered entity to hire an independent organization to assess the risk of an impermissible use or disclosure to determine if breach notification is required. We do not believe such a requirement is necessary, although covered entities are free to engage independent organizations to assist in making such determinations provided that, if access to protected health information is required, business associate agreements are entered into to protect the information. Further, we believe the modifications in this final rule are conducive to more uniform risk assessments across covered entities and business associates. Additionally, as with the interim final rule, we note that covered entities and business associates have the burden of proof, pursuant to § 164.414, to demonstrate that all notifications were provided or that an impermissible use or disclosure did not constitute a breach and to maintain documentation (e.g., of the risk assessment demonstrating that there was a low probability that the protected health information had been compromised or of the assessment that the impermissible use or disclosure falls within one of the other exceptions to breach), pursuant to 45 CFR 164.530(j)(1)(iv), as necessary to meet this burden of proof. Thus, covered entities and business associates have adequate incentive to conduct reasonable and diligent risk assessments.

Finally, after reviewing and considering the comments received regarding the exceptions to the definition of breach in the interim final rule, the Department adopts these exceptions without modification in this final rule. Although the substance of these exceptions has not changed, these exceptions are now located at paragraph (1) of the definition of breach instead of paragraph (2) to accommodate the modifications discussed above. We respond to the public comments addressing these exceptions, as well as other comments received on the definition of ''breach,'' below.

Response to Other Public Comments

Comment: Many commenters expressed concern that violations of the minimum necessary standard may trigger breach notification obligations.

Response: We do not believe it would be appropriate to exempt minimum necessary violations from the breach notification obligations as we do not believe that all minimum necessary violations present a low probability that the protected health information has been compromised. Thus, uses or disclosures that impermissibly involve more than the minimum necessary information, in violation of §§ 164.502(b) and 164.514(d), may qualify as breaches. Such incidents must be evaluated as any other impermissible uses or disclosures to determine whether breach notification is not required.

As explained above, there are several factors to be considered when determining the probability that the protected health information involved in an impermissible use or disclosure has been compromised, including the

unauthorized person who used the information or to whom the disclosure was made. Thus, where a minimum necessary violation occurs in a disclosure to a business associate or as an internal use within a covered entity or business associate, the fact that the information was not acquired by a third party would be considered as part of the risk assessment and may help lead to the conclusion that there is a low probability that the protected health information has been compromised. Alternatively, covered entities and business associates may determine that certain minimum necessary violations fall within the exceptions to the definition of breach at § 164.402(1)(i) or (1)(ii).

We note that the Privacy Rule's minimum necessary standard requires a covered entity to make reasonable efforts to limit access to protected health information to those persons or classes of persons who need access to protected health information to carry out their duties and to disclose an amount of protected health information reasonably necessary to achieve the purpose of a disclosure. The Privacy Rule requires covered entities to determine and define in their policies and procedures how the minimum necessary standard applies to their own uses and disclosures. Thus, covered entities are in a good position to know when such policies and procedures have been violated and to assess the probability that the incident has compromised the security or privacy of the information. Finally, we will consider including further guidance regarding the interaction between the minimum necessary standard and the breach notification requirements in the guidance required by section 13405(b)(1)(B) of the HITECH Act.

Comment: Several commenters asked that we clarify the differences between ''acquisition,'' ''access,'' ''use,'' and ''disclosure'' in the exceptions in the final rule. These commenters expressed confusion regarding the use of these terms in the first two exceptions to the definition of breach, stating that the term ''acquisition'' connotes a disclosure of information, and thus, the exception regarding unintentional acquisition, access, or use of protected health information by a workforce member or person acting under the authority of a covered entity or business associate implicitly includes disclosures of protected health information.

Response: While the Privacy Rule uses the terms ''use'' and ''disclosure,'' we included both ''acquisition'' and ''access'' in the regulatory text for consistency with the statutory language. We interpret ''acquisition'' and ''access'' to information based on their plain meanings and believe that both terms are encompassed within the current definitions of ''use'' and ''disclosure'' in the HIPAA Rules. For example, an acquisition may be a ''use'' or ''disclosure'' depending on who acquired the information—i.e., a workforce member or someone outside the covered entity, such as a business associate.

Comment: Several commenters supported our interpretations of the statutory terms ''employee,'' ''same facility,'' and ''similarly situated individual'' with respect to the exceptions to the definition of breach.

Response: We retain these clarifications in this final rule.

Comment: Some commenters asked that we use the term ''use'' instead of ''disclosure'' to describe the type of information exchange contemplated by the exception for certain inadvertent disclosures among persons similarly authorized to access protected health information at a covered entity or business associate since the information must be shared within a covered entity or business associate for the exception to apply.

Response: We clarify that the exception at paragraph (1)(ii) of the definition of ''breach'' is intended to apply to certain ''disclosures'' that may occur ''at'' a covered entity, business associate, or organized health care arrangement in which the covered entity participates—e.g., to persons onsite at a covered entity's facility that are not workforce members, such as physicians with staff privileges at a hospital. For impermissible ''uses'' of protected health information among workforce members of a covered entity or a business associate, a covered entity or business associate should determine whether the exception to breach at paragraph (1)(i) regarding certain unintentional acquisition, access, or use by a workforce member or person acting under the authority of a covered entity or business associate applies.

Comment: One commenter asked if breach notification is required in cases where an impermissible use or disclosure originally qualifies for either of the exceptions to breach at § 164.402(1)(i) or (1)(ii) at the time the incident occurs but later no longer fits within the exception because the protected health information is further used or disclosed in an impermissible manner.

Response: The applicability of an exception to breach must be judged at the time the incident is discovered and evaluated. If an exception to breach is determined to apply such that notification is not warranted, the inquiry into that breach ends; however, the covered entity or business associate should take appropriate steps to ensure that the information is not further used or disclosed impermissibly. If, sometime after making the determination that the exception applied, the information is impermissibly used or disclosed, the covered entity or business associate should treat that incident as a separate impermissible use or disclosure that warrants evaluation as a breach on its own. As explained more fully below, we treat a breach as having occurred at the time of the impermissible use or disclosure, which in the case of the first two exceptions to breach, is at the time of the ''further'' impermissible use or disclosure.

Comment: One commenter asked that we broaden the application of the inadvertent disclosure exception to apply to all routine disclosures between covered entities. Other commenters asked that the rule exempt from the breach notification obligations situations in which a covered entity discloses information to a business associate or another covered entity. Commenters noted that because covered entities and business associates are required to protect the privacy of protected health information, there is little risk that even an impermissible disclosure between such entities would compromise the security or privacy of the information.

Response: We do not agree that such situations warrant a blanket exception from the breach notification rules. In appropriate cases, some of these impermissible disclosures among covered entities and covered entities and business associates may fall within the existing exceptions to breach at paragraphs (1)(i) and (ii) of the definition. Otherwise, such disclosures must be evaluated as to the probability that the protected health information has been compromised based on a risk assessment of a number of factors. While the fact that the recipient of an impermissible disclosure is a covered entity or business associate with obligations to protect the privacy and security of protected health information is a consideration with respect to assessing the risk that the protected health information has been compromised, it is not the only factor. For example, a covered entity or business associate must also evaluate the extent to which the risk to the protected health information has been mitigated.

Comment: Several commenters suggested that the exceptions to breach should not apply to situations where

workforce members or employees further use or disclose information they unintentionally or inadvertently acquired, accessed, or used, even if such further use or disclosure is permitted under the Privacy Rule. Additionally, these commenters suggested that the breach exceptions should apply only in cases in which the workforce member or employee has taken appropriate steps to mitigate the unintentional acquisition, access, or use of protected health information, such as by alerting the sender of the misdirected information, if applicable, and returning or destroying it.

Response: We do not believe it is appropriate to prohibit the sharing of protected health information for permissible purposes following an unintentional or inadvertent error by a workforce member or an employee. Doing so would restrict access and disclosure of the protected health information for necessary treatment and other important purposes to the extent the workforce member or employee needed access to the information in the future for authorized purposes, which would adversely affect health care delivery. We believe that the rule strikes an appropriate balance by not allowing workforce member errors to be excepted from the definition of breach in cases where the workforce member takes the information he or she has mistakenly obtained and then misuses it.

With respect to requiring workforce members or employees to take appropriate steps to mitigate their unintentional access to protected health information, we note that the Privacy Rule already requires covered entities to ensure as part of their minimum necessary policies and procedures that workforce members have appropriate access to protected health information. Therefore, covered entities should ensure that workforce members who gain access in an unauthorized manner to protected health information do not continue to have such unauthorized access. This may require having policies which require workforce members to return or destroy the information to which they obtained unauthorized access. Further, covered entities must implement reasonable safeguards to protect against impermissible uses and disclosures, including further impermissible uses and disclosures by a workforce member who has gained unauthorized access to protected health information.

Comment: One commenter asked that we include an exception in the final rule for situations in which a laptop is lost and recovered and a forensic analysis shows that the protected health information on the computer was not accessed. The commenter stated that because the forensic analysis showed that the information was not compromised, a risk assessment should not be required.

Response: We do not include an explicit exception for this particular scenario. As we explained above, in cases where a lost laptop is recovered, the fact that a forensic analysis of the computer shows that its information was not accessed is a relevant consideration for the risk assessment, and entities in such situations may be able to demonstrate a low probability that the information has been compromised. However, covered entities and business associates still must document their risk assessments in these cases. We also note, as we did in the interim final rule, if a computer is lost or stolen, we do not consider it reasonable to delay breach notification based on the hope that the computer will be recovered.

Comment: Some commenters asked that we create an exception to breach to cover certain routine impermissible disclosures of protected health information. For example, commenters asked that we except from notification disclosures made as a result of the covered entity mailing information to a patient's old address, faxing information to the wrong number, disclosures made as a result of leaving a voice message at the wrong number reminding a patient of an upcoming appointment, or, in situations where patients have identical or similar names, contacting the wrong patient to inform him or her that lab results were ready.

Response: We decline to create such an exception. The ability of a covered entity or business associate to demonstrate that a particular situation poses a low probability that the protected health information was compromised is very fact specific and will depend on an assessment of all of the factors discussed above, such as to whom the information was disclosed, what information was disclosed, and what mitigation has taken place. We also note that, in some cases, some of the situations contemplated by the commenters may fall within an existing exception. For example, if a covered entity mails protected health information about an individual to a wrong address, the impermissible disclosure may fall into the exception at paragraph (1)(iii) of the definition of breach if the information is returned, undelivered and unopened, to the covered entity, such that an unauthorized recipient could not reasonably have retained the information. If, however, the information was not returned or if the covered entity was informed by the unauthorized recipient that he had received and opened the mail in error, the covered entity would need to complete a risk assessment to determine the probability that the protected health information had been compromised as a result of the impermissible disclosure.

Comment: Several commenters asked that we harmonize the final rule with the FTC's Health Breach Notification final rule.

Response: Although the FTC and HHS breach notification rules generally apply to different entities, HHS has worked closely with the FTC to ensure both sets of regulations were harmonized to the greatest extent possible by including the same or similar requirements within the constraints of the statutory language. In addition, in the few situations where an entity provides PHRs to customers of a HIPAA covered entity through a business associate arrangement but also provides PHRs directly to the public and a breach of its records occurs, in certain cases, the FTC will deem compliance with certain provisions of HHS' rule as compliance with FTC's rule. See 74 FR 42964. In particular, in such situations, it may be appropriate for the vendor to provide the same breach notice to all its PHR customers since it has a direct relationship with all the affected individuals. Thus, in those limited circumstances where a vendor of PHRs (1) provides notice to individuals on behalf of a HIPAA covered entity, (2) has dealt directly with these individuals in managing their PHR accounts, and (3) provides notice to its customers at the same time, the FTC will deem compliance with HHS requirements governing the timing, method, and content of notice to be compliance with the corresponding FTC rule provisions. Note, however, that the PHR vendor still must comply with all other FTC rule requirements, including the requirement to notify the FTC within ten business days after discovering the breach.

b. Definition of ''Unsecured Protected Health Information''

Interim Final Rule

Section 13402(h)(1)(A) of the Act defines ''unsecured protected health information'' as ''protected health information'' that is not secured through the use of a technology or methodology specified by the Secretary in guidance issued under [section 13402(h)(2)].'' The Act at section 13402(h)(2) requires that the Secretary specify in the guidance the technologies and methodologies that

render protected health information unusable, unreadable, or indecipherable to unauthorized individuals. Accordingly, the interim final rule defined ''unsecured protected health information'' as protected health information that is not rendered unusable, unreadable, or indecipherable to unauthorized individuals through the use of a technology or methodology specified by the Secretary in guidance. This guidance, which was published in updated form within the preamble to the interim final rule and made available on the HHS Web site, specifies that only encryption and destruction, consistent with National Institute of Standards and Technology (NIST) guidelines, renders protected health information unusable, unreadable, or indecipherable to unauthorized individuals such that notification is not required in the event of a breach of such information.

Overview of Public Comments

While we received a number of technical and other comments on the guidance, we did not receive any comments on the language of the above definition itself. We intend to address the comments on the guidance in our next update to the guidance.

Final Rule

The final rule modifies the interim final rule's definition of ''unsecured protected health information'' to replace the term ''unauthorized individuals'' in the definition with ''unauthorized persons.'' The term ''individual'' is defined in § 160.103 to mean the person who is the subject of the protected health information, which is not what is intended with the reference to ''individual'' in the definition of ''unsecured protected health information.'' Accordingly, the final rule uses more appropriately the term ''unauthorized persons.'' The final rule also modifies the definition to remove the term ''on the HHS Web site'' as unnecessary language. While we remove the reference to the HHS Web site from the regulatory text, we do plan to continue to post updates to the guidance on the Web site as they are issued.

2. Section 164.404—Notification to Individuals

Interim Final Rule

Section 13402(a) of the Act provides that a covered entity that accesses, maintains, retains, modifies, records, stores, destroys, or otherwise holds, uses, or discloses unsecured protected health information shall, in the case of a breach of such information that is discovered by the covered entity, notify each affected individual whose unsecured protected health information has been, or is reasonably believed by the covered entity to have been, accessed, acquired, or disclosed as a result of such breach. Accordingly, § 164.404(a)(1) of the interim final rule included the general rule that a covered entity shall, following the discovery of a breach of unsecured protected health information, notify each individual whose unsecured protected health information has been, or is reasonably believed to have been accessed, acquired, used, or disclosed as a result of such breach.

Breaches Treated as Discovered

Section 13402(c) of the HITECH Act states that a breach shall be treated as discovered by a covered entity or business associate as of the first day on which such breach is known or should reasonably have been known to the covered entity or business associate. The Act also specifies that this discovery is triggered as soon as any person, other than the individual committing the breach, who is an employee, officer, or other agent of the covered entity or business associate knows or should reasonably have known of the breach.

Section 164.404(a)(2) of the interim final rule implemented the Act's discovery provision, with respect to covered entities by stating that a breach shall be treated as discovered by a covered entity on the first day the breach is known to the covered entity, or by exercising reasonable diligence would have been known to the covered entity. The interim final rule incorporated the term ''by exercising reasonable diligence,'' which is used in the HIPAA Enforcement Rule and defined to mean the ''business care and prudence expected from a person seeking to satisfy a legal requirement under similar circumstances.''

Section 164.404(a)(2) of the interim final rule further provided, in accordance with the Act, that a covered entity is deemed to have knowledge of a breach if such breach is known, or by exercising reasonable diligence would have been known, to any person other than the person committing the breach, who is a workforce member or agent of the covered entity. Thus, the breach is treated as discovered by the covered entity at the time the workforce member or other agent has knowledge of the breach. The rule also clarified that the federal common law of agency controls in determining who is an agent of the covered entity, which is consistent with how agency liability is determined under the HIPAA Rules.

Overview of Public Comments

Several commenters argued that a breach should be treated as discovered by a covered entity only after management has been notified of the incident. Commenters stated that the Department should not hold an entity responsible for knowing of a breach if an appropriately trained employee fails to inform the proper persons within the entity of a breach. Other commenters asked for guidance and more clarification regarding what it means for a covered entity or business associate to be exercising reasonable diligence, such as what frequency of monitoring for breaches is expected or what types of systems must covered entities and business associates have in place to detect breaches.

Final Rule

We retain § 164.404(a)(2) in this final rule without modification. We decline to adopt the suggestion that a covered entity be deemed to have discovered a breach only when management is notified of the breach. The HITECH Act itself provides that a breach is to be treated as discovered by a covered entity or business associate if ''any person, other than the individual committing the breach, that is an employee, officer, or other agent of such entity or associate'' knows or should reasonably have known of the breach. This concept is also consistent with the HIPAA Enforcement Rule and the Federal common law of agency. We encourage covered entities and business associates to ensure their workforce members and other agents are adequately trained on the importance of prompt reporting of privacy and security incidents.

With respect to those commenters asking for guidance on what it means for a covered entity to be exercising reasonable diligence, we note that the term reasonable diligence, as defined in § 160.401, means the business care and prudence expected from a person seeking to satisfy a legal requirement under similar circumstances. The determination of whether a person acted with reasonable diligence is generally a factual one, since what is reasonable depends on the circumstances. Factors to be considered include whether a covered entity or business associate took reasonable steps to learn of breaches and whether there were indications of breaches that a person seeking to satisfy the Rule would have investigated under similar circumstances. Covered entities and business associates may wish to look to how other covered entities and business associates operating under

similar circumstances conduct themselves for a standard of practice.

Timeliness

Section 13402(d) of the Act and the implementing regulations at § 164.404(b) require covered entities to notify individuals of a breach without unreasonable delay but in no case later than 60 calendar days from the discovery of the breach, except in certain circumstances where law enforcement has requested a delay. Under this rule, the time period for breach notification begins when the incident is first known, not when the investigation of the incident is complete, even if it is initially unclear whether the incident constitutes a breach as defined in the rule. A covered entity is expected to make the individual notifications as soon as reasonably possible after the covered entity takes a reasonable time to investigate the circumstances surrounding the breach in order to collect and develop the information required to be included in the notice to the individual. The 60 days is an outer limit and therefore, in some cases, it may be an ''unreasonable delay'' to wait until the 60th day to provide notification.

Overview of Public Comments

While some commenters generally were supportive of this provision in the interim final rule, others argued that the 60-day timeframe for notification to individuals is unreasonable and requested more time, such as 120 days, to provide the notifications. Some commenters argued that the clock on the 60-day timeframe should not begin to run until after a covered entity has completed its investigation and determined that a breach has occurred. Another commenter expressed the need for clarification about the types of delays in notifying individuals that would be considered reasonable and whether a covered entity's resources would be taken into account in determining whether any delay was reasonable.

Final Rule

We retain § 164.404(b) in this final rule without modification. This is the standard expressly provided for in the statute and we otherwise do not believe it necessary or prudent to extend the timeframe. Covered entities and business associates have been operating under this timeliness standard since the issuance of the interim final rule and we believe a longer time period to notify individuals of breaches of unsecured protected health information could adversely impact affected individuals and the ability to mitigate adverse consequences. For the same reasons, we continue to provide that the time period begins to run when the incident becomes known, not when it is determined that a breach as defined by the rule has occurred. There is sufficient time within this standard both to conduct a prompt investigation of the incident and to notify affected individuals.

With respect to what constitutes a reasonable versus unreasonable delay within the 60-day timeframe, such determinations are fact specific and there are many factors that may be relevant, including the nature of the breach, number of individuals affected, and resources of the covered entity.

Content of the Notification

Section 13402(f) of the HITECH Act set forth the content requirements for the breach notice to the individual. Section 164.404(c) of the interim final rule incorporated the statutory elements, requiring the following information be included in the notices, to the extent possible: (1) A brief description of what happened, including the date of the breach and the date of the discovery of the breach, if known; (2) a description of the types of unsecured protected health information that were involved in the breach (such as whether full name, social security number, date of birth, home address, account number, diagnosis, disability code, or other types of information were involved); (3) any steps individuals should take to protect themselves from potential harm resulting from the breach; (4) a brief description of what the covered entity involved is doing to investigate the breach, mitigate the harm to individuals, and to protect against any further breaches; and (5) contact procedures for individuals to ask questions or learn additional information, which shall include a toll-free telephone number, an email address, Web site, or postal address.

The interim final rule added the term ''diagnosis,'' to the parenthetical listing of examples of types of protected health information, which was not in the statute, to make clear that, where appropriate, a covered entity may need to indicate in the notification to the individual whether and what types of treatment information were involved in a breach. In addition, with respect to a covered entity's mitigation, the interim final rule replaced the statutory term ''mitigate losses'' with ''mitigate harm to individuals'' to make clear that the notification should describe the steps the covered entity is taking to mitigate potential harm to individuals resulting from the breach and that such harm is not limited to economic loss.

To address the readability and accessibility of the notice, the interim final rule made a number of clarifications. First, the Department included in the interim final rule a requirement that the breach notices be written in plain language so that individuals will be able to understand them more easily, which means the notice should be written at an appropriate reading level, using clear language and syntax, and not include any extraneous material that might diminish the message it is trying to convey.

Second, the interim final rule explained that some covered entities may have obligations under other laws with respect to their communication with affected individuals. For example, to the extent a covered entity is obligated to comply with Title VI of the Civil Rights Act of 1964, the covered entity must take reasonable steps to ensure meaningful access for Limited English Proficient persons to the services of the covered entity, which could include translating the notice into frequently encountered languages. Similarly, to the extent that a covered entity is required to comply with Section 504 of the Rehabilitation Act of 1973 or the Americans with Disabilities Act of 1990, the covered entity has an obligation to take steps that may be necessary to ensure effective communication with individuals with disabilities, which could include making the notice available in alternate formats, such as Braille, large print, or audio.

Overview of Public Comments

Several commenters stated that the content requirements for breach notification were too vague. Some commenters asked that we provide templates or sample notices to be used by covered entities. Other commenters asked for more specific guidance about particular required content elements of the notice, such as what information should be provided to individuals about a covered entity's or business associate's mitigation efforts and regarding any employee sanctions, particularly if a company has policies that require certain employment actions be kept confidential. It was also suggested that we publish a list of actions to be included in the notices based on the type of breach with respect to the steps individuals should take to protect themselves from harm. Some commenters also asked that the Department clarify that the requirement

to include ''a brief description of what happened'' would not require the covered entity or business associate to describe how the breach occurred such that it would create a roadmap for future breaches.

Final Rule

We retain § 164.404(c) in this final rule without modification. The content requirements in the Rule generally mirror the content requirements in the statute and each element is an important component of the notice to ensure individuals receive the information they need to protect themselves to the extent possible from the consequences of a breach and to learn what is being done to mitigate the breach and prevent future breaches. At the same time, the content provisions are sufficiently flexible to allow covered entities and business associates to tailor the breach notices based on the circumstances surrounding the breach and of the entity. In our experience in administering the Rule since 2009, the Rule provides sufficient flexibility to describe to the individual the circumstances surrounding the breach in a more general manner that still provides the individual with pertinent information but that does not provide a roadmap to third parties for future breaches. For example, the notice need not explain the exact type of vulnerability in the security of a covered entity's electronic records system that led to unauthorized access and how that vulnerability was exploited. Similarly, a covered entity has flexibility in describing what the covered entity is doing in response to a breach. Where employee sanctions are relevant based on the circumstances of the breach, a covered entity may determine that it wants to describe the sanctions imposed more generally and nothing in the Rule would require that the notice include the names of the employees involved. For example, a covered entity may want to indicate generally that the employees involved have been appropriately disciplined, particularly if multiple employees received varying levels of sanctions based on their degrees of involvement in the breach. In other cases, it may benefit the covered entity to be more specific so as to better assure individuals that the entity is appropriately addressing the situation, such as indicating that an employee who improperly accessed and sold patient information was promptly terminated.

With respect to templates, examples, or other guidance, the Department anticipates providing additional guidance in the future.

Methods of Notification

Section 13402(e)(1) of the HITECH Act provides for both actual written notice to affected individuals, as well as substitute notice to affected individuals if contact information is insufficient or out-of-date. Specifically, the statute requires breach notifications to be sent by first-class mail at the last known address of the individual or next of kin if the individual is deceased, or by electronic mail if specified as the preferred method by the individual. The Act also provides that the notification may be provided in one or more mailings as the information becomes available. Where there is insufficient or out-of-date contact information that precludes direct written notice to the individual, the statute requires that a substitute form of notice be provided to the individual. If there is insufficient contact information for 10 or more individuals, the Act requires that the substitute notice be a conspicuous posting on the home page of the covered entity's Web site or notice in major print or broadcast media in the geographic areas where the affected individuals likely reside, and in either case, that a toll-free number be included where individuals can learn whether their information was possibly included in the breach. Finally, the Act provides that a covered entity may provide notice by telephone or other means to individuals, in addition to direct written notice by first-class mail or email, in urgent situations involving possible imminent misuse of the individual's information.

Section 164.404(d) of the interim final rule set forth these methods for providing breach notification to affected individuals. Section 164.404(d)(1)(i) of the interim final rule required a covered entity to provide breach notice to an affected individual in written form by first-class mail at the individual's last known address. The interim final rule also permitted covered entities to provide this written notice in the form of electronic mail if the individual has agreed to receive electronic notice and that agreement has not been withdrawn.

The Department clarified that, consistent with § 164.502(g) of the Privacy Rule, where the individual affected by a breach is a minor or otherwise lacks legal capacity due to a physical or mental condition, notice to the parent or other person who is the personal representative of the individual would satisfy the requirements of § 164.404(d)(1). Additionally, with respect to deceased individuals, the interim final rule at § 164.404(d)(1)(ii) provided that notice of a breach be sent to either the individual's next of kin or personal representative, as such term is used for purposes of the Privacy Rule, recognizing that in some cases, a covered entity may have contact information for a personal representative of a deceased individual rather than the next of kin. To address administrative and privacy concerns with a covered entity being required to obtain contact information for the next of kin of a deceased patient in cases where the individual did not otherwise provide the information while alive, the interim final rule also clarified that a covered entity is only required to provide notice to the next of kin or personal representative if the covered entity both knows the individual is deceased and has the address of the next of kin or personal representative of the decedent.

If a covered entity does not have sufficient contact information for some or all of the affected individuals, or if some notices are returned as undeliverable, the interim final rule required a covered entity to provide substitute notice for the unreachable individuals in accordance with § 164.404(d)(2). The interim final rule required that substitute notice be provided as soon as reasonably possible after the covered entity is aware that it has insufficient or out-of-date contact information for one or more affected individuals and that the notice contain all the elements that § 164.404(c) requires be included in the direct written notice to individuals. With respect to decedents, however, the interim final rule provided that a covered entity is not required to provide substitute notice for the next of kin or personal representative in cases where the covered entity either does not have contact information or has out-of-date contact information for the next of kin or personal representative.

Section 164.404(d)(2) of the interim final rule required that, whatever method used, the substitute form of notice be reasonably calculated to reach the individuals for whom it is being provided. If there are fewer than 10 individuals for whom the covered entity has insufficient or out-of-date contact information to provide the written notice, § 164.404(d)(2)(i) of the interim final rule permitted the covered entity to provide substitute notice to such individuals through an alternative form of written notice, by telephone, or other means. For example, if a covered entity learned that the home address it has for one of its patients was out-of-date, but it had the patient's email address or telephone number, it could provide

substitute notice by email (even if the patient had not agreed to electronic notice) or by phone. Alternatively, posting a notice on the Web site of the covered entity or at another location may be appropriate if the covered entity lacks any current contact information for the patients, so long as the posting is done in a manner that is reasonably calculated to reach the individuals.

If a covered entity has insufficient or out-of-date contact information for 10 or more individuals, then § 164.404(d)(2)(ii) of the interim final rule required the covered entity to provide substitute notice through either a conspicuous posting for a period of 90 days on the home page of its Web site or conspicuous notice in major print or broadcast media in geographic areas where the individuals affected by the breach likely reside. For either method involving 10 or more individuals, the covered entity was also required to have a toll-free phone number, active for 90 days, where an individual can learn whether the individual's unsecured protected health information may be included in the breach and to include the number in the notice.

If a covered entity chooses to provide substitute notice on its Web site, the covered entity may provide all the information described at § 164.404(c) directly on its home page (''home page'' includes the home page for visitors to the covered entity's Web site and the landing page or login page for existing account holders) or may provide a prominent hyperlink on its home page to the notice containing such information.

If the covered entity does not have or does not wish to use a Web site for the substitute notice, the interim final rule required the covered entity to provide substitute notice of the breach in major print or broadcast media in geographic areas where the individuals affected by the breach likely reside. What is considered major print or broadcast media for a metropolitan area may be very different from what is considered major print or broadcast media in a rural area, such that the use of local, city, or state-wide media may be appropriate depending on the circumstances. Further, multiple media outlets may need to be utilized to reasonably reach individuals in different regions or States. In any event, substitute media notice, as with substitute Web notice, must be conspicuous and thus, covered entities should consider the location and duration of the notice to ensure the notice is reasonably calculated to reach the affected individuals.

Finally, we clarified that covered entities with out-of-date or insufficient contact information for some individuals can attempt to update the contact information so that they can provide direct written notification, in order to limit the number of individuals for whom substitute notice is required and, thus, potentially avoid the obligation to provide substitute notice through a Web site or major print or broadcast media under § 164.404(d)(2)(ii).

In accordance with the statute, § 164.404(d)(3) makes clear that notice to the individual by telephone or other means may be provided, in addition to the direct written notice required by § 164.404(d)(1), in cases deemed by the covered entity to require urgency because of possible imminent misuse of unsecured protected health information.

Overview of Public Comments

Several commenters questioned which entity has the responsibility for providing notifications to individuals when a breach occurs at or by a business associate and whether a covered entity could delegate its breach notification obligations to a business associate. Some commenters asked about the notification obligations in cases where a covered entity's business associate that experiences a breach is also a covered entity itself. Others requested clarification regarding the obligations for providing breach notification where multiple covered entities and business associates are involved in health information exchange and it may be unclear where a breach occurred and/or which entity has responsibility for the breach.

Additionally, many commenters suggested that covered entities be permitted to provide notification to individuals via telephone or orally instead of via written communication, or at a work address instead of a home address, if the individual has specified one of these alternative methods or locations as preferred for receiving breach notification. Commenters raised potential privacy concerns with communicating with individuals via mail to their home, particularly where the individual has received highly confidential medical services, such as substance abuse or mental health services, and others who may have access to the mail may not otherwise be aware of such condition or treatment. Some commenters argued that because the Privacy Rule requires covered entities to accommodate reasonable requests by individuals to receive communications by alternative means or at alternative locations, the same standard should apply to the provision of breach notification.

Finally, several commenters expressed concern over the substitute notice required in cases in which the covered entity has insufficient or out-of-date contact information for affected individuals. Many of these commenters stated that providing notification via Web posting or media publication is an inappropriate method of providing substitute notice, except in cases in which the covered entity can reasonably define the universe of affected individuals. In other cases, such notice will not give individuals who view the notice enough information to determine if they are affected by a breach, and may cause unaffected individuals unnecessary alarm. Some commenters recommended that covered entities instead be required to use reasonable efforts to identify alternative means of providing direct notice to the affected individuals, such as by phone or email, or to only require substitute media or Web notice when a covered entity cannot reach 10 or more individuals directly by mail, phone, or email. Other commenters argued that the substitute notice requirements, particularly the requirement to establish a toll-free number, may be cost prohibitive to smaller covered entities. It was also suggested that smaller covered entities, particularly those in rural areas, should be allowed to provide substitute notice via handouts or postings at the covered entity's physical location even in cases where the entity has insufficient contact information for more than 10 individuals.

Final Rule

We retain § 164.404(d) in this final rule without modification. In response to questions raised with respect to a breach at or by a business associate, we note that the covered entity ultimately maintains the obligation to notify affected individuals of the breach under § 164.404, although a covered entity is free to delegate the responsibility to the business associate that suffered the breach or to another of its business associates. This is the case even if the breach of the covered entity's protected health information occurred at or by a business associate that is also a covered entity. For example, if a covered provider (Provider A) hires another covered provider's practice (Provider B) as a business associate to perform his billing and other back office functions, and a breach of Provider A's protected health information occurs at Provider B while performing these functions for Provider A, it remains Provider A's responsibility to provide breach notification to the affected individuals, although Provider A may delegate this

responsibility to Provider B as its business associate.

Covered entities and business associates should consider which entity is in the best position to provide notice to the individual, which may depend on various circumstances, such as the functions the business associate performs on behalf of the covered entity and which entity has the relationship with the individual.

Similarly, when multiple covered entities participate in electronic health information exchange and there is a breach of unsecured protected health information at a Health Information Organization (HIO), the obligation to notify individuals of the breach falls to the covered entities. We recognize that it may be difficult to determine what breached information is attributable to which covered entity's individuals. For example, an HIO may store centralized electronic health records (EHRs) for a community, with each EHR including information generated by multiple covered entities. In such circumstances, it may be necessary for the HIO to notify all potentially affected covered entities and for those covered entities to delegate to the HIO the responsibility of sending the required notifications to the affected individuals. This would avoid the confusion of individuals receiving more than one notification about the same breach.

In response to the commenters who suggested that covered entities be permitted to accommodate reasonable requests by individuals to receive breach notifications by alternative means or at alternative locations, we provide the following guidance. The HITECH Act requires a covered entity to provide breach notification to an affected individual in written form either at the last known address of the individual or email address, if the individual agrees to receive notice electronically, where the covered entity has sufficient contact information to do so. The Act and this rule do not prohibit a covered entity from sending a breach notice to an alternative address rather than a home address, such as a work address or post office box, or the individual's email address of choice, if the individual requests communications be sent to such an address. Further, a covered health care provider (and health plan, if potential endangerment is raised by the individual) is required by the Privacy Rule at § 164.522 to accommodate any such reasonable requests.

In response to those commenters who urged that we allow breach notices to be provided orally or via telephone to individuals receiving highly confidential treatment services where the individual has requested to receive communications in such a manner, we note that the HITECH Act specifically refers to ''written'' notice to be provided to individuals. However, we understand the privacy concerns raised. We, thus, clarify that in the limited circumstances in which an individual has agreed only to receive communications from a covered health care provider orally or by telephone, the provider is permitted under the Rule to telephone the individual to request and have the individual pick up their written breach notice from the provider directly. In cases in which the individual does not agree or wish to travel to the provider to pick up the written breach notice, the health care provider should provide all of the information in the breach notice over the phone to the individual, document that it has done so, and the Department will exercise enforcement discretion in such cases with respect to the ''written notice'' requirement. We stress that our enforcement discretion applies only to cases where the individual affirmatively chooses not to receive communications from a covered health care provider at any written addresses or email addresses, and not to situations where providing telephonic notice is simply less burdensome or easier on a provider and the entity has a valid address, or email address if applicable, on file for the affected individual.

Finally, with respect to commenters who expressed concerns with the substitute media and Web notice provisions of the interim final rule, we emphasize that these are statutory requirements that have been incorporated into the Rule. Section 13402(e)(1)(B) of the HITECH Act expressly requires that a covered entity that has insufficient or out-of-date contact information for 10 or more individuals provide substitute notification to such individuals via posting on their Web site or notification in major print or broadcast media in the areas in which the affected individuals likely reside. Additionally, the statute requires such ''notice in media or web posting will include a toll-free phone number where an individual can learn whether or not the individual's unsecured protected health information is possibly included in the breach.'' Thus, we retain these requirements in this final rule.

Response to Other Public Comments

Comment: One commenter expressed concern about providing breach notification to individuals by first-class mail because it could require some entities, such as those that have Web-based relationships with individuals, to collect more information about individuals (e.g., physical addresses) than they currently do.

Response: The Rule allows a covered entity to provide written breach notice to an affected individual by email if the individual agrees to electronic notice and such agreement has not been withdrawn. We would expect that covered entities that have primarily or solely an online relationship with individuals would ask and encourage individuals to receive breach notices by email and that generally individuals would agree. However, an individual that does not affirmatively agree to receive breach notices by email, or that withdraws a prior agreement, has a right to notice by first-class mail.

Comment: One commenter suggested that we excuse a covered entity from providing notification of a breach to an individual where a licensed health care professional has determined in the exercise of professional judgment that the provision of such notice is likely to cause substantial harm to the individual. The commenter appeared to be concerned due to the nature of the services it provides—mental health services—and the distress breach notification could cause for certain of its patients.

Response: The statute does not include such an exception to the provision of breach notification, and we do not include one in this Rule. An affected individual has a right to be informed of breaches of unsecured protected health information so the individual can take steps if appropriate to protect themselves from the consequences. In situations where a health care provider believes that the provision of written breach notification to an individual may cause extreme anguish or distress, based on the individual's mental state or other circumstances, the provider may telephone the individual prior to the time the breach notice is mailed or have them come into the provider's office to discuss the situation. However, we note that the breach notification must still be mailed without unreasonable delay and in no case later than 60 calendar days after discovery of the breach. Where a provider is aware that an individual has a personal representative due to incapacity or other health condition, the breach notification may be sent to the personal representative.

Comment: Many commenters expressed support for allowing covered entities to provide breach notification to a deceased individual's personal representative instead of to the next of

kin. One commenter suggested that we also allow covered entities to provide breach notification to the emergency contact provided by a deceased individual prior to death as this is the information they collect from individuals and yet this person may not be the next of kin or a personal representative of the deceased individual.

Response: We do not believe it appropriate to permit covered entities to send breach notifications to a deceased individual's emergency contact where such person is not a personal representative (such as an executor or administrator of the decedent's estate) or next of kin of the decedent, as such notices may convey information about the decedent's care the decedent never wished the emergency contact to have and/or may go to a person who has no authority to act on the notice.

Comment: To reduce the costs associated with sending breach notifications, one commenter asked that we adopt the Department of Labor's standard for providing COBRA Election Notices to allow a covered entity to: (1) Where a breach affects both a plan participant and the participant's spouse, send one breach notice addressed to both if both spouses reside at the same address; and (2) where a breach affects a dependent child (of any age) under a plan, send a breach notice to either the plan participant and/or the participant's spouse, provided the dependent child resides at the same address. The commenter stated the notice should clearly identify the individuals or classes of individuals to whom the notice applies.

Response: A covered entity is permitted to send one breach notice addressed to both a plan participant and the participant's spouse or other dependents under the plan who are affected by a breach, so long as they all reside at a single address and the covered entity clearly identifies on the notice the individuals to which the notice applies. Further, a covered entity may send a notice regarding the breach of a dependent child's protected health information addressed to the plan participant and/or participant's spouse living with the dependent child, so long as the participant and/or participant's spouse are the personal representatives of the dependent child and the notice clearly identifies to whom it applies. Such notices by first-class mail would meet the written notice requirements of § 164.404(d)(1)(i). However, one breach notice covering both the plan participant and the dependents under the plan mailed to the plan participant's address would not suffice if the address of one or more dependents affected by the breach was different than the participant's address. Further, where a plan participant (and/or spouse) is not the personal representative of a dependent under the plan, a covered entity must address a breach notice to the dependent himself or herself.

Comment: Several commenters expressed support for the acknowledgment in the preamble to the interim final rule that some covered entities may have obligations under Civil Rights laws to ensure that breach notifications are provided to individuals in alternative languages, and in alternative formats, such as Braille, large print, or audio, where appropriate. Some commenters requested additional guidance regarding how to ensure compliance with these laws with respect to breach notifications.

Response: Additional guidance on how to comply with Title VI of the Civil Rights Act of 1964, Section 504 of the Rehabilitation Act of 1973, and the Americans with Disabilities Act of 1990, is available on the OCR Web site at *http://www.hhs.gov/ocr/civilrights/*. Further, covered entities with questions on how to comply may contact one of OCR's ten regional offices. Contact information is available at *http://www.hhs.gov/ocr/office/about/rgn-hqaddresses.html*.

Comment: Some commenters suggested that the final rule adopt a substitute notification provision similar to that in many State laws that allows for substitute notification, rather than direct written notice, to the individual in the event of breaches affecting a very large number of individuals, such as over 250,000 or 500,000, where the costs of notification would be extremely high.

Response: The Act does not waive direct written notice to the individual when a breach has affected a threshold number of individuals and we do not do so in this rule.

Comment: One commenter requested confirmation that a covered entity could make multiple attempts to provide direct written notice to individuals within the 60-day timeframe before the individual counts towards the 10 or more threshold for providing substitute Web or media notice.

Response: We clarify that a covered entity can attempt to cure out-of-date contact information on individuals when notices are returned as undeliverable by the United States Postal Service to avoid substitute notice so long as a covered entity does so promptly upon receiving the returned notices and no later than 60 calendar days from discovery of the breach. However, at the time the covered entity is aware that it will be unable to reach 10 or more individuals with direct written notice, the covered entity should provide substitute Web or media notice as soon as reasonably possible thereafter, which may be prior to the end of the 60-day period depending on the circumstances.

Comment: One commenter stated that the required content of the breach notice itself, when made available to the public through the Web or media, could lead to the identification of individuals affected by the breach in some cases, undermining the intent of HIPAA's privacy and security protections.

Response: It is unclear the circumstances to which the commenter refers. For example, the notification must include the types of protected health information involved (e.g., social security numbers, dates of birth, full names). However, this is not a requirement to include in the notice the actual names or other identifiers of the affected individuals. We believe covered entities are able to post breach notices in a manner that does not identify particular individuals affected by a breach and thus, must do so.

Comment: One commenter asked that OCR engage in an educational campaign to ensure that covered entities and business associates understand their obligations under the breach notification rule.

Response: Published guidance is the primary method that the Department uses to educate and provide technical assistance to covered entities and business associates. We intend to issue guidance on these requirements in the future as questions are raised or clarifications sought.

3. Section 164.406—Notification to the Media

Section 13402(e)(2) of the HITECH Act, implemented at § 164.406 of the interim final rule, requires that a covered entity provide notice of a breach to prominent media outlets serving a State or jurisdiction, following the discovery of a breach if the unsecured protected health information of more than 500 residents of such State or jurisdiction is, or is reasonably believed to have been, accessed, acquired, or disclosed during such breach. This media notice is in addition to, not a substitute for, individual notice. In accordance with the Act, § 164.406(b) of the interim final rule required covered entities to notify prominent media outlets without unreasonable delay and in no case later than 60 calendar days after discovery of the breach. Section 164.406(c) of the interim final rule required that the

notification to the media include the same information required to be included in the notification to the individual under § 164.404(c).

The interim final rule did not define ''prominent media outlet'' because what constitutes a prominent media outlet will differ depending upon the State or jurisdiction affected. For a breach affecting more than 500 individuals across a particular state, a prominent media outlet may be a major, general interest newspaper with a daily circulation throughout the entire state. In contrast, a newspaper serving only one town and distributed on a monthly basis, or a daily newspaper of specialized interest (such as sports or politics) would not be viewed as a prominent media outlet. Where a breach affects more than 500 individuals in a limited jurisdiction, such as a city, then a prominent media outlet may be a major, general-interest newspaper with daily circulation throughout the city, even though the newspaper does not serve the whole State.

With regard to the term ''State,'' the existing definition of ''State'' at § 160.103 of the HIPAA Rules applies. Section § 160.103 defines ''State'' to mean ''any one of the several States, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, and Guam.'' We also expressly provided in the regulation that ''State'' for purposes of notice to the media includes American Samoa and the Northern Mariana Islands, because they were included in the HITECH Act's definition of ''State'' in addition to what appears in the definition at § 160.103. With respect to what was meant by ''jurisdiction'' as opposed to a ''State,'' jurisdiction is a geographic area smaller than a state, such as a county, city, or town.

The interim final rule also clarified that some breaches involving more than 500 individuals who are residents in multiple States may not require notice to the media. For example, if a covered entity discovers a breach of 600 individuals, 200 of which reside in Virginia, 200 of which reside in Maryland, and 200 of which reside in the District of Columbia, the breach did not affect more than 500 residents of any one State or jurisdiction, and as such, notification is not required to be provided to the media pursuant to § 164.406. However, individual notification under § 164.404 would be required, as would notification to the Secretary under § 164.408 because the breach involved 500 or more individuals.

The Department also recognized that in some cases a breach may occur at a business associate and involve the protected health information of multiple covered entities. In such cases, a covered entity involved would only be required to provide notification to the media if the information breached included the protected health information of more than 500 individuals located in any one State or jurisdiction. For example, if a business associate discovers a breach affecting 800 individuals in a State, the business associate must notify the appropriate covered entity (or covered entities) subject to § 164.410 (discussed below). If 450 of the affected individuals are patients of one covered entity and the remaining 350 are patients of another covered entity, because the breach has not affected more than 500 individuals at either covered entity, there is no obligation to provide notification to the media under this section.

Section 164.406(c) requires that the notice to the media include the same content as that required for notification to the individual under § 164.404(c), and we emphasized that this provision does not replace either direct written or substitute notice to the individual under § 164.404.

Overview of Public Comments

In general, we received few comments on this provision of the interim final rule. One commenter expressed general support for this provision because it does not require the covered entity to incur the cost of printing or running the media notice and asked for clarification that this policy places no requirement on the media to publically report the information provided by a covered entity. Another commenter asked whether a covered entity could fulfill the requirements for providing media notification by posting a press release on the covered entity's Web site.

Final Rule

We retain § 164.406 in this final rule with one minor change. As described in Section IV above, to align the definition of ''State'' in the HIPAA Rules with the definition of the same term used in the HITECH Act, the Department has modified the definition of ''State'' at § 160.103 to include reference to American Samoa and the Northern Mariana Islands. Given this change, it is not necessary to include specific reference to American Samoa and the Northern Mariana Islands at § 164.406 and we remove it in this final rule.

In response to public comments, we clarify that § 164.406 does not require a covered entity to incur any cost to print or run media notice about a breach of unsecured protected health information (unlike the obligations for providing substitute notice to individuals in § 164.404(d)(2) if there is insufficient or out-of-date contact information for 10 or more affected individuals) nor does it obligate prominent media outlets who receive notification of a breach from a covered entity to print or run information about the breach. We also emphasize that posting a press release regarding a breach of unsecured protected health information on the home page of the covered entity's Web site will not fulfill the obligation to provide notice to the media (although covered entities are free to post a press release regarding a breach on their Web site). To fulfill the obligation, notification, which may be in the form of a press release, must be provided directly to prominent media outlets serving the State or jurisdiction where the affected individuals reside.

4. Section 164.408—Notification to the Secretary

Section 13402(e)(3) of the HITECH Act requires covered entities to notify the Secretary of breaches of unsecured protected health information. The Act requires covered entities to report breaches affecting 500 or more individuals to the Secretary immediately. For breaches affecting fewer than 500 individuals, covered entities may maintain a log of all such breaches occurring during the year and annually submit such log to the Secretary.

To implement the statutory provisions, § 164.408(a) contains the general rule that requires a covered entity to notify the Secretary following the discovery of a breach of unsecured protected health information. With respect to breaches involving 500 or more individuals, we interpreted the term ''immediately'' in the statute to require notification be sent to the Secretary concurrently with the notification sent to the individual under § 164.404 (i.e., without unreasonable delay but in no case later than 60 calendar days following discovery of a breach). The rule provided that these notifications be provided in a manner to be specified on the HHS Web site. Further, as required by section 13402(e)(4) of the Act, the interim final rule stated that the Secretary would begin to post and maintain on the HHS Web site a list of covered entities that submit reports of breaches of unsecured protected health information involving more than 500 individuals.

Under these provisions, covered entities must notify the Secretary of all discovered breaches involving more than 500 individuals, without regard to

whether the breach involved more than 500 residents of a particular State or jurisdiction (the threshold for triggering notification to the media under § 164.406 of the interim final rule). Thus, where a covered entity has discovered a breach involving 600 individuals, 300 of which reside in Maryland and 300 of which reside in the District of Columbia, notification of the breach must be provided to the Secretary concurrently with notification to the affected individuals. However, in this example, the breach would not trigger the requirement to notify the media under § 164.406 because the breach did not involve more than 500 residents of any one State or jurisdiction.

For breaches involving less than 500 individuals, § 164.408(c) requires a covered entity to maintain a log or other documentation of such breaches and to submit information annually to the Secretary for breaches occurring during the preceding calendar year. The interim final rule required the submission of this information to the Secretary no later than 60 days after the end of each calendar year. As with notification of the larger breaches, the interim final rule required that information about breaches involving less than 500 individuals be provided to the Secretary in the manner specified on the HHS Web site.

Although covered entities need only provide notification to the Secretary of breaches involving less than 500 individuals annually, they must still provide notification of such breaches to affected individuals without unreasonable delay and not later than 60 days after discovery of the breach pursuant to § 164.404. In addition, pursuant to § 164.414(a), a covered entity must follow the documentation requirements that otherwise apply to the HIPAA Privacy Rule under § 164.530 with respect to the requirements of this rule. Thus, pursuant to § 164.530(j)(2), covered entities must maintain the internal log or other documentation for six years. Further, as with other required documentation, a covered entity must make such information available to the Secretary upon request for compliance and enforcement purposes in accordance with § 160.310.

Overview of Public Comments

Some commenters expressed concern regarding the timing of providing notification to the Secretary of breaches affecting fewer than 500 individuals. These commenters asked when notification should be provided if a covered entity discovers, after the reporting deadline, a breach that occurred in the previous year. Several others commented on the interim final rule's process for providing the Secretary with breach notification. Some commenters asked that this process be revised to allow covered entities to maintain a log of all breaches affecting fewer than 500 individuals and then submit that log, via attachment (such as an Excel spreadsheet), to the Secretary on an annual basis. These commenters stated that submitting reports of these smaller breaches in this manner would be much less burdensome than submitting the reports individually. Other commenters asked that we provide a template log for entities to use to document smaller breaches for annual submission to the Secretary. Additionally, several commenters suggested that there be access or authentication controls for submitting breach reports because of concerns of false breach reports being submitted to the Secretary without the covered entity's knowledge.

Final Rule

The final rule retains § 164.408(c) with one modification. The modification clarifies that covered entities are required to notify the Secretary of all breaches of unsecured protected health information affecting fewer than 500 individuals not later than 60 days after the end of the calendar year in which the breaches were ''discovered,'' not in which the breaches ''occurred.'' We recognize that there may be situations where, despite having reasonable and appropriate breach detection systems in place, a breach may go undetected for some time. In these cases, if a breach of unsecured protected health information affecting fewer than 500 individuals that occurred in the previous year is discovered, the covered entity has until 60 days after the end of the calendar year in which the breach was discovered to provide notice to the Secretary. We emphasize, however, that this modification does not alter a covered entity's obligation to promptly report the breach to affected individuals without unreasonable delay but in no cases later than 60 calendar days after discovery of the breach.

In response to the comments suggesting that covered entities be permitted to submit a log of all smaller breaches to the Secretary instead of submitting each breach individually through the online form, we agree that the current process may be burdensome for some entities and are considering alternative ways to receive such reports.

With respect to the commenters who asked that access or authentication controls be added to the breach reporting form, we do not believe this is necessary at the present time. Since the Department began receiving and processing breach reports on September 23, 2009, we have not yet received a report that has been falsely submitted by an individual or entity not acting on behalf of the covered entity. Additionally, we emphasize that following receipt of a breach report that affects 500 or more individuals, we contact the covered entity identified in the breach report and verify the information in the report before we post any information about the breach on the HHS Web site. If circumstances change in the future, we will explore options for modifying the process.

Response to Other Public Comments

Comment: One commenter asked that the final rule should not interpret the term ''immediately'' in the statute to mean without unreasonable delay, but in no case later than 60 days, but rather to mean as soon as the breach is discovered. Another commenter asked that the final rule expand the timeframe for providing notification to the Secretary to no later than 120 days after discovery of a breach.

Response: We believe that our interpretation of ''immediately'' with respect to notification to the Secretary for breaches affecting 500 or more individuals is reasonable and appropriate and thus, retain the provision that requires such notice be provided contemporaneously with notice to the individual. Requiring contemporaneous notice allows the notice to the Secretary to include all of the information provided in the notice to the individual and better ensures that a covered entity does not report information to the Secretary that later turns out to be incorrect because the entity did not have sufficient time to conduct an investigation into the facts surrounding the breach. In addition, this interpretation satisfies the statutory requirement that notifications of larger breaches be provided to the Secretary immediately (as they occur) as compared to the reports of smaller breaches the statute allows be reported annually to the Secretary.

Comment: Some commenters asked for further guidance on submitting online breach notifications to the Secretary. Additionally, some commenters asked that HHS provide a confirmation to submitters that an initial breach report or an addendum to a breach report has been successfully submitted.

Response: Since the publication of the interim final rule, OCR has posted

instructions for filling out and submitting the breach form on its Web site: *http://www.hhs.gov/ocr/privacy/hipaa/administrative/breachnotificationrule/brinstruction.html.* We will continue to examine the instructions for submitting breach notification to the Secretary and will update this information, as necessary, to ensure that covered entities are able to navigate and submit the form easily. The Department has also made changes to the process to ensure that covered entities receive a confirmation following their submission of breach notification to the Secretary. Additionally, we note that the breach reporting form does include an option for indicating that a submission is an addendum to a previous submission. OCR updates the original breach report, as appropriate, with any additional or modified information submitted in an addendum.

Comment: With respect to the posting of breaches affecting 500 or more individuals on the HHS Web site, some commenters stated that these breach submissions must be verified with the covered entity before they are posted publicly. Other commenters asked for clarification of what information will be posted, while another commenter asked that we post only the name of the covered entity involved in the breach. Finally, one commenter suggested that we only post these breaches on our Web site for a six month period.

Response: To provide helpful information to the public, OCR currently posts the following information regarding breaches affecting 500 or more individuals: name of the covered entity (and if applicable, the business associate) involved; State where the covered entity is located; number of individuals affected by the breach; the date of the breach; type of breach (e.g., theft, loss, unauthorized access/disclosure); and location of the breached information (e.g., laptop, paper records, desktop computer). Prior to posting this information, OCR verifies the information in the breach notification report with the covered entity. We do not believe it would serve the public to only disclose the name of the covered entity involved in each of the breaches, because the additional information enables members of the public to understand the nature of the breach and to determine if the breach affects them directly. In terms of how long information about each of the breaches is to remain posted, we intend to maintain the information on our Web site for as long as there is public interest and the data can remain posted in a manner that gives the public access effectively and efficiently.

5. Section 164.410—Notification by a Business Associate

Interim Final Rule

Section 13402(b) of the HITECH Act requires a business associate of a covered entity that accesses, maintains, retains, modifies, records, destroys, or otherwise holds, uses, or discloses unsecured protected health information to notify the covered entity when it discovers a breach of such information. The Act requires business associates to provide such notification to covered entities without unreasonable delay and in no case later than 60 days from discovery of the breach. Additionally, the Act requires business associates to provide covered entities with the identity of each individual whose unsecured protected health information has, or is reasonably believed to have been, affected by the breach. Section 164.410(a) implements section 13402(b) of the Act.

A business associate is required to notify the covered entity of the breach of unsecured protected health information so that the covered entity can notify affected individuals. In the interim final rule, we clarified that a business associate that maintains the protected health information of multiple covered entities need notify only the covered entity(s) to which the breached information relates. However, in cases in which a breach involves the unsecured protected health information of multiple covered entities and it is unclear to whom the breached information relates, it may be necessary to notify all potentially affected covered entities.

Section 164.410(a)(2) provides that a breach shall be treated as discovered by a business associate as of the first day on which such breach is known to the business associate or, by exercising reasonable diligence, would have been known to the business associate. As with a covered entity, a business associate shall be deemed to have knowledge of a breach if the breach is known, or by exercising reasonable diligence would have been known, to any person, other than the person committing the breach, who is an employee, officer, or other agent of the business associate (determined in accordance with the Federal common law of agency). Similarly, as with knowledge imputed to covered entities, the Federal common law of agency controls in determining who is an agent of the business associate.

Section 164.410(b) requires that a business associate provide notice of a breach of unsecured protected health information to a covered entity without unreasonable delay and in no case later than 60 days following the discovery of a breach. With respect to timing, if a business associate is acting as an agent of a covered entity, then, pursuant to § 164.404(a)(2), the business associate's discovery of the breach will be imputed to the covered entity. In such circumstances, the covered entity must provide notifications under § 164.404(a) based on the time the business associate discovers the breach, not from the time the business associate notifies the covered entity. In contrast, if the business associate is not an agent of the covered entity, then the covered entity is required to provide notification based on the time the business associate notifies the covered entity of the breach. We encouraged covered entities and business associates to address the timing of this notification in their business associate contracts.

Section 164.410(c)(1) requires business associates, to the extent possible, to provide covered entities with the identity of each individual whose unsecured protected health information has been, or is reasonably believed to have been, breached. Depending on the circumstances, business associates could provide the covered entity with immediate notification of the breach and then follow up with the required information in § 164.410(c) when available but without unreasonable delay and within 60 days.

Section 164.410(c)(1) requires business associates to provide this information ''to the extent possible,'' recognizing that there may be situations in which a business associate may be unaware of the identification of the individuals whose unsecured protected health information was breached. For example, a business associate that is a record storage company that holds hundreds of boxes of paper medical records on behalf of a covered entity may be unaware of the names of the individuals whose records are stored. Thus, if the business associate discovers that several boxes are missing, it may be unable to provide the covered entity with a list of the individuals whose information has been breached. In such circumstances, it is not our intent that the business associate delay notification of the breach to the covered entity, when the covered entity may be better able to identify the individuals affected.

Depending on the circumstances surrounding a breach of unsecured protected health information, a business

associate may be in the best position to gather the information the covered entity is required by § 164.404(c) to include in the notification to the individual about the breach. Therefore, in addition to the identification of affected individuals, § 164.410(c)(2) requires a business associate to provide the covered entity with any other available information that the covered entity is required to include in the notification to the individual under § 164.404(c), either at the time it provides notice to the covered entity of the breach or promptly thereafter as information becomes available. Because we allow this information to be provided to a covered entity after the initial notification of the breach as it becomes available, a business associate should not delay the initial notification to the covered entity of the breach in order to collect information needed for the notification to the individual. To ensure the covered entity is aware of all the available facts surrounding a breach, the Rule also requires that a business associate provide this information even if it becomes available after notifications have been sent to affected individuals or after the 60-day period specified in § 164.410(b) has elapsed.

We clarified that business associates and covered entities would continue to have the flexibility to set forth specific obligations for each party, such as who will provide notice to individuals and when the notification from the business associate to the covered entity will be required, following a breach of unsecured protected health information, so long as all required notifications are provided and the other requirements of the interim final rule were met. We encouraged the parties to consider which entity is in the best position to provide notice to the individual, which may depend on circumstances, such as the functions the business associate performs on behalf of the covered entity and which entity has the relationship with the individual. We also encouraged the parties to ensure the individual does not receive notifications from both the covered entity and the business associate about the same breach, which may be confusing to the individual.

Overview of Public Comments

Many commenters expressed concern over the interim final rule's treatment of a covered entity's knowledge of a breach that occurs at or by a business associate. Some commenters stated that a covered entity's knowledge of a breach should begin when the business associate notifies them of the breach, regardless of whether the business associate is an agent of the covered entity or a non-agent independent contractor. If knowledge is imputed when the business associate discovers the breach, one commenter argued that a covered entity would not have sufficient time to provide the required notifications to individuals in a timely manner. Other commenters argued that all business associates should be treated as agents of the covered entity, such that the business associate's knowledge of a breach is imputed to the covered entity. Finally, some commenters asked for more guidance on when a business associate is acting as an agent versus as an independent contractor and how to determine this status under the Federal common law of agency.

Final Rule

The final rule modifies § 164.410 only to make the following technical and non-substantive correction: in paragraph (a)(2) of § 164.410, the first sentence is revised to refer to paragraph (a)(1) rather than paragraph (1).

With respect to the commenters who expressed concern that a covered entity's knowledge of a breach depends not only on a business associate's discovery of the breach but also on the covered entity's relationship with the business associate, we acknowledge that there are many different types of relationships that can develop between covered entities and business associates based upon the function the business associate performs on behalf of the covered entity. In some situations, a business associate will be acting as an agent of the covered entity, and as such, it makes sense to treat the business associate's knowledge of a breach analogous to the knowledge of one of the covered entity's own employees. However, in other situations, because a business associate may not be an agent of the covered entity, it would not be reasonable to impute the business associate's knowledge directly to the covered entity, and therefore, the covered entity's knowledge depends on notification from the business associate.

Furthermore, the use of the Federal common law of agency to determine the business associate's status with respect to the covered entity is consistent with the approach taken in the Enforcement Rule for determining agency liability under the HIPAA Rules. Thus, we believe the use of the standard is appropriate here and should be familiar to most entities. We provide additional guidance regarding who is an agent above in our response to comments on the HITECH modifications to the HIPAA Enforcement Rule. Because of the agency implications on the timing of breach notifications, we encourage covered entities to discuss and define in their business associate agreements the requirements regarding how, when, and to whom a business associate should notify the covered entity of a potential breach.

Response to Other Public Comments

Comment: Several commenters asked OCR to provide sample business associate agreement language to outline the covered entity's and business associate's obligations following a breach of unsecured protected health information.

Response: A covered entity's and business associate's obligations following a breach of unsecured protected health information will vary depending on the relationship. For example, whether a business associate will send the breach notices to affected individuals and/or to notify the Secretary (and media, if applicable) on behalf of a covered entity is a business decision of the parties and how quickly a business associate is to notify a covered entity of a breach within the required timeframe may be based on a number of factors, such as whether the business associate is an agent of the covered entity. However, to help covered entities and business associates implement the new business associate agreement requirements generally under the HITECH modifications to the HIPAA Rules, the Department has published sample business associate agreement provisions on its web site.

Comment: Some commenters asked what happens if a covered entity and a business associate disagree about whether an impermissible use or disclosure is a breach that requires notification. These commenters asked if both parties must be in agreement before breach notification obligations are triggered.

Response: The covered entity is ultimately responsible for providing individuals with notification of breaches and, as indicated above, the clock for notifying individuals of breaches begins upon knowledge of the incident, even if it is not yet clear whether the incident qualifies as a breach for purposes of this rule. Further, this final rule clarifies that the default presumption is that an impermissible use or disclosure is a breach unless it can be determined through a risk assessment that there is a low probability that the data may be compromised. This standard should allow for more uniform application of the risk assessment approach across covered entities and business associates.

Comment: One commenter stated that the requirement that a business

associate notify a covered entity of a breach of unsecured protected health information is duplicative of a business associate's other obligations to notify the covered entity of privacy violations and security incidents.

Response: Business associates are required to report to covered entities any security incidents or uses or disclosures of protected health information not provided for by their business associate agreements, which include but are broader than breaches of unsecured protected health information under this Rule. For example, a security incident need not lead to unauthorized access to protected health information (and thus, is not a breach) but is still an event that should be reported to the covered entity. Further, when a security incident occurs that does rise to the level of a breach, the breach notice to the covered entity suffices to meet the requirement to report the security incident to the covered entity (however, a covered entity may require through the business associate agreement that additional information be reported). Therefore, these requirements are not duplicative.

6. Law Enforcement Delay

Interim Final Rule

Section 13402(g) of the HITECH Act provides that if a law enforcement official determines that a notification, notice, or posting required under this section would impede a criminal investigation or cause damage to national security, such notification, notice, or posting shall be delayed in the same manner as provided under 45 CFR 164.528(a)(2) of the Privacy Rule in the case of a disclosure covered under such section. Section 164.412 implements section 13402(g) of the Act, requiring a covered entity or business associate to temporarily delay notification to the individual, the media (if applicable), to a covered entity by a business associate, and to the Secretary if instructed to do so by a law enforcement official.

Section 164.412(a), based on the requirements of 45 CFR 164.528(a)(2)(i) of the Privacy Rule, provides for a temporary delay of notification in situations in which a law enforcement official provides a statement in writing that the delay is necessary because notification would impede a criminal investigation or cause damage to national security, and specifies the time for which a delay is required. In such instances, the covered entity is required to delay the notification, notice, or posting for the time period specified by the official.

Similarly, § 164.412(b), based on 45 CFR 164.528(a)(2)(ii) of the Privacy Rule, requires a covered entity or business associate to temporarily delay a notification, notice, or posting if a law enforcement official states orally that a notification would impede a criminal investigation or cause damage to national security. However, in this case, the covered entity or business associate must document the statement and the identity of the official and delay notification for no longer than 30 days, unless a written statement meeting the above requirements is provided during that time. We interpreted these provisions as tolling the time within which notification is required under §§ 164.404, 164.406, 164.408, and 164.410, as applicable.

Final Rule

The Department did not receive public comments on this provision of the interim final rule. We retain § 164.412 in this final rule without modification.

7. Section 164.414—Administrative Requirements and Burden of Proof

Interim Final Rule

Section 164.414(a) requires covered entities to comply with the administrative requirements of § 164.530(b), (d), (e), (g), (h), (i), and (j) of the Privacy Rule with respect to the breach notification provisions of this subpart. These Privacy Rule provisions, for example, require covered entities and business associates to develop and document policies and procedures, train workforce members on and have sanctions for failure to comply with these policies and procedures, permit individuals to file complaints regarding these policies and procedures or a failure to comply with them, and require covered entities to refrain from intimidating or retaliatory acts. Thus, a covered entity is required to consider and incorporate the breach notification requirements with respect to its administrative compliance and other obligations.

Section 164.414(b) provides that, following an impermissible use or disclosure under the Privacy Rule, covered entities and business associates have the burden of demonstrating that all notifications were made as required by this subpart. Additionally, as part of demonstrating that all required notifications were made, a covered entity or business associate, as applicable, also must be able to demonstrate that an impermissible use or disclosure did not constitute a breach, as such term is defined at § 164.402, in cases where the covered entity or business associate determined that notifications were not required. To conform to these provisions, § 160.534 of the HIPAA Enforcement Rule makes clear that, during any administrative hearing, the covered entity has the burden of going forward and the burden of persuasion with respect to these issues.

Thus, when a covered entity or business associate knows of an impermissible use or disclosure of protected health information, it should maintain documentation that all required notifications were made, or, alternatively, to demonstrate that notification was not required: (1) Its risk assessment (discussed above in § 164.402) demonstrating a low probability that the protected health information has been compromised by the impermissible use or disclosure or (2) the application of any other exceptions to the definition of ''breach.''

Overview of Public Comments

One commenter stated that it is critical that all employees are trained and knowledgeable about what constitutes a breach, so that the covered entity or business associate can provide the required notifications within the required timeframe. The commenter also maintained that OCR should emphasize the necessity of this training.

With respect to the burden of proof placed upon covered entities and business associates, one commenter agreed that covered entities and business associates should have the burden to demonstrate that all notifications were provided following a breach of unsecured protected health information. However, the commenter asked that we include a presumption that an impermissible use or disclosure of protected health information did not constitute a breach if a covered entity or business associate has implemented a breach notification policy, completed a risk assessment, and documented that it followed its policy in reaching a conclusion that breach notification was not required.

Final Rule

We retain § 164.414 in this final rule without modification. We emphasize the importance of ensuring that all workforce members are appropriately trained and knowledgeable about what constitutes a breach and on the policies and procedures for reporting, analyzing, and documenting a possible breach of unsecured protected health information. We note that because this final rule modifies the definition of breach as stated in the interim final rule, covered

entities will need to update their policies and procedures and retrain workforce members as necessary to reflect such modifications.

With respect to this burden of proof, section 13402 of the statute places the burden of proof on a covered entity or business associate, if applicable, to demonstrate that all notifications were made as required. Therefore, section 164.530(j)(1)(iv) requires covered entities to maintain documentation to meet this burden of proof. This includes documentation that all required notifications have been provided or that no breach occurred and notification was not necessary. If a covered entity's determination with respect to whether a breach occurred is called into question, the covered entity should produce the documentation that demonstrates the reasonableness of its conclusions based on the findings of its risk assessment.

8. Technical Corrections

The interim final rule made several technical changes to align the HIPAA Rules in light of the new breach notification requirements of subpart D. See 74 FR 42755–56. We did not receive comments on these changes. We retain the technical corrections made in the interim final rule and also make an additional technical correction by adding ''and'' to the end of § 160.534(b)(1)(iii) to make clear the relationship between § 160.534(b)(1)(iii) and the new § 160.534(b)(1)(iv).

9. Preemption

Interim Final Rule

The interim final rule clarified that contrary State law will be preempted by these breach notification regulations. Section 1178 of the Social Security Act, 42 U.S.C. 1320d–7, which was added by HIPAA, provides that HIPAA administrative simplification provisions generally preempt conflicting State law. Section 160.203 states that a standard, requirement, or implementation specification that is adopted as regulation at 45 CFR parts 160, 162, or 164 and that is ''contrary to a provision of State law preempts the provision of State law.'' Thus, whether a State law is contrary to these breach notification regulations is to be determined based on the definition of ''contrary'' at § 160.202, which states that a State law is contrary if ''[a] covered entity would find it impossible to comply with both the State and Federal requirements'' or if the State law ''stands as an obstacle to the accomplishment and execution of the full purposes and objectives'' of the breach notification provisions in the Act. Covered entities must analyze relevant State laws with respect to the breach requirements to understand the interaction and apply this preemption standard appropriately.

In the interim final rule, we stated our belief that, in general, covered entities can comply with both the applicable State laws and this regulation and that in most cases, a single notification can satisfy the notification requirements under State laws and this regulation. For example, if a State breach notification law requires notification be sent to the individual in a shorter time frame than is required by this regulation, a covered entity that sends the notice within the time frame required by the State law will also be in compliance with this regulation's timeliness requirements.

Additionally, since the Act and rule are flexible in terms of how the elements are to be described, and do not prohibit additional elements from being included in the notice, in general, Federal requirements contain flexibility for covered entities to develop a notice that satisfies both laws.

Overview of Public Comments

While some commenters were pleased that the breach notification rule preempts conflicting State law, other commenters expressed confusion or concern with this preemption standard. Many commenters stated that despite the fact that in most cases a covered entity may only need to provide one notification to satisfy both State and Federal law, there will be some cases in which a covered entity will have to provide multiple notices to the same individual to ensure compliance with all relevant laws. This will result in confusion for the individual and increased costs for the covered entity. Some of these commenters suggested that this Federal breach notification law should preempt all State breach notification laws, or alternatively, that HHS should work with Congress and the States to harmonize the breach notification laws such that only one notice is required following a breach.

Final Rule

We maintain the preemption standard discussed in the interim final rule, which is based on section 1128 of the Social Security Act and applies to the HITECH Act's breach notification provisions by virtue of section 13421 of the HITECH Act. We continue to believe that, generally, covered entities are able to comply with both State and Federal requirements for providing breach notification with one breach notice based on the flexibility provided to entities in this Rule. However, even in the exceptional case, we do not have authority to preempt a State breach notification law that is not contrary to this Rule.

10. Responses to Other Public Comments

Comment: One commenter asked whether penalties are automatically assessed following a violation of the breach notification rule or if this is done at OCR's discretion and whether civil money penalties can be assessed for the underlying cause of a breach of unsecured protected health information where a covered entity has provided all required breach notifications.

Response: OCR's enforcement of the breach notification rule will be carried out pursuant to the Enforcement Rule. Pursuant to the Enforcement Rule, OCR may impose a civil money penalty for a failure to comply with the breach notification rule. OCR also has the discretion to work with the covered entity to achieve voluntary compliance through informal resolution, except in cases in which it has found a violation due to willful neglect. Because every breach of unsecured protected health information must have an underlying impermissible use or disclosure under the Privacy Rule, OCR also has the authority to impose a civil money penalty for the underlying Privacy Rule violation, even in cases where all required breach notifications were provided.

VI. Modifications to the HIPAA Privacy Rule Under GINA

A. Background

The Genetic Information Nondiscrimination Act of 2008 (''GINA''), Public Law 110–233, 122 Stat. 881, prohibits discrimination based on an individual's genetic information in both the health coverage and employment contexts. With respect to health coverage, Title I of GINA generally prohibits discrimination in premiums or contributions for group coverage based on genetic information, proscribes the use of genetic information as a basis for determining eligibility or setting premiums in the individual and Medicare supplemental (Medigap) insurance markets, and limits the ability of group health plans, health insurance issuers, and Medigap issuers to collect genetic information or to request or require that individuals undergo genetic testing. Title II of GINA generally prohibits use of genetic information in the employment context, restricts employers and other entities covered by Title II from requesting, requiring, or purchasing genetic

information, and strictly limits such entities from disclosing genetic information. The Departments of Labor, Treasury, and Health and Human Services (HHS) are responsible for administering and enforcing the GINA Title I nondiscrimination provisions, and the Equal Employment Opportunity Commission (EEOC) is responsible for administering and enforcing the GINA Title II nondiscrimination provisions.[13]

In addition to these nondiscrimination provisions, section 105 of Title I of GINA contains new privacy protections for genetic information, which require the Secretary of HHS to revise the Privacy Rule to clarify that genetic information is health information and to prohibit group health plans, health insurance issuers (including HMOs), and issuers of Medicare supplemental policies from using or disclosing genetic information for underwriting purposes.[14]

B. Overview of the Proposed Rule

On October 7, 2009, the Department published a notice of proposed rulemaking (NPRM or ''proposed rule'') to strengthen the privacy protections for genetic information under the HIPAA Privacy Rule by implementing the protections for genetic information required by GINA [15] and making related changes to the Rule. In particular, in accordance with section 105 of GINA and the Department's general authority under sections 262 and 264 of HIPAA, the Department proposed to: (1) Explicitly provide that genetic information is health information for purposes of the Privacy Rule; (2) prohibit all health plans covered by the HIPAA Privacy Rule from using or disclosing protected health information that is genetic information for underwriting purposes; (3) revise the provisions relating to the Notice of Privacy Practices for health plans that perform underwriting; (4) make a number of conforming changes to definitions and other provisions of the Rule; and (5) make technical corrections to update the definition of ''health plan.''

The 60-day public comment period for the proposed rule closed on December 7, 2009, and the Department received approximately twenty-five comments in response to its proposal.[16] After considering the public comments, the Department is issuing this final rule to strengthen the privacy protections for genetic information in accordance with GINA and the Department's general authority under sections 262 and 264 of HIPAA. In developing this rule, the Department consulted with the Departments of Labor and Treasury, as required by section 105(b)(1) of GINA, to ensure, to the extent practicable, consistency across the regulations. In addition, the Department coordinated with the EEOC in the development of these regulations.

The provisions of the proposed rule and the public comments received that were within the scope of the proposed rule are described in more detail below in the section-by-section description of the final rule.

C. Section-by-Section Description of Final Rule and Response to Public Comments

1. Scope: Extension of Required Protections to All Health Plans Subject to the HIPAA Privacy Rule

Proposed Rule

Section 105 of GINA requires HHS to modify the Privacy Rule to prohibit ''a covered entity that is a group health plan, health insurance issuer that issues health insurance coverage, or issuer of a medicare [sic] supplemental policy'' from using or disclosing genetic information for underwriting purposes. Section 105 of GINA provides that the terms ''group health plan'' and ''health insurance coverage'' have the meanings given such terms under section 2791 of the Public Health Service Act (PHSA) (42 U.S.C. 300gg–91), and that the term ''medicare [sic] supplemental policy'' has the meaning given such term in section 1882(g) of the Social Security Act. In addition, the term ''health insurance issuer,'' as defined at 42 U.S.C. 300gg–91, includes a health maintenance organization (HMO). These four types of entities (i.e., group health plans, health insurance issuers, and health maintenance organizations, as defined in the PHSA, as well as issuers of Medicare supplemental policies), correspond to the types of covered entities listed at subparagraphs (i) through (iii) and (vi) of paragraph (1) of the definition of ''health plan'' at § 160.103 in the HIPAA Privacy Rule, issued under HIPAA's Administrative Simplification provisions. These also are the entities to which HIPAA's nondiscrimination provisions apply and to which the nondiscrimination provisions of GINA Title I were directed.

However, in addition to these four types of entities, the HIPAA Privacy Rule also includes a number of other entities within the definition of ''health plan'': (1) Long-term care policies (excluding nursing home fixed-indemnity policies); (2) employee welfare benefit plans or other arrangements that are established or maintained for the purpose of offering or providing health benefits to the employees of two or more employers (to the extent that they are not group health plans or health insurance issuers); (3) high risk pools that are mechanisms established under State law to provide health insurance coverage or comparable coverage to eligible individuals; (4) certain public benefit programs, such as Medicare Part A and B, Medicaid, the military and veterans' health care programs, the Indian Health Service program, and others; as well as (5) any other individual or group plan, or combination of individual or group plans that provides or pays for the cost of medical care (as the term ''medical care'' is defined in section 2791(a)(2) of the PHSA, 42 U.S.C. 300gg–91(a)(2)). This last category includes, for example, certain ''excepted benefits'' plans described at 42 U.S.C. 300gg–91(c)(2), such as limited scope dental or vision benefits plans. See the definition of ''health plan'' at § 160.103.

In the NPRM, the Department, using both its authority under GINA as well as its broad authority under HIPAA, proposed to apply the prohibition on using and disclosing protected health information that is genetic information for underwriting to all health plans that are subject to the Privacy Rule, rather than solely to the plans GINA explicitly requires be subject to the prohibition. As explained in the proposed rule, the HIPAA Administrative Simplification provisions provide the Secretary with

[13] The Departments of Labor (Employee Benefits Security Administration), Treasury (Internal Revenue Service), and HHS (Centers for Medicare & Medicaid Services (CMS)) have issued regulations in a separate rulemaking (at 74 FR 51664) to implement sections 101–103 of GINA, which amended: section 702 of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1182); section 2702 of the Public Health Service Act (42 U.S.C. 300gg–1) (renumbered as section 2705 by the Affordable Care Act); and section 9802 of the Internal Revenue Code of 1986. Section 104 of GINA applies to Medigap issuers, which are subject to the provisions of section 1882 of the Social Security Act that are implemented by CMS, and which incorporate by reference certain provisions in a model regulation of the National Association of Insurance Commissioners (NAIC). The NAIC amended its model regulation on September 24, 2008, to conform to section 104 of GINA, and the amended regulation was published by CMS in the **Federal Register** on April 24, 2009, at 74 FR 18808. With respect to Title II of GINA, the EEOC issued final regulations on November 9, 2010, at 75 FR 68912.

[14] Section 105 of GINA, entitled ''Privacy and Confidentiality,'' amends Part C of Title XI of the Social Security Act by adding section 1180 to address the application of the HIPAA Privacy Rule to genetic information.

[15] Any reference in this preamble to GINA is a reference to Title I of GINA, except as otherwise indicated.

[16] The public comments are available at *http://www.regulations.gov*.

broad authority to craft privacy standards that uniformly apply to all health plans, regardless of whether such health plans are governed by other portions of the HIPAA statute. In addition, the Department indicated in the proposed rule that nothing in GINA explicitly or implicitly curtails this broad authority of the Secretary to promulgate privacy standards for any and all health plans that are governed by the HIPAA Administrative Simplification provisions.

Under the Privacy Rule, and consistent with HIPAA, an individual's privacy interests and rights with respect to the use and disclosure of protected health information are protected uniformly without regard to the type of health plan that holds the information. Thus, under the Privacy Rule, individuals can expect and benefit from privacy protections that do not diminish based on the type of health plan from which they obtain health coverage. In developing the proposed rule, the Department believed that individuals' interests in uniform protection under the Privacy Rule against the use or disclosure of their genetic information for underwriting purposes would outweigh any adverse impact on health plans that are not covered by GINA, particularly since it was not expected that all of the health plans subject to the Privacy Rule use or disclose protected health information that is genetic information for underwriting (or even perform underwriting generally, in the case of some of the public benefit plans). For these reasons, the Department proposed to apply the prohibition on using or disclosing protected health information that is genetic information for underwriting purposes to all health plans that are HIPAA covered entities.

Overview of Public Comments

The Department received comments both in support of and against the proposed application of the prohibition on using or disclosing genetic information for underwriting purposes to all health plans covered by the Privacy Rule. Several commenters agreed that the extension of the proposed requirements to all health plans is an appropriate exercise of the Secretary's discretion under HIPAA and is necessary to protect the privacy interests of all individuals without regard to the type of health plan holding individuals' health information, and stated that such an extension would further encourage individuals to take advantage of genetic services. In addition, one commenter in support of the proposal indicated that sixteen States also regulate the use of genetic information in disability insurance, and ten States regulate its use in long-term care insurance, and it is expected that these numbers will continue to increase. The commenter stated that as States move forward in this area it was appropriate for the Federal government to do so as well. However, this and one other commenter, while generally in support of extending the prohibition on using or disclosing genetic information for underwriting to all health plans, also recommended that the Department monitor the impact of such a prohibition on long-term care insurers.

A few commenters did not support the Department's proposal and argued that the prohibition against using or disclosing genetic information for underwriting purposes in the Privacy Rule should apply only to those plans to which GINA expressly applies. Commenters argued that applying the prohibition beyond the health plans identified in GINA was contrary to GINA and its intent.

Certain commenters expressed particular disagreement and concern with applying the prohibition on the use of genetic information for underwriting to long-term care insurers. One commenter argued that there was clear Congressional intent in the legislative history of GINA to exempt ''excepted benefits,'' particularly long-term care insurance, from any prohibitions under GINA and thus, the Privacy Rule should not apply the prohibition on underwriting with genetic information to issuers of long term care policies. The commenter also argued that the GINA prohibition should not apply to long-term care insurers because long-term care plans have different characteristics from other health plans and applying the GINA prohibition to long-term care insurers would jeopardize the ability of long-term care insurers to adequately underwrite and thus, the viability of the long-term care insurance market. The commenter explained that this would be due to the fact that when underwriting, long term care insurers look to determine an individual's probability of needing long-term care in the future and diagnosis of a particular condition is not the only way this may be determined and in some cases may not even be relevant to such a determination. The Department also heard similar concerns about the potential negative impact of an underwriting prohibition on the economic viability of the long-term market, from certain members of Congress who wrote to the Secretary on this issue, as well as from certain outside parties during fact finding meetings held by the Department.

Final Rule

The final rule adopts the approach of the proposed rule to apply the prohibition on using or disclosing protected health information that is genetic information for underwriting purposes to all health plans that are covered entities under the HIPAA Privacy Rule, including those to which GINA does not expressly apply, except with regard to issuers of long term care policies. We continue to disagree with the commenters that stated such an extension would conflict with GINA and is outside the scope of our authority. As explained more fully in the proposed rule, the Department has broad authority under HIPAA to regulate a health plan's uses and disclosures of protected health information, including genetic information, to protect an individual's privacy interests. See 74 FR 51698, 51699–51700. It does not follow that by exempting ''excepted benefits'' from the prohibitions under GINA that Congress intended to restrict the Department's broad authority under HIPAA. Further, there is no conflict with GINA in extending the same privacy protections outlined in GINA to those health plans that are not covered by GINA but are otherwise covered by the HIPAA Privacy Rule. GINA and section 264 of HIPAA are not irreconcilably inconsistent but rather operate concurrently without conflict. Lastly, GINA did not override HIPAA, and did not displace the Department's authority to prohibit uses and disclosures of genetic information that GINA does not otherwise prohibit. Therefore, nothing in GINA explicitly or implicitly curtails the broad authority of the Secretary to promulgate privacy standards for any and all health plans that are governed by the HIPAA Administrative Simplification provisions.

We also continue to believe that individuals have a strong privacy interest in not having their genetic information used in an adverse manner for underwriting purposes and to believe that this privacy interest outweighs any adverse impact on most health plans covered by the Privacy Rule. With respect to most health plans not subject to GINA, the public comment did not indicate that a prohibition on using genetic information for underwriting would have significant adverse impacts on the viability of these plans. Nor did the public comment generally provide information showing that these health plans actually use or disclose protected health information that is genetic information for underwriting, or plan to

do so in the future (or even perform underwriting generally, in the case of some of the public benefit plans).

However, as indicated above, the Department did hear from a number of sources about the potential adverse impact a prohibition on using genetic information for underwriting would have on the ability of a long-term care insurer to effectively underwrite and thus, on the viability of the long-term care insurance market generally. The Department recognizes the importance of long-term care insurance coverage and the need to ensure its continued availability. The Department also acknowledges that, at this time, it does not have the information necessary to more precisely and carefully measure the extent of such an impact on the long-term market in order to appropriately balance an individual's privacy interests with such an impact. Thus, this final rule excludes long-term care plans from the underwriting prohibition.

While we exempt long-term care plans from the underwriting prohibition in this final rule, we continue to believe an individual has a strong privacy interest in the way his or her genetic information is used for the underwriting of long-term care insurance. At the current time, however, we do not have sufficient information to determine the proper balance between the individual's privacy interests and the industry's concerns about the cost effects of excluding genetic information. For that reason, we are looking into ways to obtain further information on this issue, such as through a study by the National Association of Insurance Commissioners (NAIC) on the tension between the use of genetic information for underwriting and the associated privacy concerns in the context of their model long-term care rules. Based on the information the Department may obtain, the Department will reassess how best to move forward in this area in the future.

Long-term care plans, while not subject to the underwriting prohibition, continue to be bound by the Privacy Rule, as are all other covered health plans, to protect genetic information from improper uses and disclosures, and to only use or disclose genetic information as required or expressly permitted by the Rule, or as otherwise authorized by the individual who is the subject of the genetic information.

2. Section 160.101—Statutory Basis and Purpose

We have revised § 160.101, which describes the statutory basis of the HIPAA Rules, to include a reference to section 1180 of the Social Security Act, as added by section 105 of GINA (Pub. L. 110–233).

3. Section 160.103—Definitions

The final rule modifies § 160.103 of the Privacy Rule to: (1) Revise the definition of ''health information'' to make clear that the term includes ''genetic information;'' (2) add definitions for the GINA-related terms of ''family member,'' ''genetic information,'' ''genetic services,'' ''genetic test,'' and ''manifestation or manifested;'' and (3) make technical corrections to the definition of ''health plan.'' With respect to the GINA-related terms, the final rule adopts definitions that are generally consistent with the definitions of such terms promulgated in the implementing regulations for sections 101–103 of GINA. This will facilitate compliance for those health plans subject to both the privacy as well as the nondiscrimination provisions of GINA.

a. Definition of ''Health information''

Proposed Rule

Prior to enactment of GINA, the Department issued guidance that genetic information is health information protected by the Privacy Rule to the extent that such information is individually identifiable and held by a covered entity (subject to the general exclusions from the definition of ''protected health information'').[17] Section 105 of GINA requires the Secretary to revise the Privacy Rule to make clear that genetic information is health information under the Rule. Thus, the Department proposed to modify the definition of ''health information'' at § 160.103 to explicitly provide that such term includes genetic information.

Overview of Public Comments

The Department received a few comments expressing specific support for and one comment against the proposed inclusion of the term ''genetic information'' in the definition of ''health information.'' The commenters supporting the revision to the definition of ''health information'' indicated that such an inclusion was necessary to clarify that genetic information is health information. The commenter against the proposed inclusion to the definition argued that although GINA directs the Department to treat genetic information as health information, the language of GINA does not require a change to the definition of ''health information,'' and this change would create costs for health plans, which would have to update all their policies and procedures to reflect the change.

Final Rule

The final rule adopts the proposed modification to the definition of ''health information'' at § 160.103. This modification to the definition is a necessary clarification to the Privacy Rule based on the statutory language. Given that revising the definition of ''health information'' to include genetic information does not substantively change the scope of the Privacy Rule, it is unclear why such a change alone would require revisions to a health plan's policies and procedures. Health plans that perform underwriting will otherwise need to revise their policies and procedures as necessary to comply with this final rule, as well as the modifications to the HIPAA Rules required by the Health Information Technology for Economic and Clinical Health (HITECH) Act. Thus, to the extent the concern about this modification stems from the fact that a health plan's policies and procedures quote the prior regulatory definition of ''health information,'' the health plan can revise the definition at the time it is otherwise updating its policies and procedures to comply with these rules.

b. Definition of ''Genetic Information''

Proposed Rule

The term ''genetic information'' is defined in GINA and establishes what information is protected by the statute. Section 105 of GINA provides that the term ''genetic information'' in section 105 shall have the same meaning given the term in section 2791 of the PHSA (42 U.S.C. 300gg–91), as amended by section 102 of GINA. Section 102(a)(4) of GINA defines ''genetic information'' to mean, with respect to any individual, information about: (1) Such individual's genetic tests; (2) the genetic tests of family members of such individual; and (3) the manifestation of a disease or disorder in family members of such individual (i.e., family medical history). GINA also provides that the term ''genetic information'' includes, with respect to any individual, any request for, or receipt of, genetic services, or participation in clinical research which includes genetic services, by such

[17] See, e.g., Frequently Asked Question number 354, available at *http://www.hhs.gov/ocr/privacy/hipaa/faq/protected_health_information/354.html*, which states: *Question:* Does the HIPAA Privacy Rule protect genetic information? *Answer:* Yes, genetic information is health information protected by the Privacy Rule. Like other health information, to be protected it must meet the definition of protected health information: it must be individually identifiable and maintained by a covered health care provider, health plan, or health care clearinghouse. See also 45 CFR 160.103.

individual or family member of such individual. GINA expressly provides that the term ''genetic information'' shall not include information about the sex or age of any individual. This basic definition of ''genetic information'' in section 102(a)(4) of GINA (and that is to apply for purposes of section 105) is also expanded by section 102(a)(3), which provides that any reference to genetic information concerning an individual or family member in the PHSA shall include: with respect to an individual or family member of an individual who is a pregnant woman, the genetic information of any fetus carried by such pregnant woman; and with respect to an individual or family member utilizing an assisted reproductive technology, the genetic information of any embryo legally held by the individual or family member. The Department proposed to include this statutory definition of ''genetic information'' in § 160.103.

Overview of Public Comments

Most commenters did not address the proposed definition of ''genetic information'' in their comments on the proposed rule. However, one commenter stated that it was unclear what information may fall within the scope of the term ''genetic information'' and whether such term may be construed to include traditional medical information or medical tests used in underwriting today.

Final Rule

The final rule adopts without modification the definition of ''genetic information'' proposed in the NPRM. This definition is consistent with the definition found in the implementing regulations for sections 101–103 of GINA and with which compliance is already required by most health plans. The term ''genetic information'' includes information about the genetic tests of the individual or of the individual's family members and about diseases or disorders manifested in an individual's family members (i.e., family health history). Thus, information about manifested diseases, disorders, or conditions of the individual or medical tests that do not meet the rule's definition of ''genetic test,'' such as HIV tests, complete blood counts, cholesterol or liver function tests, or tests to detect for the presence of alcohol or drugs, are not genetic information, and such information may be used or disclosed for underwriting purposes. Conversely, family health histories and information about genetic tests, such as tests to determine whether an individual or family member has a gene variant associated with breast cancer, are genetic information, and such information may not be used or disclosed for underwriting purposes. The definitions of ''manifestation or manifested'' and ''genetic test'' are discussed more fully below.

c. Definition of ''Genetic Test''

Proposed Rule

As explained above, GINA provides that the term ''genetic information'' includes information about an individual's genetic tests or the genetic tests of family members of the individual. Section 105 of GINA provides that the term ''genetic test'' shall have the same meaning as the term has in section 2791 of the PHSA (42 U.S.C. 300gg–91), as amended by section 102 of GINA. Section 102(a)(4) of GINA amends section 2791(d) of the PHSA to define ''genetic test'' to mean ''an analysis of human DNA, RNA, chromosomes, proteins, or metabolites, that detects genotypes, mutations, or chromosomal changes.'' GINA further clarifies that the term ''genetic test'' does not include an analysis of proteins or metabolites that does not detect genotypes, mutations, or chromosomal changes, nor does it include an analysis of proteins or metabolites that is directly related to a manifested disease, disorder, or pathological condition that could reasonably be detected by a health care professional with appropriate training and expertise in the field of medicine involved.

Consistent with the statutory definition, the Department proposed to define ''genetic test'' at § 160.103 as an analysis of human DNA, RNA, chromosomes, proteins, or metabolites, if the analysis detects genotypes, mutations, or chromosomal changes, and to provide in the definition that ''genetic test'' does not include an analysis of proteins or metabolites that is directly related to a manifested disease, disorder, or pathological condition. While the statute refers to a ''manifested'' disease as one that could reasonably be detected by a health care professional with appropriate training and expertise in the field of medicine involved, the statute does not define ''manifested.'' Consequently, for clarity, the Department proposed a definition of ''manifested,'' as described below.

Overview of Public Comments

The Department received one comment requesting that the Department include examples within the regulatory text of the definition and another comment stated that it is not clear what constitutes a genetic test under the definition.

Final Rule

The final rule adopts without modification the definition of ''genetic test'' as proposed in the NPRM. This definition is consistent with the definition found in the implementing regulations for sections 101–103 of GINA and with which compliance is already required by most health plans. Under this definition, a test to determine whether an individual has a gene variant associated with breast cancer (such as the BRCA1 or BRCA2 variant) is a genetic test. Similarly, a test to determine whether an individual has a genetic variant associated with hereditary nonpolyposis colorectal cancer is a genetic test. Such tests are genetic in nature because they detect genotypes, mutations, or chromosomal changes. In contrast, medical tests that do not detect genotypes, mutations, or chromosomal changes, are not genetic tests. For example, HIV tests, complete blood counts, cholesterol tests, liver function tests, or tests for the presence of alcohol or drugs are not genetic tests. Consistent with the approach taken generally with the HIPAA Privacy Rule, the Department declines to include these examples in the regulatory text. The Department intends to issue future guidance on its web site about this issue.

d. Definition of ''Genetic Services''

Proposed Rule

GINA provides that the term ''genetic information'' includes, with respect to any individual, any request for, or receipt of, genetic services, or participation in clinical research which includes genetic services, by such individual or any family member of such individual. Section 102(a)(4) of GINA defines ''genetic services'' to mean: (1) A genetic test; (2) genetic counseling (including obtaining, interpreting, or assessing genetic information); or (3) genetic education. Thus, the fact that an individual or a family member of the individual requested or received a genetic test, counseling, or education is information protected under GINA. Genetic counseling and education are means by which individuals can obtain information and support about potential risks for genetic diseases and disorders. The Department proposed to add the statutory definition of ''genetic services'' to the Privacy Rule.

Overview of Public Comments

The Department received one comment requesting that the

Department add language to the definition to make clear that the genetic tests, genetic counseling, or genetic education of a family member of an individual are specifically covered by the term.

Final Rule

The final rule adopts without modification the definition of ''genetic services'' proposed in the NPRM. This definition is consistent with the definition found in the implementing regulations for sections 101–103 of GINA and with which compliance is already required by most health plans. The Department does not believe it necessary to add the term ''family member'' to the definition of ''genetic services'' because the definition of ''genetic information'' makes clear that information about any request for, or receipt of, genetic services by a family member of an individual is protected information.

e. Definition of ''Family Member''

Proposed Rule

The term ''family member'' is used in the definition of ''genetic information'' in GINA to indicate that an individual's genetic information also includes information about the genetic tests of the individual's family members, as well as family medical history. Section 105 of GINA states that the term ''family member'' shall have the meaning given such term in section 2791 of the PHSA (42 U.S.C. 300gg–91), as amended by GINA section 102(a)(4), which defines ''family member'' to mean, with respect to any individual: (1) A dependent (as such term is used for purposes of section 2701(f)(2) of the PHSA, 42 U.S.C. 300gg(f)(2)) of such individual; or (2) any other individual who is a first-degree, second-degree, third-degree, or fourth-degree relative of such individual or of a dependent of the individual. Section 2701(f)(2) of the PHSA uses the term ''dependent'' to mean an individual who is or may become eligible for coverage under the terms of a group health plan because of a relationship to the plan participant.

The Department proposed to incorporate GINA's definition of ''family member'' into the Privacy Rule. The proposed rule also clarified within the definition that relatives by affinity (such as by marriage or adoption) are to be treated the same as relatives by consanguinity (that is, relatives who share a common biological ancestor) and that, in determining the degree of relationship, relatives by less than full consanguinity (such as half-siblings, who share only one parent) are treated the same as relatives by full consanguinity (such as siblings who share both parents). The NPRM explained that this broad interpretation of ''family member'' was consistent with GINA's legislative history, which suggests that the term ''family member'' is to be broadly construed to provide the maximum protection against discrimination.[18] In addition, the Department proposed to include in the definition of ''family member'' non-exhaustive lists of persons who are first-, second-, third-, or fourth-degree relatives. Finally, within the definition of ''family member,'' the Department proposed to refer to the definition of ''dependent'' contained in the implementing regulations at 45 CFR 144.103 rather to the PHSA directly.

Overview of Public Comments

One commenter expressed support for including relatives by affinity and by less than full consanguinity, agreeing that this interpretation is consistent with Congressional intent and provides the most privacy protection for individuals. This commenter also was supportive of including non-exhaustive lists of persons who are first-, second-, third-, and fourth-degree relatives to add clarity to the definition.

Final Rule

As we received only support with regard to the definition of ''family member,'' the final rule adopts without modification the definition of ''family member'' proposed in the NPRM. This definition also is consistent with the definition found in the implementing regulations for sections 101–103 of GINA and with which compliance is already required by most health plans.

f. Definition of ''Manifestation or Manifested''

Proposed Rule

Although not separately defined by GINA, the terms ''manifestation'' or ''manifested'' are used in GINA in three important contexts. First, GINA uses the term ''manifestation'' to incorporate ''family medical history'' into the definition of ''genetic information'' by stating that ''genetic information'' includes, with respect to an individual, the manifestation of a disease or disorder in family members of such individual. Second, GINA uses the term ''manifested'' to exclude from the definition of ''genetic test'' those tests that analyze a physical malady rather than genetic makeup by excluding from the definition analyses of proteins or metabolites that are directly related to a manifested disease, disorder, or pathological condition. Third, GINA uses the term ''manifestation'' to clarify that nothing in Title I of GINA should be construed to limit the ability of a health plan to adjust premiums or contribution amounts for a group health plan based on the manifestation of a disease or disorder of an individual enrolled in the plan.[19] However, GINA provides that, in such case, the manifestation of a disease or disorder in one individual cannot also be used as genetic information about other group members and to further increase the premium for the plan. Similarly, for the individual health insurance market, GINA clarifies that it does not prohibit a health plan from establishing rules for eligibility for an individual to enroll in coverage or from adjusting premium or contribution amounts for an individual based on the manifestation of a disease or disorder in that individual or in a family member of such individual where such family member is covered under the individual's policy. However, under GINA, the manifestation of a disease or disorder in one individual cannot also be used as genetic information about other individuals and to further increase premiums or contribution amounts.

Given the importance of the term ''manifested'' or ''manifestation,'' the Department proposed to define the term. Although GINA does not define the term, it is clear from the statutory definition of ''genetic test'' that a manifested disease or disorder is one ''that could reasonably be detected by a health care professional with appropriate training and expertise in the field of medicine involved.'' Accordingly, the proposed rule defined the term ''manifestation or manifested'' to mean, with respect to a disease, disorder, or pathological condition, that an individual has been or could reasonably be diagnosed with the disease, disorder, or pathological condition by a health care professional with appropriate training and expertise in the field of medicine involved. The proposed definition also provided that a disease, disorder, or pathological condition is not manifested if the diagnosis is based principally on genetic information. This clarification was included due to the fact that variants of genes associated with diseases have varying degrees of predictive power for

[18] *See* House Report 110–28, Part 2 at 27.

[19] We note that the Affordable Care Act, enacted on March 23, 2010, includes a provision effective for plan years beginning on or after January 1, 2014, that prohibits insurers from discriminating against individuals or charging individuals higher rates based on pre-existing conditions. See Public Law 111–148.

later development of the disease. In some cases, an individual may have a genetic variant for a disease and yet never develop the disease. In other cases, the presence of a genetic variant indicates that the individual will eventually develop the disease, such as is the case with Huntington's disease. However, an individual may obtain a positive test that shows the genetic variant for Huntington's disease decades before any clinical symptoms appear. Under the proposed definition, the presence of a genetic variant alone would not constitute the diagnosis of a disease even in cases where it is certain the individual possessing the genetic variant will eventually develop the disease, such as with Huntington's disease.

Overview of Public Comments

A few commenters expressed support for adopting the proposed definition of ''manifestation or manifested'' because it would provide clarity to the rule and the scope of the underwriting prohibition. One commenter requested that the Department include the examples provided in the preamble to the proposed rule directly within the regulatory definition. A few commenters raised concerns about the inclusion in the proposed definition of the clarification that ''a disease, disorder, or pathological condition is not manifested if the diagnosis is based principally on genetic information.'' It was argued that the proposed definition was too narrow because, for some diseases, disorders, or pathological conditions, a genetic test is the primary means of diagnosing the condition and further that genetic tests will more frequently be used to diagnose diseases or conditions in the future given the continuing evolution of genetics. It was also argued that the proposed definition went beyond GINA by indicating how a manifested disease or disorder is diagnosed.

Final Rule

The final rule adopts without modification the definition of ''manifestation or manifested'' proposed in the NPRM. The definition is consistent with the definition of ''manifestation or manifested'' found in the implementing regulations for the non-discrimination provisions of sections 101–103 of GINA and with which compliance is already required for most health plans. In developing this definition, the agencies consulted with technical experts at the National Human Genome Research Institute within the National Institutes of Health (NIH). In addition, for the reasons stated above regarding the varying degrees of predictive power genes provide in terms of ultimate development of a disease, as well as of the fact that a genetic test for a disease may precede clinical signs or symptoms by years or even decades, the Department does not believe that the definition is too narrow but rather that it is consistent with the provisions of GINA that protect genetic information from being used for health coverage determinations. Finally, the definition does not preclude a health care provider from performing one or more genetic tests to confirm a diagnosis so long as the diagnosis is not based solely or principally on the result of the genetic test.

To illustrate the definition, we provide the following examples, which were also included in the NPRM:

- An individual may have a family member that has been diagnosed with Huntington's disease and also have a genetic test result that indicates the presence of the Huntington's disease gene variant in the individual. However, when the individual is examined by a neurologist (a physician with appropriate training and expertise for diagnosing Huntington's disease) because the individual has begun to suffer from occasional moodiness and disorientation (symptoms which are associated with Huntington's disease), and the results of the examination do not support a diagnosis of Huntington's disease, then Huntington's disease is not manifested with respect to the individual. In contrast, if the individual exhibits additional neurological and behavioral symptoms, and the results of the examination support a diagnosis of Huntington's disease by the neurologist, then Huntington's disease is manifested with respect to the individual.
- An individual has had several family members with colon cancer, one of whom underwent genetic testing which detected a mutation in the MSH2 gene associated with hereditary nonpolyposis colorectal cancer (HNPCC). On the recommendation of his physician (a health care professional with appropriate training and expertise in the field of medicine involved), the individual undergoes a targeted genetic test to look for the specific mutation found in the family member of the individual to determine if the individual himself is at increased risk for cancer. The genetic test shows that the individual also carries the mutation but the individual's colonoscopy indicates no signs of disease and the individual has no symptoms. Because the individual has no signs or symptoms of colorectal cancer that could be used by the individual's physician to diagnose the cancer, HNPCC is not a manifested disease with respect to the individual. In contrast, if the individual undergoes a colonoscopy or other medical tests that indicate the presence of HNPCC, and the individual's physician makes a diagnosis of HNPCC, HNPCC is a manifested disease with respect to the individual.
- If a health care professional with appropriate expertise makes a diagnosis based on the symptoms of the patient, and uses genetic tests to confirm the diagnosis, the disease will be considered manifested, despite the use of genetic information. For example, if a neurologist sees a patient with uncontrolled movements, a loss of intellectual faculties, and emotional disturbances, and the neurologist suspects the presence of Huntington's disease, the neurologist may confirm the diagnosis with a genetic test. While genetic information is used as part of the diagnosis, the genetic information is not the sole or principal basis for the diagnosis, and, therefore, the Huntington's disease would be considered a manifested disease of the patient.

As with the definition of ''genetic test,'' the Department declines to include these examples in the regulatory text as this is inconsistent with the approach generally taken in the HIPAA Privacy Rule. The Department intends to issue future guidance on its web site with respect to the Rule's protections for genetic information.

g. Definition of ''Health Plan''

Proposed Rule

The Department proposed to make technical corrections to update the definition of ''health plan'' by revising and renumbering the definition to: Include specific reference to the Voluntary Prescription Drug Benefit Program under Part D of title XVIII of the Social Security Act, 42 U.S.C. 1395w–101 through 1395w–152; remove the specific reference to the Civilian Health and Medical Program of the Uniformed Services (CHAMPUS) (as defined in 10 U.S.C. 1072(4)), as this program is now part of the TRICARE health care program under title 10 of the United States Code, and revise the reference to the title 10 health care program accordingly to read more generally ''health care program for the uniformed services'' rather than ''health care program for active military personnel''; and reflect that Part C of title XVIII of the Social Security Act, 42 U.S.C. 1395w–21 through 1395w–28, is now called the Medicare Advantage program.

Overview of Public Comments

The Department did not receive any comments on the proposed technical corrections to the definition of ''health plan.''

Final Rule

The final rule incorporates the technical corrections to the definition.

4. Section 164.501—Definitions

The Department proposed to modify § 164.501 to add a definition of ''underwriting purposes'' and to make conforming changes to the definitions of ''payment'' and ''health care operations.''

a. Definition of ''Underwriting Purposes''

Proposed Rule

Section 105 of GINA provides that the term ''underwriting purposes'' means, with respect to a group health plan, health insurance coverage, or Medicare supplemental policy: (A) Rules for, or determination of, eligibility (including enrollment and continued eligibility) for, or determination of, benefits under the plan, coverage, or policy; (B) the computation of premium or contribution amounts under the plan, coverage, or policy; (C) the application of any pre-existing condition exclusion under the plan, coverage, or policy; and (D) other activities related to the creation, renewal, or replacement of a contract of health insurance or health benefits.

The Department proposed to adopt GINA's statutory definition of ''underwriting purposes'' in § 164.501 of the Privacy Rule, but also proposed to include certain clarifications for consistency with the regulations promulgated to implement the nondiscrimination provisions in sections 101 through 103 of GINA. In particular, the Department proposed to include a parenthetical to explain that the rules for, or determination of eligibility for, or determination of, benefits under the plan include changes in deductibles or other cost-sharing mechanisms in return for activities such as completing a health risk assessment or participating in a wellness program. The proposed rule also included a parenthetical to make clear that the computation of premium or contribution amounts under the plan, coverage, or policy includes discounts, rebates, payments in kind, or other premium differential mechanisms in return for activities such as completing a health risk assessment or participating in a wellness program. Finally, we proposed a provision within the definition to clarify that ''underwriting purposes'' does not include determinations of medical appropriateness where an individual seeks a benefit under the plan, coverage, or policy.

Overview of Public Comments

About ten commenters addressed the proposed definition of ''underwriting purposes.'' Four commenters generally supported the proposed definition. Other commenters expressed concern with the definition's inclusion of discounts, rebates, payments in kind, or other premium differential mechanisms in return for activities such as completing a health risk assessment (HRA) or participating in a wellness program. These commenters were concerned that prohibiting the use of genetic information, particularly family health history, for such purposes would have a detrimental impact on wellness and disease management programs. One commenter was concerned that the definition would prohibit dental insurance plans from offering preventive prognostic features to enrollees as part of the plan that test for susceptibility to dental decay and periodontal diseases. Enrollees that test positive would be provided with additional plan benefits as a supplement to the standard benefits to cover more aggressive preventive services. Finally, a few commenters were concerned that the broad definition of ''underwriting purposes'' would preclude plans from using HRAs and offering wellness programs even if no genetic information is requested or used. For example, one commenter was concerned that the definition would prohibit the use of ''personal habit'' information, such as information about smoking, or alcohol or drug use.

Final Rule

The final rule adopts the proposed definition of ''underwriting purposes'' but moves the definition to within the underwriting prohibition at § 164.502(a)(5)(i). This makes clear that the definition applies only for purposes of the prohibition on a health plan's use or disclosure of genetic information for underwriting purposes. As discussed more fully below with respect to the definition of ''health care operations,'' we move the definition of ''underwriting purposes'' and retain the term ''underwriting'' within the definition of ''health care operations'' in response to several public comments expressing concern that the proposed rule would no longer allow health plans to use or disclose any protected health information (i.e., even non-genetic information) for underwriting.

The adopted definition is consistent with the definition promulgated in the interim final regulations to implement sections 101–103 of GINA and with which compliance is already required by most health plans. We decline to exclude wellness programs and the use of HRAs from the definition because, as discussed in the interim final regulations issued by DOL, Treasury, and HHS, GINA Title I does not include an exception for wellness programs.[20] However, we emphasize that health plans may continue to provide incentives for completing HRAs and participating in wellness programs in manners that do not involve the use or disclosure of genetic information. For example, ''personal habit'' information about an individual, such as smoking status and alcohol and drug use, is not genetic information and thus, may be used by health plans for underwriting purposes. Further, DOL has issued guidance which makes clear that health plans may continue to collect family health history through the use of HRAs that are not tied to any reward.[21]

In addition, the definition of ''underwriting purposes'' includes an exception for determinations of medical appropriateness where an individual seeks a benefit under the plan, coverage, or policy. Thus, to the extent that an individual is seeking a particular benefit under the plan and the health plan needs genetic information to determine the medical appropriateness of providing the benefit to the individual, the plan may use or disclose the minimum necessary genetic information to determine the medical appropriateness of providing the benefit. For example, if a health plan covers yearly mammograms for individuals under age 40 only in cases where the individual can demonstrate she is at increased risk for breast cancer, the plan can ask an individual under age 40 to provide the results of a genetic test or family health history and use such information to determine medical appropriateness prior to paying a claim for the mammogram. The medical appropriateness exception would also cover situations where a dental plan requires the results of a genetic test prior to offering a supplemental benefit for more aggressive preventive services to the extent the individual seeks such a benefit. For example, a dental plan may provide information to all of its enrollees about how to take advantage of

[20] See 74 FR 51669, footnote 12.

[21] See Q14 at *http://www.dol.gov/ebsa/faqs/faq-GINA.html.*

such a benefit, and when an enrollee contacts the plan about obtaining the benefit, may require the individual to take and provide the results of a genetic test to determine the medical appropriateness of providing the supplemental benefit to the individual.

b. Definition of ''Health Care Operations''

Proposed Rule

The definition of ''health care operations'' at § 164.501 includes at paragraph (3) ''underwriting, premium rating, and other activities relating to the creation, renewal or replacement of a contract of health insurance or benefits * * *.'' To avoid confusion with the use of both ''underwriting'' and ''underwriting purposes'' in the Privacy Rule, and in recognition of the fact that the proposed definition of ''underwriting purposes'' includes activities that fall within both the definitions of ''payment'' and ''health care operations'' in the Rule, the Department proposed to remove the term ''underwriting'' from the definition of ''health care operations.'' We also proposed to add the term ''enrollment'' to the express list of health care operations activities to make clear that the removal of the term ''underwriting'' would not impact the use or disclosure of protected health information that is not genetic information for enrollment purposes. These proposed revisions were not intended to be substantive changes to the definition and thus, health plans would be permitted to continue to use or disclose protected health information, except genetic information, for underwriting purposes.

Overview of Public Comments

The Department received a few comments on the proposed revisions to the definition of ''health care operations.'' One commenter supported the inclusion of the word ''enrollment.'' A few commenters, however, expressed concern and confusion that the removal of the term ''underwriting'' from the definition of ''health care operations'' would no longer permit uses or disclosures of even non-genetic protected health information for underwriting.

Final Rule

Due to the confusion and concern expressed by the commenters regarding the removal of the term ''underwriting'' from the definition, we retain the term ''underwriting'' within the definition of ''health care operations'' at § 164.501 However, to make clear that a health plan may continue to use or disclose only protected health information that is not genetic information for underwriting, we include a reference to the prohibition on using or disclosing genetic information for underwriting purposes within the definition. The final rule also retains the term ''enrollment'' within the definition because we believe it is helpful to clarify that this is a permitted health care operations activity.

c. Definition of ''Payment''

Proposed Rule

The definition of ''payment'' in the Privacy Rule at § 164.501 includes activities, such as ''determinations of eligibility or coverage'' by a health plan, some of which may fall within the definition of ''underwriting purposes.'' To avoid any implication that a health plan would be permitted to use or disclose protected health information for ''payment'' purposes that are otherwise prohibited by the underwriting prohibition, we proposed to include a cross-reference in the definition of ''payment'' to the prohibition. Further, we believed the inclusion of such a cross-reference to be necessary to properly align the definition of ''payment'' in the Privacy Rule with the nondiscrimination provisions of GINA Title I and their implementing regulations. GINA provides a rule of construction at section 102(a)(2), which adds paragraph 2702(c)(3) of the PHSA, to make clear that health plans are not prohibited from obtaining and using the results of a genetic test in making determinations regarding payment, as such term is defined by the HIPAA Privacy Rule. Thus, the proposed exception would make clear that GINA's rule of construction regarding payment does not allow a health plan to use the results of genetic tests for activities that would otherwise constitute ''underwriting purposes,'' such as for determinations of eligibility for benefits.

Overview of Public Comments

The Department received two comments on the proposed change to the definition of ''payment,'' one supporting the change and one indicating it is unnecessary.

Final Rule

For the reasons described above, the final rule adopts the proposed change to the definition of ''payment.''

5. Section 164.502(a)—Uses and Disclosures of Protected Health Information: General Rules

a. Prohibition

Proposed Rule

To implement section 105 of GINA, the Department proposed a new prohibition on health plans using or disclosing protected health information that is genetic information for underwriting purposes at § 164.502(a)(3). We made clear that such a provision would operate notwithstanding the other provisions in the Privacy Rule permitting uses and disclosures, and proposed a conforming change to § 164.502(a)(1)(iv) to clarify further that an authorization could not be used to permit a use or disclosure of genetic information for underwriting purposes.

Overview of Public Comments

Some commenters expressly supported the proposed modification to the Privacy Rule to include the prohibition, and the proposed clarification that an authorization cannot be used to otherwise permit a prohibited use or disclosure of genetic information. One commenter suggested adding the examples from the preamble to the regulatory text, as well as language to the regulatory text to clarify that the prohibition applies to genetic information obtained by a health plan prior to the passage of GINA.

Final Rule

The final rule adopts the proposed prohibition on a health plan's use or disclosure of genetic information for underwriting purposes, except with regard to health plans that are issuers of long term care policies, as explained above in section VI.C.1 regarding to which plans the final rule applies. This prohibition, located in this final rule at § 164.502(a)(5), applies to all genetic information from the compliance date of these modifications forward, regardless of when or where the genetic information originated. We do not believe a clarification of this fact in the regulatory text is necessary.

Consistent with Sec. 101(a) of the statute, this prohibition should not be construed to limit the ability of a health plan to adjust premiums or contribution amounts for a group health plan based on the manifestation of a disease or disorder of an individual enrolled in the plan, even though a health plan cannot use the manifestation of a disease or disorder in one individual as genetic information about other group members and to further increase the premium for the plan. Similarly, for the individual

health insurance market, a health plan is not prohibited from establishing rules for eligibility for an individual to enroll in coverage or from adjusting premium or contribution amounts for an individual based on the manifestation of a disease or disorder in that individual or in a family member of such individual where such family member is covered under the individual's policy, even though the health plan cannot use the manifestation of a disease or disorder in one individual as genetic information about other individuals to further increase premiums or contribution amounts for those other individuals.

To illustrate how the prohibition operates, we reiterate the following examples (but for the reasons explained above, decline to include them in the regulatory text). If a health insurance issuer, with respect to an employer-sponsored group health plan, uses an individual's family medical history or the results of genetic tests maintained in the group health plan's claims experience information to adjust the plan's blended, aggregate premium rate for the upcoming year, the issuer would be using protected health information that is genetic information for underwriting purposes in violation of § 164.502(a)(5)(i). Similarly, if a group health plan uses family medical history provided by an individual incidental to the collection of other information on a health risk assessment to grant a premium reduction to the individual, the group health plan would be using genetic information for underwriting purposes in violation of § 164.502(a)(5)(i).

The prohibition is limited to health plans. A health care provider may use or disclose genetic information as it sees fit for treatment of an individual. If a covered entity, such as an HMO, acts as both a health plan and health care provider, it may use genetic information for purposes of treatment, to determine the medical appropriateness of a benefit, and as otherwise permitted by the Privacy Rule, but may not use such genetic information for underwriting purposes. Such covered entities, in particular, should ensure that appropriate staff members are trained on the permissible and impermissible uses of genetic information.

6. Section 164.504(f)(1)(ii)—Requirements for Group Health Plans

Proposed Rule

Section 164.504(f)(1)(ii) permits a group health plan, or health insurance issuer or HMO with respect to the group health plan, to disclose summary health information to the plan sponsor if the plan sponsor requests the information for the purpose of obtaining premium bids from health plans for providing health insurance coverage under the group health plan, or for modifying, amending, or terminating the group health plan. As this provision permits activities that constitute ''underwriting purposes,'' as defined by GINA and the proposed rule, the Department proposed to modify § 164.504(f)(1)(ii) to clarify that § 164.504(f)(1)(ii) would not allow a disclosure of protected health information that is otherwise prohibited by the underwriting prohibition.

Overview of Public Comments

The Department received one comment in support of this modification.

Final Rule

The final rule adopts the modification to § 164.504(f)(1)(ii).

7. Section 164.506—Uses and Disclosures To Carry Out Treatment, Payment, or Health Care Operations

Proposed Rule

Section 164.506(a) of the Privacy Rule sets out the uses and disclosures a covered entity is permitted to make to carry out treatment, payment, or health care operations. In light of the fact that the proposed definition of ''underwriting purposes'' encompasses activities that fall both within the definitions of ''payment'' and ''health care operations'' under the Privacy Rule, the Department proposed to add a cross-reference in § 164.506(a) to the new underwriting prohibition to make clear that § 164.506 of the Privacy Rule would not permit health plans to use or disclose an individual's protected health information that is genetic information for underwriting, even though such a use or disclosure is considered payment or health care operations.

Overview of Public Comments

The Department received one comment in support of this modification.

Final Rule

The final rule adopts the modification to § 164.506(a).

8. Section 164.514(g)—Uses and Disclosures for Activities Relating to the Creation, Renewal, or Replacement of a Contract of Health Insurance or Health Benefits

Proposed Rule

Section 164.514(g) of the Privacy Rule prohibits a health plan that receives protected health information for underwriting, premium rating, or other activities relating to the creation, renewal, or replacement of a contract for health insurance or health benefits, from using or disclosing such protected health information for any other purpose (except as required by law) if the health insurance or health benefits are not placed with the health plan. The Department proposed conforming amendments to § 164.514(g) to: (1) Remove the term ''underwriting'' to avoid confusion given the new definition of ''underwriting purposes,'' which encompasses the activities described above; and (2) make clear that a health plan that receives protected health information that is genetic information for the above purposes is not permitted to use or disclose such information for underwriting purposes. The proposed removal of the term ''underwriting'' from § 164.514(g) was not intended as a substantive change to the scope of the provision.

Overview of Public Comments

One commenter suggested that the Department reconsider the removal of the term ''underwriting'' from this section as it could be viewed as a substantive change to the scope of the provision, and expressed concern that the modification would prohibit a health plan from using or disclosing genetic information as required by other law.

Final Rule

The final rule modifies § 164.514(g) to refer to the prohibition, now at § 164.502(a)(5). However, as with the definition of ''health care operations,'' we do not remove the term ''underwriting'' to avoid unnecessary confusion. We also clarify that a health plan may continue to use or disclose protected health information that is genetic information as required by other law, except to the extent doing so would be inconsistent with the prohibition in GINA and this final rule at § 164.502(a)(5)(i) against using or disclosing genetic information for underwriting purposes.

9. Section 164.520—Notice of Privacy Practices for Protected Health Information

Proposed Rule

As discussed above in Section IV with regard to the changes made to § 164.520 pursuant to the HITECH Act, § 164.520 of the Privacy Rule sets out the requirements for most covered entities to have and distribute a Notice of Privacy Practices (NPP). With respect to the NPP, the Department believes that

individuals should be informed of their new rights and protections under this rule with respect to genetic information in the health coverage context. Thus, the Department proposed in § 164.520(b)(1)(iii)(D) to require health plans that use or disclose protected health information for underwriting to include a statement in their NPP that they are prohibited from using or disclosing protected health information that is genetic information about an individual for such purposes. Without such a specific statement, individuals would not be aware of this restriction and the general statements regarding permitted uses and disclosures for treatment, payment, and health care operations in the NPP of a health plan that performs underwriting would not be accurate (i.e., the NPP would state that the health plan may use or disclose PHI for purposes of payment and health care operations, which would not be true with respect to genetic information when the use or disclosure is for underwriting purposes).

The preamble explained that the proposed prohibition on using or disclosing genetic information for underwriting and the proposed requirement to explicitly include a statement regarding the prohibition would represent a material change to the NPP of health plans that perform underwriting, and the Privacy Rule requires at § 164.520(c)(1)(i)(C) that plans provide notice to individuals covered by the plan within 60 days of any material revision to the NPP. As in the NPRM issued to implement HITECH Act provisions, the Department requested comment on ways to inform individuals of this change to privacy practices without unduly burdening health plans and provided several possible alternatives. The Department also explained that the obligation to revise the NPP for the reasons described above would fall only on health plans that intend to use or disclose protected health information for activities that constitute ''underwriting purposes.'' Thus, health care providers, as well as health plans that do not perform underwriting, would not be required to revise their NPPs.

Overview of Public Comments

One commenter supported informing individuals in the NPP that health plans are prohibited from using or disclosing genetic information for underwriting purposes. One commenter asked the Department to clarify that where a health plan has already made a change to the NPP to comply with a statute, such as with GINA, and has sent the revised NPP to members, the health plan would not be required to make another change to its NPP to comply with the regulation.

A number of comments addressed the issue of the timing and manner of distributing revised NPPs. In general, commenters recommended various alternatives, including: (1) Require health plans to provide a revised NPP to members in the next annual mailing; (2) require health plans to provide either a revised NPP or a supplement to members in the next annual mailing and to post the revised NPP or supplement on the health plan Web site immediately; (3) retain the existing 60-day deadline for providing a revised NPP to individuals or provide for a 30-day extension; and (4) allow for distribution via electronic processes for more efficient delivery of NPPs to members.

Final Rule

The final rule adopts the requirement for health plans that perform underwriting to include in their NPPs a statement that they are prohibited from using or disclosing genetic information for such purposes, except with regard to issuers of long term care policies, which are not subject to the underwriting prohibition. Health plans that have already modified and redistributed their NPPs to reflect the statutory prohibition are not required to do so again, provided the changes to the NPP are consistent with this rule. We also modify the NPP distribution requirements for health plans where there are material changes. These modifications are discussed above in Section IV with regard to material changes to the NPP resulting from changes pursuant to the HITECH Act.

10. Other Comments

Comment: One commenter requested clarification on preemption with regard to the new underwriting prohibition.

Response: Pursuant to subpart B of Part 160 of the HIPAA Administrative Simplification Rules, to the extent that a provision of State law requires a use or disclosure of genetic information for an activity that would otherwise constitute ''underwriting purposes,'' such State law would be preempted by the Privacy Rule unless an exception at § 160.203 applies. In contrast, State laws that provide greater privacy protection for genetic information than the Privacy Rule continue to remain in place.

Comment: One commenter asked how a health care provider should ensure that releasing an individual's information to a health plan will not result in an inappropriate disclosure to the health plan for underwriting purposes. This commenter also asked what the rules are for access to protected health information about an individual by the individual's extended family members seeking to determine if they are affected by a genetic trait.

Response: With respect to the first question, these rules do not apply to health care providers. A covered health provider may continue to disclose protected health information, including genetic information, where doing so meets the minimum necessary standard, to health plans for payment purposes. Under this Rule, the onus is on the health plan to not use or disclose protected health information it receives for such purposes for prohibited underwriting purposes. Further, health plans continue to be required by the Privacy Rule to limit requests of protected health information to the minimum necessary when requesting such information from other covered entities. The regulations implementing sections 101–103 of GINA also restrict the ability of health plans covered by those rules to request genetic information.

With respect to the second question, to the extent that an individual's genetic information is needed for the treatment purposes of a family member, a covered health care provider is permitted to disclose such information, subject to any agreed-upon restriction, to another provider for the treatment of the family member. See FAQ #512 at *http://www.hhs.gov/ocr/privacy/hipaa/faq/right_to_request_a_restriction/512.html*, which makes clear that a health care provider may share genetic information about an individual with providers treating family members of the individual who are seeking to identify their own genetic health risks, provided the individual has not requested and the health care provider has not agreed to a restriction on such disclosure.

Comment: One commenter requested that the rule require that health plans conducting or sponsoring research involving genetic information provide research participants with an explicit statement to ensure the individuals understand that such information may not and will not be used for underwriting purposes.

Response: We decline to require such a statement. The regulations implementing sections 101–103 of GINA already require a statement to that effect as a condition of the health plan requesting that a research participant undergo a genetic test as part of the research. See, e.g., 45 CFR 144.122(c)(5). Further, this rule requires that health plans that perform underwriting inform individuals through their NPPs that the

plans may not use or disclose genetic information for such purposes.

Comment: One commenter asked that the HIPAA de-identification standard be strengthened to provide better protection for health information, including genetic information.

Response: The Privacy Rule's de-identification standard is outside the scope of this rulemaking.

VII. Regulatory Analyses

A. Introduction

We have prepared a regulatory impact statement in compliance with Executive Order 12866 (September 1993, Regulatory Planning and Review), Executive Order 13563 (January 2011, Improving Regulation and Regulatory Review), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), the Unfunded Mandates Reform Act of 1995 (UMRA) (March 22, 1995, Pub. L. 104–4), and Executive Order 13132 on Federalism. We begin with a discussion of Executive Orders 12866 and 13563 and then present a more detailed analysis of costs and benefits. Finally, relying on information explained in the cost-benefit analysis, we discuss issues related to the RFA, UMRA, and Federalism considerations.

1. Executive Order 12866 and Executive Order 13563

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 must be prepared for major rules that have economically significant effects ($100 million or more in any one year) or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or Tribal government or communities (58 FR 51741). Based on the following analysis, this rule has been designated as an economically significant regulatory action within the meaning of section 3(f)(4) of Executive Order 12866. Accordingly, the rule has been reviewed by the Office of Management and Budget.

To summarize, we estimate that the rule will result in new first-year costs of between $114 million and $225.4 million. Annualizing the midpoints of our cost estimates at three and seven percent over ten years produces costs of $35.2 million and $42.8 million, respectively.[22]

We estimate that the effects of the requirement for covered entities (including indirect costs incurred by third party administrators, which frequently send out notices on behalf of health plans) to issue new notices of privacy practices, as a result of the final changes to the HIPAA Privacy Rule under both the HITECH Act and GINA, will result in new costs of $55.9 million within 12 months of the effective date of the final rule. Annualizing the costs over 10 years at 3 percent and 7 percent results in annual NPP costs of approximately $6.6 million and $8 million, respectively. We have revised our cost estimate for NPP revisions since the proposed rule to reflect the increased flexibility provided in the final rule, which allows health plans to include their new NPPs in their usual, annual mailing rather than send them to individuals in a separate mailing. We also note that combining GINA and HITECH requirements into a single rule results in lower costs than would be incurred if covered entities were required to revise their NPPs multiple times to comply with separate rulemakings.

Additionally, we have revised the annual estimated cost to comply with the final breach notification provisions. As we discuss below, we acknowledge there may still be some underreporting of breaches, however we do anticipate that the overall number of breaches will decrease in the future. As such, Table 2 below shows the costs of complying with the provisions of the breach notification final rule, which have been revised based on our experience with the number of breach notifications we have received from covered entities during calendar years 2010 and 2011. We estimate the total annual cost for the breach notification rule to be approximately $14.5 million. Annualizing over 10 years at 3% and 7% produces annual breach implementation costs of approximately $17 million and $20.6 million.

With regard to the business associate provisions of the final rule, we assume that business associates currently comply with the HIPAA Privacy Rule use and disclosure provisions as required by their business associate contracts. However, with regard to the Security Rule, while we continue to believe that most business associates have implemented security protections that meet the Security Rule requirements as part of the assurances provided to covered entities through their contracts, we recognize that some smaller or less sophisticated business associates may not have engaged in the formal administrative safeguards required by the HIPAA Security Rule, and may not have written policies and procedures for compliance. For these business associates, we estimate that the costs to come into compliance with the Security Rule will be between approximately $22.6 million and $113 million. Annualizing the midpoint estimate ($67.8 million) at 3 percent and 7 percent produces costs of $7.9 million and $9.7 million, respectively.

Although we also continue to believe that most business associates have made a good faith attempt to conform their agreements with subcontractors to HIPAA requirements, we acknowledge the possibility that some business associates may make such efforts for the first time now that they and their subcontractors are subject to direct liability under the Rules. For this fraction of business associates, we estimate that the costs to bring subcontracts into compliance with the business associate agreement requirements will be between $21 million and $42 million. Annualizing the midpoint of those estimates ($31.5 million) at 3 percent and 7 percent results in costs of $3.7 million and $4.5 million, respectively.

There may be other costs we are not able to monetize because we lack data, and the rule may produce savings that may offset some or all of the added costs. We discuss these unquantified costs and benefits of the rule at the end of the Regulatory Impact Analysis.

As a result of the economic impact, and other costs that are described but not quantified in the regulatory analysis below, OMB has determined that this rule is an economically significant regulatory action within the meaning of section 3(f)(4) of Executive Order 12866. We present our analysis of the costs and benefits of the rule in sections C and D below.

2. Entities Subject to the Rule

This rule impacts covered health care providers, health insurance issuers, and third party administrators acting on behalf of health plans, which we estimate to total 698,238 entities. The rule also applies to approximately 1–2

[22] The breach notification provisions are the rule's only source of ongoing, annual costs. Therefore, with respect to breach, we annualize costs incurred on an annual basis. For the other provisions, we calculate annualized opportunity costs based on costs expended only in the first year of implementation.

million business associates and an unknown number of subcontractors.[23]

Table 1 below shows the number of covered entities by class of provider and insurer that will be affected by the Rule.

TABLE 1—NUMBER OF COVERED ENTITIES BY NAICS CODE[24]

NAICS	Providers/suppliers	Number of entities	Estimated number of small entities[25]
622	Hospitals (General Medical and Surgical, Psychiatric, Substance Abuse, Other Specialty).	4,060	4,060
623	Nursing Facilities (Nursing Care Facilities, Residential Mental Retardation Facilities, Residential Mental Health and Substance Abuse Facilities, Community Care Facilities for the Elderly, Continuing Care Retirement Communities).	34,400	34,400
6211–6213	Office of MDs, DOs, Mental Health Practitioners, Dentists, PT, OT, ST, Audiologists.	419,286	419,286
6214	Outpatient Care Centers (Family Planning Centers, Outpatient Mental Health and Drug Abuse Centers, Other Outpatient Health Centers, HMO Medical Centers, Kidney Dialysis Centers, Freestanding Ambulatory Surgical and Emergency Centers, All Other Outpatient Care Centers).	13,962	13,962
6215	Medical Diagnostic, and Imaging Service Covered Entities.	7,879	7,879
6216	Home Health Service Covered Entities	15,329	15,329
6219	Other Ambulatory Care Service Covered Entities (Ambulance and Other).	5,879	5,879
N/A	Durable Medical Equipment Suppliers[26]	107,567	107,567
4611	Pharmacies[27]	88,396	88,396
524114	Health Insurance Carriers[28]	730	276
524292	Third Party Administrators Working on Behalf of Covered Health Plans[29].	750	750
Total Entities		698,238	697,784

B. Why is this rule needed?

This final rule is needed to strengthen and expand the privacy and security protections for individuals' health information and privacy rights established under the HIPAA, as mandated by the HITECH Act and GINA. These enhancements are necessary to ensure continued adequate protections for health information, as well as trust in the health care system, particularly as the adoption and use of electronic health records increases. Importantly, among other changes, the rule makes business associates of covered entities directly liable for Federal penalties for failures to comply with certain provisions of the rule. This expansion in liability closes a large gap in protection that existed prior to these modifications with respect to business associates, which are the cause of many of the security breaches for which the Department receives breach reports.

The final rule also lays out standards for when individuals and the Secretary must be informed that a breach of protected health information has occurred so that individuals may take measures to protect themselves from risks associated with the breach. By establishing requirements for notifying individuals and making business associates directly liable for complying with certain provisions of the Privacy and Security rules, we expect the number of breaches of protected health information to decline over time.

This final rule also makes changes to the HIPAA rules, such as those that streamline the research authorization process, that are designed to increase flexibility for, and decrease burden on, the regulated entities, as well as to harmonize certain requirements with those under the Department's Human Subjects Protections regulations.

C. Costs

1. Breach Notification Costs

The preamble to the interim final rule published on August 24, 2009, contained a regulatory impact statement estimating the economic burden of implementing the rule. We are revising that impact statement in this final rule based upon our experience with collecting breach notifications from covered entities during calendar years 2010 and 2011.

The analysis that follows is very similar to the analysis set forth in the preamble to the interim final rule; however, instead of using information

[23] Although we do not have data on the numbers of business associates, our enforcement experience leads us to believe that each covered entity has, on average, two to three business associates, for a total of 1–2 million business associates. This number likely overestimates the number of business associates, as some entities may be business associates to multiple covered entities. We do not have a basis for estimating the number of subcontractors that will be subject to the rule.

[24] Office of Advocacy, SBA, *http://www.sba.gov/advo/research/data.html*.

[25] Because the vast majority of covered providers are small entities, we include all providers in our estimates of small providers.

[26] Centers for Medicare & Medicaid Services covered entities.

[27] The Chain Pharmacy Industry *http://www.nacds.org/wmspage.cfm?parm1=507*.

[28] Source: HHS ASPE analysis of 2010 NAIC Supplemental Health Care Exhibit data.

[29] We include third party administrators in our count of covered entities, although they are business associates, because the nature of their representation of the majority of ERISA plans makes them an appropriate ''surrogate'' for those plans.

from *http://www.datalossdb.org* to estimate the number of breaches that would occur each year, we have used the breach notifications provided to the Secretary during calendar years 2010 and 2011 to project the ongoing, annual costs to covered entities for implementing the breach notification provisions. Several commenters noted that significantly more breaches would occur each year than the interim final rule anticipated, and we acknowledge that the estimates provided in the interim final rule were significantly lower than our experience has been to date. As such, we believe that relying on our experience receiving notifications addresses the concerns of the commenters who thought we were underestimating the number of breaches that would occur each year. Based upon this information, we have revised the projected annual cost to implement these breach notification provisions.

We acknowledge that there may still be some underreporting of breaches as the obligations of the regulation may not yet have penetrated down to all covered entities and business associates. At the same time, we expect that some types of incidents being reported today may not in the future as covered entities and business associates become more familiar with the definition of breach and more adept at performing risk assessments and determining whether a breach has occurred. We have received breach notifications from covered entities in several situations in which notification was not necessary, such as where there was no underlying impermissible use or disclosure under the Privacy Rule or where one of the exceptions to breach clearly applied to the situation. This is the type of over-reporting that we expect to diminish in the future. Additionally, covered entities and business associates are beginning to recognize areas of potential weakness and to take systemic actions to prevent breaches from occurring in the future, such as encrypting portable devices to avoid having to provide breach notifications in the event the device is lost or stolen.

Table 2 shows the costs of the provisions of the final rule based on the breach notifications we have received from covered entities during calendar years 2010 and 2011. We also present the costs required for investigating breaches and the amount of time we anticipate individuals will spend calling the toll-free number for substitute notice. We estimate the total cost for the breach notification rule to be approximately $14.5 million. Discounting at 3 percent and 7 percent and annualizing over 10 years results in costs of $17 million and $20.6 million, respectively.

TABLE 2—SUMMARY OF ANNUAL COMPLIANCE COST FOR BREACH NOTIFICATION IN 2011 DOLLARS

Cost elements	Number of breaches	Number of affected individuals	Cost/breach	Cost/affected individuals	Cost
E-mail and 1st Class Mail	19,000	6,710,000	$182	$0.517	$3,467,122
Substitute Notices: Media Notice	1,190	6,605,500	480	0.086	571,200
Substitute Notices: Toll-Free Number	1,190	[30] 660,550	1,526	2.750	1,816,379
Imputed cost to affected individuals who call the toll-free line	1,190	660,550	1,725	3.108	2,052,665
Notice to Media of Breach: Over 500	250	6,600,000	62	0.002	15,420
Report to the Secretary: 500 or More	250	6,600,000	62	0.002	15,420
Investigation Costs: Under 500	18,750	324,050	281	16.29	5,277,456
Investigation Costs: 500 or More	250	6,600,000	3,350	0.127	837,500
Annual Report to the Secretary: Under 500	18,750	110,000	23	3.84	422,438
Total Cost					14,475,600

[30] As we explain below in the section on substitute notice, we project that 6,605,500 individuals will be affected by breaches that may require substitute notice, but we expect that at most 10% of affected individuals will call the toll-free line for information.

In this revised analysis, we rely entirely on our experience with breach notifications received by the Secretary during calendar years 2010 and 2011, for projecting the ongoing, annual costs of the breach notification rule. Based on our experience in those years, we project the likely number of breaches, number of affected individuals, and costs associated with this regulation. We have not attempted to predict future costs because, as discussed above, while we anticipate the overall number of breaches and the overall costs of implementing the breach notification provisions to fall over time, we do not currently have enough data to establish such a trend.

Affected Entities

The entities affected by the breach notification regulation are outlined in the impact statement of the interim final rule. HIPAA covered entities and their business associates must comply with these regulations. We estimate that approximately 700,000 HIPAA covered entities will be subject to the final rule, although many fewer will experience a breach requiring them to fulfill the breach notification requirements.

How many breaches will require notification?

Although this final rule modifies the definition of breach at § 164.402 to remove the harm standard, we do not believe that this will have a significant effect on the number of breaches reported to HHS or on the number of individuals affected. As discussed in Section V above, this final rule removes the harm standard and implements a more objective risk assessment for evaluating whether an impermissible use or disclosure is a breach. As a result, covered entities must still perform a risk assessment following an impermissible use or disclosure of protected health information to determine the probability that the protected health information has been compromised. Events such as hacking into an unencrypted database and theft of unsecured protected health information would in almost all cases constitute a breach in this final rule, just as they would under the interim final rule's definition of breach. However, given the further clarity in this rule as to the standard and factors to be considered, other incidents that may not have been considered a breach under the interim final rule may be considered a breach under this final rule (or in some cases, vice versa).

Instead of relying on data from *http://www.datalossdb.org* to estimate the number of breaches and the number of individuals affected by such breaches

each year, this final rule uses breach notification reports submitted to the Secretary by covered entities to revise our previous estimates. We believe these reports provide us with much more complete information from which to project the overall cost of implementing this regulation.

Beginning September 23, 2009, covered entities were obligated to notify the Secretary of all breaches of protected health information occurring on or after that date. As of September 23, 2009, covered entities must report breaches affecting 500 or more individuals to the Secretary without unreasonable delay and in no case later than 60 days from discovery of the breach, while breaches affecting fewer individuals must be reported to the Secretary within 60 days of the end of the calendar year in which the breach occurred.

Based on our experience receiving breach notifications during calendar years 2010 and 2011, we project that HHS will receive approximately 19,000 breach notifications from covered entities annually or, on average, approximately 1,583 breach notifications each month. Approximately 250 such notifications will report breaches affecting 500 or more individuals and the remaining 18,750 reported breaches will affect fewer than 500 individuals.

We project that approximately 6.71 million individuals will be affected by the 19,000 breaches reported to HHS each year, which is, on average, roughly 353 affected individuals per breach.

As in the interim final rule, we have assumed that no State has a notification requirement, despite the fact that this will overestimate the burden imposed on covered entities because covered entities have trained their staffs and have prepared procedures to follow when a breach occurs to comply with existing breach notification requirements of most of the States. To ameliorate the overstatement of our cost estimate somewhat, we have assumed the costs for training personnel and for developing procedures for the most part have already been expended and are therefore in the baseline. We did not include these costs in our analysis of the annual costs.

We have followed the same approach to estimating the costs as outlined in the interim final rule. We examined the cost of notifying affected individuals by first class mail, issuing substitute notice in major media or on a Web site along with a toll-free phone number, notifying prominent media in the event of a breach involving more than 500 individuals, and notifying the Secretary of a breach, as well as the costs of investigating and documenting breaches. Some commenters requested that we include the cost of modifying contracts with business associates to potentially define the breach notification obligations between the parties. We note that costs to modify business associate agreements generally to comply with the new HITECH provisions are discussed elsewhere in this impact analysis.

Cost of Notifying Affected Individuals by First Class Mail or Email

Section 164.404 requires all covered entities to notify affected individuals of a breach either by first class mail, or if the individual has agreed, by email. In the interim final rule, we assumed that approximately one half of notices sent to affected individuals would be sent via first-class mail, while the rest would be sent via email. By comparison, in the Federal Trade Commission's (FTC) final breach notification rule, the FTC assumed that 90 percent of the notices sent to individuals affected by a breach requiring notification under the FTC rule would be emailed and only 10 percent would be sent by regular first class mail. Since the firms that the FTC regulates are primarily web-based, assuming that the vast majority of communications would be conducted through email is a reasonable assumption. For HIPAA covered entities, however, 90 percent of which are small businesses or nonprofit organizations that engage the entire U.S. population in providing health care services, we believed that notification through email would be much more limited than in the case of the entities the FTC regulates. Some physician offices have been slow to adopt email communication with their patients for various reasons. We, therefore, assumed that only 50 percent of individuals affected as a result of a breach of unsecured protected health information would receive email notices. As we did not receive any comments on this assumption, we retain it here.

As discussed in our analysis in the interim final rule, there will be certain costs that both email and first-class mail notification will share. The cost of drafting and preparing the notice will apply to both forms. The median hourly wage for the labor category of a healthcare practitioner and technical worker in 2011 was approximately $42.96, including 50 percent for fringe benefits.[31] If we assume 30 minutes per breach for composing the letter, the cost equals $21.48. We assume that it will also take 30 minutes per breach for an administrative assistant to prepare the letter in either email or printed formats and to document the letter to comply with §§ 164.414(a) and 164.530(j). The median hourly wage for office and administrative support staff is $22.53, including 50 percent for benefits. For the 30 minutes, we estimate $11.27 per breach. The combined labor cost for composing and preparing the document is approximately $32.75 per breach. Half of this cost will be allocated to the first-class letter and the other half to the emails.

Although computer costs for sending email will be insignificant, it will take staff time to select the email address from the entity's mailing list. We assume that an office worker could process and send 200 emails per hour at a cost of $22.53 per hour. For each mailed notice, we assume $0.06 for paper and envelope and $0.45 for a first class stamp, totaling $0.51 per letter. We estimate another $22.53 per hour to prepare the mailing by hand at a rate of 100 letters per hour.

Based on our revised estimate of the number of breaches that will occur in a year, we can multiply the number of breaches by the cost of composing and preparing a notice (19,000 × $32.75) equals $622,250. Allocating half the costs to emailing and the same amount to regular mail yields $311,125 to each category.

Splitting our estimate of the number of affected individuals evenly between email and regular mail gives us 3,355,000 affected individuals for each notice category. As we did in the interim final rule, for emails we divide affected individuals by the number of emails processed in an hour (200) and multiply the result (16,775 hours) by the hourly cost of $22.53, giving us $377,940. To this number we add the $311,125 giving us an estimated cost for email notices of $689,066.

We follow the same method for estimating the cost of mailing notices using postal mail plus the cost of postage and supplies. Dividing 100 letters per hour into 3,355,000 yields 33,550 hours, which is then multiplied by $22.53 to reach $755,882 in labor costs to prepare the mailing. Adding to that the costs of postage and supplies ($1,711,050) and the costs of composing and drafting ($311,125) equals $2,778,057. Summing the cost of email and postal mail notices equals

[31] Department of Labor, Occupational Employment Statistics; Healthcare Practitioner and Technical Occupations. Available at *http://www.bls.gov/oes/current/oes_nat.htm.*

$3,467,122. Table 3 presents the results of our analysis in the order they are discussed above.

TABLE 3—COST OF E-MAIL AND FIRST CLASS MAIL TO AFFECTED INDIVIDUALS IN 2011 DOLLARS

(Annual)	Mail	Email	Total
Number of breaches	9,500	9,500	19,000
Number of affected individuals or records	3,355,000	3,355,000	6,710,000
Hours to compose and document notice	9,500 (1 hr per breach).	9,500 (1 hr per breach).	19,000
Cost to compose and document notice	$311,125	$311,125	$622,250
Hours to prepare mailing	33,550	16,775	50,325
Cost to prepare mailing	$755,882	$377,940	$1,133,822
Postage and supplies	$1,711,050	N/A	$1,711,050
Total	$2,778,057	$689,066	$3,467,122

Cost of Substitute Notice

In the event that a HIPAA covered entity is not able to contact an affected individual through email or postal mail, it must attempt to contact the person through some other means. If the number of individuals who cannot be reached through the mailings is less than ten, the entity may attempt to reach them by some other written means, or by telephone.

In the event that the covered entity is unable to contact 10 or more affected individuals through email or postal mail, the rule requires the entity to (1) publish a notice in the media (newspaper, television, or radio) or post a notice on its Web site, containing the same information contained in the mailed notice, and (2) set up a toll-free number. The toll-free number is to be included in the media notice or notice on the Web site.

Based on the breach notification reports received by the Secretary during calendar years 2010 and 2011, we project that approximately 1,190 breaches affecting 10 or more individuals will require substitute notice (including 5% of breaches involving fewer than 500 individuals, and all 250 breaches involving 500 or more individuals). While several breaches affecting only 1 individual have also required substitute notice, as stated in the interim final rule, we believe the costs for notifying fewer than 10 individuals through alternative written means or by telephone would be very small and as a result we have not attempted to estimate those costs.

The interim final rule estimated that it would cost approximately $240 to publish a public notice in a newspaper. Assuming the covered entity will publish two notices, the cost is $480. Multiplying this amount by the 1,190 estimated breaches yields $571,200. Also, as noted in the interim final rule, if a HIPAA covered entity has a Web site, we assume there will be no cost to post the notice to the Web site. We believe this overestimates the overall cost of publishing a notice, as many covered entities will elect to post the public notice only on their Web site, and not in a newspaper.

As outlined in the interim final rule, the cost of setting up a toll-free phone number is a straight forward process of contacting any one of a number of service providers who offer toll-free service. The interim final rule found that the prices for toll-free service range from $0.027 per minute for a basic mail box arrangement to $0.07 per minute. A major, national phone service company offers toll-free service for $15 per month per toll-free number and per minute charge of $0.07. There is a one-time charge of $15. As in the interim final rule, we use the costs of $15 per month plus $15 activation fee and $0.07 per minute.

Since the regulation requires providers to maintain a toll-free number for three months, the monthly charge plus initial fee per breach will be $60. To estimate the number of calls to the toll-free number, the interim final rule assumed that more individuals than those affected by the breach requiring substitute notice would call out of concern that their protected health information might have been compromised. The interim final rule estimated that a number equal to all affected individuals of all breaches would call the toll-free number. Based on our experience to date, and given that many individuals involved in breaches requiring substitute notice will receive regular notice, we now assume that less than 10 percent of individuals affected by breaches requiring substitute notice will call the toll-free line. Therefore, as we anticipate 6,605,500 total individuals will be affected by breaches requiring substitute notice,[32] we assume that no more than 10 percent, or 660,550, will call the toll-free number to determine if they are affected by the breach. We note that while this revision significantly reduces the overall cost to covered entities for providing substitute notice in situations in which there is insufficient or out-of-date contact information for 10 or more individuals, we believe this estimate is much more appropriate based on the information we have received from covered entities thus far.

Using this number and assuming that a call averages five minutes at $0.07 per minute, we estimate the total direct calling costs to equal $231,193. Added to this is $345,000 that represents the monthly fee per breach (1,190 breaches) for three months plus the one-time fee (totaling $60 per breach). This brings the total cost of setting up and maintaining toll-free lines to $576,193.

To this cost, we must also include the office staff time to answer the incoming calls at $22.53 per hour. Based on an average of five minutes per call, a staff person could handle 12 calls per hour. Dividing 12 into 660,550 equals approximately 55,046 hours and then multiplied by $22.53 equals $1,240,186. Summing all cost elements yields a total cost of $1,816,379.

To the degree that entities already maintain toll-free phone lines, our estimate overstates the costs of setting up a toll-free line as required under the rule. Table 4 presents our cost analysis for the toll-free line.

[32] This number includes all individuals affected by breaches involving 500 or more individuals (6,600,000) and 5 percent of individuals affected by breaches involving less than 500 individuals (5,500).

TABLE 4—ANNUAL COST FOR SETTING UP A TOLL-FREE LINE FOR THREE MONTHS IN 2011 DOLLARS

Costs	Number of breaches affecting fewer than 500 (5,500)	Number of breaches 500 + (250)	Number of calls	Total
Monthly Charges for 3 months + 1-time Charge ($60/breach)	$330,000	$15,000	N/A	$345,000
Direct Calling Charges @ $.07/min × 5 minutes			660,550	$231,193
Labor cost @ $22.53/hr × 5 min per call			660,550	$1,240,186
Cost to individuals @ $24.86/hr × 7.5 min per call			660,550	$2,052,665
Total				$3,869,044

As in the interim final rule, we have also imputed a cost to the time individuals will spend calling the toll-free number. In estimating the time involved, we assumed that a person will spend five minutes per call. However, the person may not get through the first time and thus may have to call back a second time which could add another 5 minutes. Taking the average between 5 and 10 minutes, we used an average time of 7.5 minutes per caller.

For purposes of imputing cost to an individual's time, we took the median compensation amount from the Bureau of Labor Statistics of $24.86 [33] for all occupations. Dividing 60 by 7.5 minutes yields 8 calls per hour. Dividing the number of calls per hour into 660,550 calls and then multiplying by $24.86, gives us a cost of $2,052,665.

Cost of Breaches Involving More Than 500 Individuals

If a covered entity experiences a breach of protected health information affecting more than 500 individuals of a State or jurisdiction, § 164.406 of the rule requires the entity to notify the media in the jurisdiction or State in which the individuals reside. In addition, § 164.408 of the rule requires the entity to notify the Secretary contemporaneously with notice to affected individuals in cases where 500 or more individuals are affected by a breach.

As stated in the interim final rule, we anticipate that a covered entity will issue a press release when it must notify the media under § 164.406. The tasks involved in issuing the press release will be the drafting of the statement and clearing it through the entity. As discussed in the interim final rule, we assume that drafting a one-page statement will contain essentially the same information provided in the notice to affected individuals and will take 1 hour of an equivalent to a GS–12 Federal employee, earning $29 per hour. Adding 50 percent to account for benefits equals $43.50. Approval of the release involves reading the document. We expect this activity to take 15 minutes. The median hourly rate for a public relations manager is approximately $44.86 in 2011.[34] Adding 50 percent for benefits equals $67.29, so one quarter of an hour equals $16.82 for approving the release. The total cost of the release equals $61.68, and multiplying this amount by the number of breaches affecting more than 500 individuals (250) equals $15,420. This amount is lower than our previous estimate because we have adopted the more customary and realistic approach of adding 50 percent to wages for benefits, rather than doubling standard wage rates to account for benefits. It should be noted that even this amount may overstate the actual costs of issuing a notice to the media.

The report to the Secretary that must be sent contemporaneously with the sending of the notices to the affected individuals will contain essentially the same information as the notice sent to the affected individuals. As stated in the interim final rule, we anticipate the time and cost to prepare the report will be the same as that required for issuing a notice to the media. The cost for reporting to the Secretary the 250 breaches affecting 500 or more individuals is $15,420.

Cost of Investigating a Breach

As a prerequisite to issuing a notice to individuals, to the media, and to the Secretary, the covered entity will need to conduct an investigation to determine the nature and cause of the breach. We estimate that the 95 percent of breaches in the under 500 category that affect fewer than 10 individuals will require 4 hours of investigation. The other 5 percent of under 500 breaches, which affect between 10 and 499 individuals, may require up to 8 hours to investigate. At an office manager's [35] time at $67 per hour ($44.65 median wage plus 50 percent for benefits) multiplied by 4 and 8 hours, results in per breach costs of approximately $268 and $536, respectively. Multiplying $268 by the number of breaches affecting fewer than 10 individuals (17,800 breaches) results in investigation costs of $4,773,616. We then multiply $536 by the number of breaches affecting 10 to 499 individuals (940 breaches), which produces investigation costs of $503,840. Adding the totals for the two groups results in investigation costs of $5,277,456 per year for breaches affecting less than 500 individuals. This estimate includes the time required to produce the documentation required by § 164.414(a). We note that this estimate is significantly higher than that in the interim final rule; however, this is due entirely to the revised estimate that there will be approximately 18,750 breaches affecting fewer than 500 individuals per year.

As stated in the interim final rule, for breaches involving 500 or more individuals, the breach investigation may take up to 100 hours to complete; however, we assume that the average investigation will take only 50 hours. At an office manager's time of $67 per hour multiplied by 50 hours, this cost equals $3,350 per breach. Multiplying this by the number of breaches (250) yields $837,500.

Cost of Submitting the Annual Breach Summary to HHS

Under § 164.408, covered entities must notify the Secretary of all breaches; however, covered entities reporting breaches affecting fewer than 500 individuals may report these breaches to the Secretary annually. Since the material for the submission has already been gathered and organized for the issuance of the notices to the affected individuals, we expect that notifying the Department will require at

[33] Department of Labor, Occupational Employment Statistics. *http://www.bls.gov/oes/current/oes_nat.htm.*

[34] *http://www.bls.gov/oes/current/oes_nat.htm.*

[35] See *www.bls.gov/oes/current/oes_nat.htm* for All Management Occupations.

most an hour of office staff time once per year. At $22.53 per hour multiplied by the total number of breaches (18,750) affecting fewer than 500 individuals, this cost equals $422,438.

2. Notifying Individuals of Their New Privacy Rights

Covered entities must provide individuals with NPPs that detail how the covered entity may use and disclose protected health information and explain individuals' rights with respect to their own health information. Because of changes to the HIPAA Rules as a result of the HITECH Act and GINA, the final rule requires covered entities to modify their NPPs and distribute them to individuals to advise them of the following: (1) For health plans that underwrite, the prohibition against health plans using or disclosing PHI that is genetic information about an individual for underwriting purposes; (2) the prohibition on the sale of protected health information without the express written authorization of the individual, as well as the other uses and disclosures for which the rule expressly requires the individual's authorization (i.e., marketing and disclosure of psychotherapy notes, as appropriate); (3) the duty of a covered entity to notify affected individuals of a breach of unsecured protected health information; (4) for entities that have stated their intent to fundraise in their notice of privacy practices, the individual's right to opt out of receiving fundraising communications from the covered entity; and (5) the right of the individual to restrict disclosures of protected health information to a health plan with respect to health care for which the individual has paid out of pocket in full.

For providers, the costs related to the NPP consist of developing and drafting the revised NPP, and, as discussed below, the potential to incur out-of-cycle printing costs for the revised notice. There are no new costs attributable to the distribution of the revised notice as providers have an ongoing obligation to hand out the NPPs when first-time patients come for their appointments. We estimate that drafting the updated NPPs will require approximately one-third of an hour of professional, legal time at a cost of about $28.[36] The total cost for attorneys for the approximately 697,000[37] health care providers in the U.S. is, therefore, expected to be approximately $20 million. Printing the NPPs involves production and supplies at a cost of $0.10 per notice. Based on our prior estimates, health care providers are currently required to print and provide the NPP to approximately 613 million new patients annually. We assume that most health care providers will spread the printing of their notices throughout the year, producing copies on a quarterly, monthly, or even more frequent schedule. Further, providers will have 8 months from the publication of the final rule before they will need to produce the revised NPPs, and, therefore, can use that time to adjust their inventory and printing schedule to transition to the revised notice without any additional expense. Thus, assuming a worst case scenario in which all providers would need to replace at most 4 months of old inventory with the revised notice, the need for off-schedule printing of the revised notice for this 4 month period would be attributed to this provision. We estimate, therefore, that providers will print not more than 204 million revised NPPs over and above their existing printing obligations ($4/12 \times 613$ million = 204 million). Printing costs for 204 million NPPs will be $20.4 million (204 million × $0.10 = $20.4 million). Therefore, the total cost for providers is approximately $40.4 million ($20 million + $20.4 million = $40.4 million).

For health plans, the costs related to the NPP consist of developing and drafting the revised NPP, and, for certain health plans, the costs of printing and mailing the notice out-of-cycle because the revision is a material change. See § 164.520(c)(1)(v)(A). With the exception of a few large health plans, most health plans do not self-administer their plans. Most plans are either health insurance issuers (approximately 730) or utilize third party administrators that act on their behalf in the capacity of business associates. We identified approximately 750 third party administrators acting as business associates for ERISA plans. We have revised our earlier estimate of 3,500 third party administrators after learning that the majority of these entities act as welfare administrators and do not administer health plans. In addition, some public non-Federal health plans may use third party administrators. Almost all of the public and ERISA plans, we believe, employ third party administrators to administer their health plans. While the third party administrators will bear the direct costs of issuing the revised NPPs, the costs will generally be passed on to the plans that contract with them. Those plans that self-administer their own plans will also incur the costs of issuing the revised NPPs. We do not know how many plans administer as well as sponsor health plans and invited comments on the number of self-administered plans. As we did not receive comments on this issue, we assume that there are not enough self-administered plans to have an effect on these estimates.

Each of the approximately 1,500 health insurance issuers and health plan administrators will experience the same kinds of costs as we estimated for providers for drafting ($28 per entity) and printing ($0.10 per notice) the NPPs. However, health insurers and plan administrators will have to mail the NPPs to policy holders. We recognize that, under the existing requirement to send new NPPs in a separate mailing to all policy holders, the costs of distributing new NPPs, including clerical time and in some cases, postage, constituted the majority of the overall costs of the rule to covered entities. However, in the proposed rule, we requested comments on alternative ways to inform individuals of material changes to their rights and protections that would be less burdensome and costly. Based on the comments and consistent with E.O. 13563, in this final rule, we have adopted an alternative to the requirement to send the new NPP to all policy holders within 60 days. After consideration, we decided to permit health plans and third party administrators working for health plans to include the revised NPP in their next annual mailing, rather than within 60 days of the material change, if they have a Web site with an NPP. See § 164.520(c)(1)(v)(A). We anticipate that most, if not all, affected entities will take advantage of this option and will not send the NPP in a separate mailing. As such, we expect that the vast majority of health insurers will not incur any out-of-cycle NPP dissemination costs.

Nonetheless, to account for any costs that might be incurred by a small

[36] See *http://www.bls.gov/oes/current/naics3_541000.htm#23–0000* for lawyers. Note that we generally calculate labor costs based on the median hourly rate, which for lawyers is $56.21 per hour. We add 50 percent to account for fringe benefits, resulting in an estimated hourly cost of $84.32.

[37] We identified 698,238 entities that must prepare and deliver NPPs that are shown in Table 1 above. This includes 696,758 HIPAA covered entities that are health care providers, including hospitals, nursing facilities, doctor offices, outpatient care centers, medical diagnostic, imaging service, home health service and other ambulatory care service covered entities, medical equipment suppliers, and pharmacies. For the purposes of our calculation, we have rounded this number to 697,000. Table 1 also includes 730 health insurance carriers and 750 third party administrators working on behalf of covered health plans. The cost estimates for these entities are addressed later.

minority of health insurers to distribute the revised NPPs in a separate mailing, we have calculated the costs to these entities of doing so. We describe our methodology in the following paragraphs, beginning with an estimated total number of NPP recipients. We then calculate the costs of printing and sending the revised NPP by separate mailings to all recipients and estimate that no more than 10 percent of these costs will actually be incurred.

Because the Privacy Rule requires that only the named insured or policy holder is notified of changes to the health plans' privacy practices even if that policy also covers dependents, we expect that only policy holders will receive the revised NPPs mandated by this rule. This assumption is consistent with the practices of public programs, such as Medicare, which has a policy of mailing one notice or a set of program materials to a household of four or fewer beneficiaries at the same address. As a result, although there are 50.7 million individual Medicare beneficiaries, the program only sends out approximately 36 million pieces of mail per mailing.

Actuarial Research Corporation (ARC), our consultant, estimated the number of policy holders for all classes of insurance products to be approximately 183.6 million, including all public programs. The data comes from the Medical Expenditure Panel Survey from 2004–2006 projected to 2010. ARC estimated 112.6 million private sector policy holders and 71.0 million public ''policy holders.'' The total, including more recent Medicare data, is 188.3 million persons (which results in roughly a split of 60 percent private policy holders and 40 percent public ''policy holders''), whom we expect to receive NPPs from their plans. The estimates do not capture policy holders who are in hospitals or nursing homes at the time of the survey, or individuals who may have been insured under more than one plan in a year, for example, because their job status changed, they have supplemental policies, or they have more than one employer, creating duplicate coverage. Therefore, ARC recommended we use 200 million for the number of NPPs that will actually be sent.

We estimate the costs of drafting, printing, and distributing the NPP to all potential recipients to be the following. First, drafting the NPP is estimated to require one-third hour of legal services at a cost of $28 × 1,500 insurance plans and insurance administrative entities, which equals $42,000. Second, we need to calculate printing and distribution costs for all potential recipients assuming the revised notice would be sent in a separate mailing. As with providers, we estimate the cost of printing the NPP, which includes the cost of paper and actual printing, to be $0.10 per notice. Therefore, we estimate the cost of printing 200 million notices for mail distribution at $20 million. Further, we estimate the cost of distributing the NPPs, including clerical time and postage in the same manner as these costs were estimated for the Breach Notification for Unsecured Protected Health Information Regulations. Thus, we assume that an office worker could process and send 100 mailings per hour at a cost of $22.53 per hour, plus a postage cost of $0.45 per mailing. If notices were required to be mailed to the 200 million beneficiaries in the sixty-day timeframe, the distribution costs would be $135 million (200 million/100 per hour × $22.53 = $45 million + $90 million (200 million × $0.45)). Total printing and distribution cost would have been $155 million, if all policy holders received separate NPP mailings. Third, as discussed above, we expect that nearly all plans and third party administrators will be able to avoid having to do a separate mailing of the revised notice under the new distribution provisions in this final rule, and that only 10 percent of these plans will incur the printing and distribution costs. Using the above estimates, we assume for this purpose that 20 million notices (200 million total notices × 10%) will be need to be printed and sent through a separate mailing, at a total cost of $15.5 million ($2 million printing + $13.5 million mailing). Therefore, the total cost to all plans for drafting, printing, and distributing the NPP is approximately $15.5 million. We note that even this total may be an overestimation of the costs because many insurers may use bulk mailing rates to distribute their NPPs which would reduce their mailing costs.

The total estimated cost for both providers and health plans to notify individuals and policy holders of changes in their privacy rights is approximately $55.9 million in the first year following implementation of the rule.

A number of commenters expressed general concern regarding the costs of printing and distributing new NPPs but did not provide estimates of the costs they anticipated or question our calculations. Two health plan commenters estimated that the costs of printing and mailing NPPs to their members could reach up to $100,000. However, they did not provide information about the facts and assumptions underlying their analyses, including the number of beneficiaries or mailings they anticipated, so we were unable to evaluate their estimates. We have addressed some of this concern by permitting health plans that maintain a notice on their web sites to include their NPPs in their annual mailings, rather than separately mailing the NPPs within 60 days of the material changes.

Table 5 below presents our analysis of costs to the providers, insurers, and third party administrators that are required to issue NPPs under the rule.[38]

TABLE 5—SUMMARY OF COMPLIANCE COST FOR NOTICES OF PRIVACY PRACTICES

Cost elements	Providers	Health insurers & third party administrators	Total (approx.)
Drafting NPPs	$20 million	$42,000	$20 million.
Printing NPPs	$20.4 million	$2 million	$22.4 million.
Mailing NPPs	N/A	$13.5 million	$13.5 million.
Total (approx.)	$40.4 million	$15.5 million	$55.9 million.

[38] Health care clearinghouses function almost exclusively as business associates with respect to the protected health information they maintain and process, and therefore have no NPP requirements.

3. Business Associates and Covered Entities and Their Contractual Relationships

The rule extends liability for failure to comply with certain provisions of the Privacy and Security Rules directly to business associates and business associate subcontractors. Prior to this rule and HITECH, these obligations applied to business associates and their subcontractors indirectly through §§ 164.504(e) and 164.314(a), which require that covered entities by contract require business associates to limit uses and disclosures and implement Security Rule-like safeguards.

This final rule implements Section 13401 of HITECH Act, which makes business associates directly liable for compliance with many of the same standards and implementation specifications, and applies the same penalties to business associates that apply to covered entities, under the Security Rule. Additionally, in accord with Section 13404 of the HITECH Act, the rule requires business associates to comply with many of the same requirements, and applies the same penalties to business associates that apply to covered entities, under the Privacy Rule. Business associates must also obtain satisfactory assurances in the form of a business associate agreement from subcontractors that the subcontractors will safeguard any protected health information in their possession. Finally, business associates must furnish any information the Secretary requires to investigate whether the business associate is in compliance with the regulations.

In the proposed rule, we assumed that business associates' compliance with their contracts range from the minimal compliance to avoid contract termination to being fully compliant. Further, we assumed that business associates in compliance with their contracts would have already designated personnel to be responsible for formulating the organization's privacy and security policies, performed a risk analysis, and invested in hardware and software to prevent and monitor for internal and external breaches of protected health information.

We also stated in the proposed rule that while business associates were previously required to comply with the HIPAA Rules according to the terms of their contracts with covered entities, and we expected that most business associates did so already, the risk of criminal and/or civil monetary penalties may spur some business associates to increase their efforts to comply with the Rules. We explained that we have no information on the degree of contract enforcement and compliance among business associates, and lack information regarding the size or type of business associates that contract with covered entities. We have only rough estimates as to the overall number of business associates, which range from approximately one million to two million depending on the number of business associates that serve multiple covered entities.

While we did not have specific information in this regard, we assumed that some business associates and subcontractors already comply with existing privacy and security standards in accordance with their indirect and contractual obligations. For them, the proposed rule would impose only a limited burden. For other business associates, depending on the current level of compliance, the proposed rule could impose significant burdens. We requested comments regarding the amount of burden and the number of affected business associates.

Several commenters stated that requiring business associates to undertake compliance with the rule in the same way as covered entities is excessive and burdensome, especially because in some cases business associates do not have the same type of relationship with individuals. Several commenters pointed to the burden on covered entities and business associates to renegotiate business associate agreements and train staff, and many specifically mentioned that compliance with the Security Rule is particularly costly. One commenter stated that it was a business associate party to ''tens of thousands'' of business associate contracts, with a significant cost to bring all into compliance.

We continue to expect that most business associates and subcontractors have made and continue to make a good-faith effort to follow the terms of their contracts. The burden of the rule on business associates and subcontractors depends on the terms of the contracts between covered entities and business associates and between the business associates and subcontractors, and the degree to which business associates and subcontractors established privacy policies and adopted security measures that comport with the HIPAA Rules. For business associates and subcontractors that have already taken HIPAA-compliant measures to protect the privacy and security of the protected health information in their possession, as required by their existing contracts, the rule imposes limited burden. We estimate the costs to other business associates later in this section.

A few commenters cited concerns about unfair competition for smaller business associate entities that they believe will not be able to compete with larger business associate entities, especially with regard to contract negotiations including indemnification and other risk allocation issues.

We understand that many small business associates are concerned about the allocation of risk and indemnification in conjunction with their business associate contracts. However, as we discuss in section IV D above, as with any contracting relationship, business associates and covered entities may include other provisions that dictate and describe their business relationship. While these may or may not include indemnification clauses or other risk-shifting provisions, these contractual provisions and relationships are outside the governance of the HIPAA Rules.

Because we understand that covered entities and business associates remain concerned with the cost to bring their business associate agreements into compliance with the final rule, we allow contracts to be phased in over one year from the compliance date or 20 months from the publication date of the final rule, and we expect and encourage covered entities and business associates to incorporate the costs of modifying contracts into the normal renegotiation of contracts as the contracts expire. As we did not receive comments to the contrary, we believe that most contracts will be renegotiated over the phase-in period. In addition, the Department has issued on its web site revised sample business associate provisions, which should lessen the costs associated with contract modifications.

As we believe covered entities generally are operating under HIPAA compliant contracts with their business associates, the transition period and availability of sample contract provisions should make it possible for these entities to incorporate any minor contract modifications into normal contract renegotiations without any appreciable added costs. We continue to believe that all covered entities have established business associate agreements with their business associates that are consistent with the requirements of the HIPAA Rules, as covered entities have been subject to direct liability under the Rules since their inception and have had more than half a dozen years to make their contracts compliant. However, to the extent that some contracts between covered entities and business associates

are not currently in full compliance with the business associate agreement provisions, these entities may experience limited costs to revise their contracts.

Although we are less certain about the current state of business associate-subcontractor relationships, we believe that most business associates have made a good faith attempt to include the appropriate contractual requirements. Still, we anticipate that some small business associates, now that they are subject to direct liability under the rules, might establish or significantly modify their subcontracts to come into compliance for the first time. Such business associates would not be eligible for the extended transition period and, as a result, would incur the costs of creating new contracts or renegotiating contracts out of cycle. In the Final Privacy Rule published in 2002, we estimated that entities would need between one and two hours to develop and tailor a business associate agreement to their particular needs. See 67 FR 53182, 53257. Taking the average of the lower and upper estimates provided in the earlier rulemaking, we estimate that developing and tailoring contract language normally would take approximately 90 minutes of professional legal services at $84.32 per hour.[39] However, as in the 2002 Final Privacy Rule (67 FR 53257), we estimate that providing model language will reduce the time required to develop contract language by at least one third. Thus, we estimate that each new or significantly modified contract between a business associate and its subcontractors will require, at most, one hour of a lawyer's time at a cost of $84.32.

We believe that no more than 25 percent of 1–2 million business associates, or 250,000–500,000 entities, would not have already made good faith efforts to achieve compliance and will need to create or significantly modify subcontracts, resulting in total costs of between $21 million and $42 million.

We expect that each business associate's lawyer will draw up one standard contract to use for all of its subcontracts. We do not attribute contract revision costs to subcontractors because the required contract provisions are not negotiable and subcontractors will need to only sign the agreement. We note that our estimated cost likely is an overestimate because the group of small business associates that may be less likely than others to have compliant contracts in place with subcontractors are, because of their size, also less likely to have any subcontractors at all.

Finally, in response to the commenters concerned with the cost and burden on business associates to come into full compliance with the Security Rule, we have taken another look at the underlying assumptions in the proposal. We continue to believe that business associates have engaged in privacy practices in compliance with their contractual obligations to use and disclose protected health information as limited by the Privacy Rule and their particular contracts with covered entities. Therefore, as we have stated above, we do not believe that the extension of liability for compliance with Privacy Rule requirements as identified in this rulemaking will impose any new costs or burdens.

With regard to the Security Rule, which was of particular concern to commenters as to the compliance costs on business associates, we also continue to believe that business associates, in providing their adequate assurances to safeguard electronic protected health information through their business associate contracts, have implemented security protections that meet the standards and required implementation specifications in the Security Rule. Further, we continue to believe that business associates have made the necessary investment in hardware and software to secure the electronic protected health information as part of the investment in the hardware and software needed for their management and processing of this information to perform their business associate functions and comply with the contract requirements at § 164.314(a). However, based on the comments, we now believe that some business associates, particularly smaller business associates that may have access to electronic protected health information for limited purposes, may not have engaged in certain of the formal administrative safeguards. For example, these entities may not have performed a risk analysis, established a risk management program, or designated a security official, and may not have written policies and procedures, conducted employee training, or documented compliance as required under §§ 164.308 and 164.316 of the Security Rule.

We do not have information on what percentage of business associates may have to engage in efforts to comply with some of the administrative safeguard standards, including documenting their policies and procedures and training their employees on the policies and procedures, nor did the comments on the impact statement offer any specific information to provide an estimate. We assume that up to 80 percent of the 1–2 million business associates, or between 800,000 and 1.6 million business associates, may handle electronic protected health information and thus may have to document their existing security protocols. Further, of these business associates, we assume that no more than 25 percent are likely to incur some cost to document their administrative safeguards and their policies and procedures as now required by statute and these regulations. We believe that our original assumption of compliance with all Security Rule requirements remains sound for the rest of the business associates, and we received no substantive comments to the contrary.

The costs of coming into full compliance with the administrative safeguard procedures, such as performance of a risk analysis and development of a risk management plan, will vary depending on the size and complexity of the business associate, the scope of their duties for the covered entity and the protected health information they must secure, and the degree to which their prior documentation of their security protocols falls short of compliance with the standards in the Security Rule. In the original Security Rule, we estimated that covered entities would need approximately 16 hours to document their policies and procedures. See 68 FR 8334, 8368. As these policies and procedures are the reflection of the risk management plan, which in turn is based on the risk analysis, we believe that this estimate would be inclusive of that time. We believe it will take business associates on average much less time to document their security related policies and procedures, because they have likely already engaged in most of the analysis associated with the adoption of security protocols, even if they may not have formally reduced all such protocols to writing, and because the scope of their responsibilities will generally be much more constrained than that of the covered entity with whom they have contracted. In addition, while covered entities must perform these tasks with respect to their entire business, generally only a small part of any business associate is involved with electronic protected health information.

Extrapolating from our estimate in the original Security Rule that entities would require approximately 16 hours to implement and document Security

[39] See *http://www.bls.gov/oes/current/naics3_541000.htm#23–0000* for lawyers. Note that we generally calculate labor costs based on the median hourly rate, which for lawyers is $56.21 per hour. We add 50 percent to account for fringe benefits, resulting in an estimated hourly cost of $84.32.

Rule compliance measures for the first time, and applying the assumption that most of these measures already are in place, we estimate that these business associates will need only between 2 and 5 hours to formalize or update their applicable administrative safeguards. We would cost the time needed to come into compliance at $56.61/hour.[40] According to these assumptions, the range of costs that any one business associate would incur to comply with the new statutory and regulatory requirements would be between $113 and $283, as first year, one-time costs. Assuming that businesses associates with access to electronic protected health information represent 80 percent of 1 to 2 million total business associates (or 800,000 to 1.6 million total), the aggregated costs for all business associates are estimated to be between approximately $22.6 million and $113 million. (25 percent of 800,000 business associates = 200,000; 200,000 × $113 (2 hr @ $56.61/hr) = $22.6 million. 25 percent of 1.6 million business associates = 400,000; 400,000 × $283 (5 hr @ $56.61/hr) = $113 million.) These costs represent one time first year costs for full compliance by business associates with the Security Rule requirements.

Table 6 below presents the range of our estimates of the costs to business associates of achieving compliance with the rules.

TABLE 6—BUSINESS ASSOCIATE COST ESTIMATES IN 2011 DOLLARS

Data element	Security rule compliance documentation	BAA between business associates and subcontractors
Estimated number of affected entities	200,000–400,000 BAs	250,000–500,000 BAs.
Hours needed to complete compliance activities	2–5 hours per BA	1 hour per BA.
Cost per hour	$56.61	$84.32.
Total cost	$22.6 million–$113 million	$21 million–$42 million.

Response to Other Public Comments

Comment: One commenter suggested that business associates will be reluctant to contract with covered entities due to perceived increased risks associated with such contracts, and covered entities will be forced to hire more staff at additional costs.

Response: While the HIPAA Rules now impose direct liability with regard to compliance, business associates were previously contractually liable for compliance with these provisions. Further, whether a covered entity uses workforce members or business associates to perform its operations remains a decision for the covered entity. As this commenter did not provide specific information about his concerns, we cannot quantify the costs associated with this comment, nor do we have a basis for concluding that business associates will refuse to contract with covered entities as a result of this rule.

Comment: One commenter suggested that requiring business associate agreements will increase the costs of litigation.

Response: As business associate agreements were required under the HIPAA Rules previously, and as the commenter did not include specific information about what costs he believes will increase, we do not believe such a requirement will increase litigation generally.

4. Qualitative Analysis of Unquantified Costs

a. Authorization for Uses and Disclosures of Protected Health Information for Marketing and Sale of Protected Health Information

The final rule modifies the definition of ''marketing'' to encompass treatment and health care operations communications to individuals about health-related products or services if the covered entity receives financial remuneration in exchange for making the communication from or on behalf of the third party whose product or service is being described. A covered entity must obtain an individual's written authorization prior to sending marketing communications to the individual.

In the proposed rule, we requested comment on the extent to which covered entities currently receive financial remuneration from third parties in exchange for sending information to individuals about the third parties' health-related products or services. In general, commenters did not indicate that complying with the final rule would be administratively burdensome, but some commenters expressed a general concern over the potential loss of revenue given the new restrictions on receiving financial remuneration from a third party to send health-related communications to an individual. These comments appear to indicate that most covered entities would not attempt to obtain authorizations for the now prohibited communications but rather would forgo making them altogether. We acknowledge the potential for some lost revenue due to these modifications in cases where covered entities are currently receiving financial remuneration from third parties to send health-related communications to individuals. However, as we do not know to what extent covered entities today currently operate in this manner, and commenters did not include specific information in this regard, we do not have data that could inform quantifying such loss.

The final rule also requires an individual's authorization before a covered entity may disclose protected health information in exchange for remuneration (i.e., ''sell'' protected health information), even if the disclosure is for an otherwise permitted disclosure under the Privacy Rule. The final rule includes several exceptions to this authorization requirement. In the proposed rule, we stated that on its face, this new prohibition would appear to increase the burden to covered entities by requiring them to obtain authorizations in situations in which no authorization is currently required. However, we believed such a scenario to be unlikely. We believed most individuals would not authorize disclosures of their protected health information when they were informed the covered entity would be remunerated for the disclosure. Thus, we believed covered entities would simply discontinue making such disclosures as it would not be

[40] We have used the median wage rate described by the U.S. Bureau of Labor Statistics in its 2011 National Compensation Survey for the category of Management Analysts (including responsibilities for designing systems and procedures), which is approximately $37.74/hr. See *http://www.bls.gov/oes/current/oes_nat.htm* . To this wage rate we have added 50 percent for benefits, which results in a total cost of $56.61/hr.

worthwhile for covered entities to continue to attempt to obtain such authorizations. We requested comment on these assumptions.

As noted above, the requirement to obtain authorization to receive remuneration to make a disclosure of protected health information contains several exceptions. In the proposed rule, we expressed our belief that covered entities would not incur additional costs to continue making most of the excepted disclosures as such exceptions were not constrained or limited in any way and thus, would not change the status quo. However, we recognized that the exception for research disclosures may impose additional burden on researchers as it was, consistent with the statute, a conditional exception. Covered entities would be able to disclose protected health information under the research exception only to the extent any remuneration received in exchange for the information did not exceed the cost to produce and transmit the information. Thus, we recognized that researchers who purchase data from covered entities may now incur additional costs as a result of the final rule, in order to obtain newly required authorizations, if they are currently paying a covered entity more than the cost to produce and transmit the protected health information (e.g., an incentive payment to produce the data) and the covered entity is not willing to accept only the costs to prepare and transmit the data. It was also recognized that some research may be jeopardized to the extent that authorizations for the entity to receive these incentive payments could not be obtained from subjects. On the other hand, to the extent covered entities agreed to receive only the costs to prepare and transmit the data, these entities would experience a loss of revenue while researchers would experience a corresponding decrease in costs, and current disclosures for research purposes could continue without authorization. While we acknowledged the potential costs under this provision, we stated that we have no information on the amounts currently paid to covered entities by researchers for protected health information, and thus, had no way to estimate the impact of the provision. We solicited comment in this area.

Overall, commenters did not indicate that obtaining authorization prior to disclosing protected health information in exchange for remuneration would result in an increased burden or cost for the covered entity. However, one commenter did estimate that obtaining additional authorizations may cost approximately $22 to $28, per patient. Some commenters indicated it may be burdensome to determine if remuneration was in fact received by the entity.

The comments on this provision did not alter our belief that, in general, covered entities would discontinue making disclosures in exchange for remuneration that require the individual's authorization, given the unlikelihood most individuals would agree to authorize such disclosures. Further, there are a number of exceptions to the general prohibition that allow a covered entity to continue to operate ''status quo'' with respect to a number of types of disclosures, even if the covered entity receives remuneration. In response to the comments, we acknowledge that it may be difficult to determine whether remuneration has been received by a covered entity, particularly since the prohibition encompasses both direct and indirect (i.e., non-financial) remuneration. We expect to issue future guidance on this topic to assist entities in complying.

With respect to the amounts currently paid to covered entities by researchers, some commenters indicated as a general concern that limiting remuneration received by covered entities from researchers may provide a disincentive for covered entities to continue assisting researchers in their efforts. However, commenters did not quantify what they are paying covered entities above the costs to prepare and transmit the data, nor did they provide information that would give the Department an idea of the extent to which covered entities receive such payments. Therefore, while we acknowledge the potential for some lost revenue to covered entities due to these modifications or some additional costs to researchers to obtain authorizations, we do not have data that could inform quantifying such costs. At the same time, we note that we have made some clarifications in the above preamble discussion regarding these provisions that we believe would lessen any such impact. Specifically, the preamble explains that we do not consider a sale of protected health information to encompass payments a covered entity may receive in the form of grants, or contracts or other arrangements to perform programs or activities, such as a research study, where any provision of protected health information to the payer is a byproduct of the service being provided. Thus, the payment by a research sponsor to a covered entity to conduct a research study is not considered a sale of protected health information even if the study involves disclosing research results that include protected health information to the sponsor. In contrast, a sale of protected health information includes disclosures of protected health information where a covered entity is receiving remuneration from or on behalf of the recipient of the data for the information itself. Thus, a disclosure of protected health information by a covered entity to a third party researcher that is conducting the research in exchange for remuneration would fall within these provisions, unless the only remuneration received is a reasonable, cost-based fee to cover the cost to prepare and transmit the data for such purposes.

b. Individual Right To Opt Out of Fundraising Communications

The current Privacy Rule requires covered entities give individuals the opportunity to opt out of receiving future fundraising communications from the entity. The HITECH Act and final rule strengthens the opt out by requiring that it be clear and conspicuous and that an individual's choice to opt out should be treated as a revocation of authorization. While the rule specified that a clear and conspicuous opt out method must not cause an individual to incur an undue burden or more than a nominal cost, proposed rule did not specify the method to be employed but rather left it up to the discretion of the covered entity. We requested comment on the extent to which the requirement that the opportunity to elect not to receive further fundraising communications be clear and conspicuous would have an impact on covered entities and their current fundraising materials.

Overall, commenters did not indicate that requiring the opt out for further fundraising to be clear and conspicuous would greatly impact covered entities and their current fundraising efforts or provide specific anticipated costs in this regard. Rather, some commenters indicated that they already provide pre-paid, pre-printed postcards for this purpose with fundraising mailings and doing so is neither costly nor imposes a significant burden on the individual who wishes to opt out of further communications. Based on this feedback and the continued flexibility in the final rule to choose the opt out method (e.g., toll-free number, post-card), we do not believe that the requirement that fundraising opt-outs be clear and conspicuous will result in significant new costs to covered entities.

Further, while some commenters did indicate that a pre-solicitation opt out would be costly for covered entities in

response to our request for comment on this issue, as a result of this general opposition, the final rule does not change the current requirement that covered entities only need to include an opt-out with any solicitation sent to an individual rather than to the first fundraising communication.

c. Individuals' Access to Protected Health Information

In this final rule, we strengthen an individual's right to receive an electronic copy of his or her protected health information. Specifically, as was proposed, the final rule requires that if an individual requests an electronic copy of protected health information that is maintained electronically in one or more designated record sets, the covered entity must provide the individual with access to the electronic information in the electronic form and format requested by the individual, if it is readily producible, or, if not, in a readable electronic form and format as agreed to by the covered entity and the individual. Also, as in the proposed rule, the final rule provides that a covered entity may charge a fee for costs associated with labor and supplies for creating an electronic copy, including electronic portable media if agreed to by the individual, and clarifies that a covered entity may charge for postage if an individual requests that the covered entity transmit portable media containing an electronic copy through mail or courier. However, covered entities may not include fees associated with maintaining systems, retrieval costs, or infrastructure costs in the fee they charge to provide an electronic copy.

We continue to believe that this requirement will not result in significant new burdens on covered entities. Individuals already had a right to access protected health information maintained in electronic designated record sets under the prior Rule, and already had a right to receive an electronic copy of such information to the extent the electronic copy was readily producible by the covered entity. The Rule provides significant flexibility to covered entities in honoring individuals' request for electronic access. While a covered entity must provide some type of electronic copy to an individual who requests one, a covered entity is not required to provide the exact form of the copy or access requested by the individual if it is not readily producible in such form. Thus, covered entities may provide readily producible electronic copies of protected health information that are currently available on their various systems. A covered entity is not required to purchase new software or systems in order to accommodate an electronic copy request for a specific form that is not readily producible by the covered entity at the time of the request, provided that the covered entity is able to provide some form of electronic copy. Further, in cases where an individual chooses not to accept the electronic copy that is readily producible by the covered entity, a hard copy may be offered.

We did hear from several commenters that some legacy or other systems, while capable of producing a hard copy as previously required under the existing access requirement, may not be capable of producing any electronic copy at present. In these cases, covered entities may incur some cost burden in order to purchase software or hardware to produce some kind of electronic copy for electronic information held in designated record sets on such legacy systems. However, covered entities are not required to purchase additional software or hardware to meet individuals' specific requests, as long as at least one type of electronic copy is available. We anticipate some cost will be incurred by covered entities with such systems; however we did not receive comments on the extent of these costs, or the number of covered entities with legacy systems that will need to incur such costs.

d. Right To Restrict Certain Disclosures to a Health Plan

The final rule requires that a covered health care provider agree in most cases to an individual's request to restrict disclosure to a health plan of the individual's protected health information that pertains to a health care service for which the individual has paid the health care provider in full out of pocket. This is a change from the prior rule, which provided individuals with the right to request a restriction on certain disclosures; however, a covered entity was not required to agree to the restriction, whatever the circumstances. We do not believe that covered health care providers will incur substantial costs to implement this expanded right for a number of reasons. First, in order to comply with the rule prior to this change, a covered entity is already required to have processes and procedures in place for accepting and considering individuals' requests for restrictions, even if, as a general matter, the covered entity declines to agree to such requests. This final rule does not require new or different processes for receiving and reviewing requests for restrictions, just that the covered entity honor, in most cases, a self-pay patient's request for a restriction to a health plan. Second, for those covered health care providers that do not currently, but will now be required to, accommodate requests by self-pay patients to restrict disclosures to a health plan, the final rule provides significant flexibility in how providers are to honor an individual's request and the preamble makes various clarifications in response to comments as to how to operationalize this new requirement. For example, the final rule makes clear that a health care provider is not required to separate or segregate records in order to ensure an individual's restriction request is honored. Rather, the final rule leaves it to the discretion of the provider as to how to flag information that is the subject of a restriction. Further, the final rule provides flexibility as to how restriction requests for certain services, such as bundled services, are to be handled, as well as what reasonable efforts should be made to obtain payment from an individual whose original form of payment has been dishonored, prior to resorting to billing the health plan for the service. Finally, in response to comments regarding the potential burden and cost of doing so, the final rule does not require health care providers to inform downstream providers who may receive the individual's protected health information, such as a pharmacy or specialist, of a restriction, given the lack of automated technologies to support such a requirement.

Notwithstanding the above, we acknowledge that there will be some additional burden on certain health care providers to ensure an individual's request to restrict a disclosure to a health plan is honored where such a request would not have been honored in the past. However, we do not have data to inform quantifying an estimated cost in this area. For example, we do not have data on the number of providers that currently accommodate requests from self-pay patients to restrict disclosures versus those that do not, the number of requests that covered health care providers receive today that would now require a restriction, nor even the number of requests for restrictions generally that covered health care providers currently receive.

e. Impact of the Genetic Information Underwriting Prohibition on Health Plans

The final rule prohibits health plans that are HIPAA covered entities, except issuers of long term care policies, from using or disclosing an individual's protected health information that is

genetic information for underwriting purposes. As we explained in the proposed rule, the rule does not affect health plans that do not currently use or disclose protected health information for underwriting purposes. Further, even with respect to health plans that perform underwriting, plans and issuers in the group market previously commented to the Department that they do not, even prior to the passage of GINA, use genetic information for underwriting purposes because pre-GINA laws and regulations prohibit them from discriminating against individuals based on any health status related factors, including genetic information. With respect to issuers in the individual health insurance market, the Department acknowledged in the proposed rule that there may be more significant policy changes associated with the prohibition on using or disclosing protected health information that is genetic information for underwriting purposes. However, the Department explained in the proposed rule that it did not have sufficient information to determine the extent of such changes, that is, to what extent issuers in the individual health insurance market use genetic information for underwriting purposes. Regardless, as we explained in the proposed rule, in the case of either the individual or group market, the Department assumed, because a prohibited use or disclosure of genetic information for underwriting purposes would also be a discriminatory use of such information under the nondiscrimination provisions of GINA Title I and its implementing regulations, that there would be no costs associated with conforming a plan's practices to comply with the underwriting prohibition that are above and beyond the costs associated with complying with the regulations implementing sections 101–103 of GINA. With respect to the health plans not covered by GINA but subject to the proposed prohibition in the Privacy Rule, the Department also assumed that the costs to comply would be minimal because such plans either: (1) do not perform underwriting, as is the case generally with public benefit plans; or (2) perform underwriting but do not in most cases use genetic information (including family medical history) for such purposes.

In general, most comments in response to the proposed rule did not provide information that contradicted the above assumptions. However, concern was expressed regarding the adverse impact of such an underwriting prohibition on the long-term care market. Given the concern regarding the impact of the underwriting prohibition on the long-term care market, the final rule exempts such plans from the prohibition. Thus, there are no costs to be attributed to long term care plans with this rule. Further, given we did not receive other comments that would lead us to question the underlying assumptions in the proposed rule, we do not expect this provision of the final rule to result in substantial new costs on health plans, particularly those that have been required to comply with the regulations implementing GINA's nondiscrimination provisions for several years now.

f. Enforcement Provisions

The amendments contained within this final rule to the HIPAA Enforcement Rule conform the regulatory language of the Rule to the enhanced enforcement provisions of the HITECH Act. Consistent with its reasoning in prior HIPAA Enforcement rulemakings,[41] the Department expects the costs covered entities, and now business associates, may incur with respect to their compliance with the Enforcement Rule, itself, should be low in most cases. That is, covered entities and business associates that comply with the HIPAA rules voluntarily, as is expected, should not incur any additional, significant costs as a result of the Enforcement Rule. Further, we believe the increased penalties and other enhancements provided by the HITECH Act and which are reflected in this final rule provide even more incentive to covered entities and business associates to take steps necessary to comply and thus not be liable for violations.

D. Qualitative Analysis of Unquantified Benefits

While we are certain that the regulatory changes in this final rule represent significant benefits, we cannot monetize their value. Many commenters agreed with our assumptions regarding the benefits to individuals, but we did not receive any comments that included specific information about quantifying those benefits. The following sections describe in greater detail the qualitative benefits of the final rule. In addition to greater privacy protections for individuals, these benefits include the results of our efforts to reduce burdens. Consistent with E.O. 13563, we conducted a retrospective review of our regulations and identified areas, such as certain research authorization requirements and disclosures to schools regarding childhood immunizations, in which we could decrease costs and increase flexibilities under the HIPAA Rules. The resulting changes are discussed below.

1. Greater Privacy Protections for Individuals

The benefits for individuals include added information on their rights through an expanded NPP, and greater rights with regard to the uses and disclosures of their personal health information through expanded requirements to: (1) Obtain authorization before a covered entity or business associate may disclose their protected health information in exchange for remuneration, (2) restrict certain disclosures to a health plan at the request of the individual, (3) strengthen the ability of individuals to opt out of further fundraising communications, and (4) limit uses and disclosures of protected health information for marketing. Individuals also will benefit from increased protection against discrimination based on their genetic information, achieved through the prohibition against health plans using or disclosing protected health information that is genetic information for underwriting purposes. Individuals also will have increased access to their protected health information in an electronic format.

Finally, under the rule, individuals' health information will be afforded greater protection by business associates of covered entities who share liability and responsibility with the covered entity for safeguarding against impermissible uses and disclosures of protected health information.

2. Breach Notification

The analysis of benefits of the breach notification regulation is as stated in the interim final rule. In summary, we stated that notifying individuals affected by a breach would alert them to and enable them to mitigate potential harms, such as identity theft resulting from the exposure of certain identifiers, and reputational harm that may result from the exposure of sensitive medical information. Further, the breach notification requirements provide incentive to covered entities and business associates to better safeguard protected health information, such as by encrypting the information, where possible.

We also believe that the modifications to the definition of breach to remove the harm standard and revise the risk assessment will ensure that covered

[41] See the preambles to the proposed and final Enforcement Rules at 70 FR 20224, 20248–49 (April 18, 2005) and 71 FR 8390, 8424 (February 16, 2006).

entities and business associates apply the rule in a more objective and uniform manner. We believe that these modifications will make the rule easier for covered entities and business associates to implement and will result in consistency of notification across entities which will benefit consumers.

3. Compound Authorizations for Research Uses and Disclosures

We proposed to permit compound authorizations for the use or disclosure of protected health information for conditioned and unconditioned research activities provided that the authorization clearly differentiates between the conditioned and unconditioned research components and clearly allows the individual the option to opt in to the unconditioned research activities. We believed that the proposed provision would reduce burden and costs on the research community by eliminating the need for multiple forms for research studies involving both a clinical trial and a related biospecimen banking activity or study and by harmonizing the Privacy Rule's authorization requirements with the informed consent requirements under the Common Rule. This change to the Rule had long been sought by the research community. While we expected burden reduction and cost savings due to these modifications, we had no data which to quantify an estimate of such savings. We requested comment on the anticipated savings that this change would bring to the research community.

As explained above, the final rule adopts the proposal to permit compound research authorizations. While almost all commenters on this topic were supportive and agreed that the change would result in reduced burdens and costs due to a reduction in forms and harmonization with the Common Rule, we did not receive significant comment that could inform our quantifying the anticipated cost-savings associated with this modification.

4. Authorizations for Future Research Uses or Disclosures

We requested comment on the Department's previous interpretation that an authorization for research uses and disclosures must include a description of each purpose of the requested use or disclosure that is study specific, and the possibility of modifying this interpretation to allow for the authorization of future research uses and disclosures. We believed that this change in interpretation would reduce burden on covered entities and researchers by reducing the need for researchers to obtain multiple authorizations from the same individual for research and further harmonizing the Privacy Rule authorization requirements with the informed consent requirements under the Common Rule.

The final rule adopts the new interpretation to allow covered entities to obtain authorizations for future research uses and disclosures to the extent such purposes are adequately described in the authorization such that it would be reasonable for the individual to expect that his or her protected health information could be used or disclosed for such future research. While we did receive comments supporting our assertions that permitting authorizations for future research uses and disclosures would reduce burden to covered entities and researchers by obviating the need for researchers to seek out past research participants to obtain authorization for future studies which they may be able to authorize at the initial time of enrollment into a study, and additionally by reducing the waivers of authorization that researchers would need to obtain from Institutional Review Boards, we did not receive specific comment on cost savings that could inform our quantifying the savings in this final rule.

5. Period of Protection for Decedent Information

We proposed to modify the current rule to limit the period for which a covered entity must protect an individual's health information to 50 years after the individual's death. We believed this would reduce the burden on both covered entities and those seeking the protected health information of persons who have been deceased for many years by eliminating the need to search for and find a personal representative of the decedent, who in many cases may not be known or even exist after so many years, to authorize the disclosure. We believed this change would also benefit family members and historians who may seek access to the medical information of these decedents for personal and public interest reasons. However, we lacked any data to be able to estimate the benefits (or any unanticipated costs) of this provision and requested comment on these assertions.

The final rule adopts the modification to limit the period of protection for decedent health information to 50 years after the date of death. While most comments responding to this proposal were very supportive of the change, agreeing with the anticipated benefits the Department had articulated (i.e., easier access to old or ancient patient health information by family, historians, archivists), the comments did not provide specific information that could inform our quantifying a cost-savings or reduction in burden associated with this change in policy.

The Department did receive one comment asserting that covered entities may keep decedent information, particularly the information of famous individuals, for longer than 50 years past the date of death in order to monetize those records. The commenter cited an example of an x-ray of a deceased celebrity being sold at an auction for $45,000. However, we do not anticipate that this is or will be a typical scenario.

6. Disclosures About a Decedent

We proposed to permit covered entities to disclose a decedent's protected health information to family members and others who were involved in the care or payment for care prior to the decedent's death, unless doing so is inconsistent with any prior expressed preference of the individual that is known to the covered entity. In the preamble to the proposed rule, we stated our belief that the proposed change would reduce burden by permitting covered entities to disclose protected health information about a decedent to family members and other persons who were involved in an individual's care while the individual was alive, without having to obtain written permission in the form of an authorization from the decedent's personal representative, who may not be known or even exist, and may be more difficult to locate as time passes. However, we had no data to permit us to estimate the reduction in burden and requested public comment on this issue.

The final rule adopts the modification as proposed. However, as with the proposed rule, we are unable to quantify any cost-savings with respect this change. While commenters confirmed that permitting such disclosures would help facilitate communications with family members and other persons who were involved in an individual's care or payment for care prior to death, we did not receive any information that could inform estimating a savings.

7. Public Health Disclosures

We proposed to create a new public health provision to permit disclosure of proof of a child's immunization by a covered entity to a school in States that have school entry or similar laws. This proposed change would have allowed a covered health care provider to release

proof of immunization to a school without having to obtain a written authorization, provided the provider obtained the agreement, which may be oral, to the disclosure from a parent, guardian or other person acting *in loco parentis* for the individual, or from the individual, if the individual was an adult or emancipated minor. We anticipated that the proposed change to the regulations would reduce the burden on parents, schools, and covered entities in obtaining and providing written authorizations, and would minimize the amount of school missed by students. However, because we lacked data on the burden reduction, we were unable to provide an estimate of the possible savings and requested comment on this point.

The final rule adopts the proposal to permit covered entities to disclose, with the oral or written agreement of a parent or guardian, a child's proof of immunization to schools in States that have school entry or similar laws. This obviates the need for a covered entity to receive formal, executed HIPAA authorizations for such disclosures. While the final rule requires that covered entities document the agreement, the final rule is flexible and does not prescribe the nature of the documentation and does not require signature by the parent, allowing covered entities the flexibility to determine what is appropriate for their purposes. For example, as the preamble indicates above, if a parent or guardian submits a written or email request to a covered entity to disclose their child's immunization records to the child's school, a copy of the request would suffice as documentation of the agreement. Likewise, if a parent or guardian calls the covered entity and requests over the phone that their child's immunization records be disclosed to the child's school, a notation in the child's medical record or elsewhere of the phone call would suffice as documentation of the agreement.

Given that the rule no longer requires a formal, executed HIPAA authorization for such disclosures and provides significant flexibility in the form of the documentation required of a parent's or guardian's agreement to the disclosure, this modification is expected to result in reduced burden and cost to covered health care providers in making these disclosures, as well as to the parents and schools involved in the process. We acknowledge that covered health care providers who wish to use these less formal processes in lieu of the authorization will need to explain their new procedure to office staff. However, given the provision's flexibility and narrow scope, we do not expect that the providers will need to do more than ensure office staff have a copy of the new procedure. Further, any one-time costs to develop and deploy the new procedure will be offset by the savings that are expected to accrue from the change over time as the disclosures are carried out. While we acknowledge the overall savings associated with this change, as with other provisions in this rule providing increased flexibility for compliance, we are unable to quantify them. For example, we do not have data on how many family doctors and other providers generally make these types of disclosures and how many requests such providers generally receive for proof of immunization, and we did not receive data from commenters that could inform our estimating savings in this area.

E. Additional Regulatory Analyses

1. Regulatory Flexibility Act

The Regulatory Flexibility Act requires agencies to analyze and consider options for reducing regulatory burden if the regulation will impose a significant burden on a substantial number of small entities. The Act requires the head of the agency to either certify that the rule would not impose such a burden or perform a regulatory flexibility analysis and consider alternatives to lessen the burden.

For the reasons stated below, it is not expected that the cost of compliance will be significant for small entities. Nor is it expected that the cost of compliance will fall disproportionately on small entities. Although many of the covered entities and business associates affected by the rule are small entities, they do not bear a disproportionate cost burden compared to the other entities subject to the rule. Further, with respect to small business associates, only the fraction of these entities that has not made a good faith effort to comply with existing requirements will experience additional costs under the rule. The Department did not receive any comments on its certification in the proposed rules. Therefore, the Secretary certifies that this rule will not have a significant economic impact on a substantial number of small entities.

The RFA generally defines a ''small entity'' as (1) a proprietary firm meeting the size standards of the Small Business Administration (SBA), (2) a nonprofit organization that is not dominant in its field, or (3) a small government jurisdiction with a population of less than 50,000. The SBA size standard for health care providers ranges between $7.0 million and $34.5 million in annual receipts. Because 90 percent or more of all health care providers meet the SBA size standard for a small business or are nonprofit organizations, we generally treat all health care providers as small entities for purposes of performing a regulatory flexibility analysis.

With respect to health insurers and third party administrators, the SBA size standard is $7.0 million in annual receipts. While some insurers are classified as nonprofit, it is possible they are dominant in their market. For example, a number of Blue Cross/Blue Shield insurers are organized as nonprofit entities; yet they dominate the health insurance market in the States where they are licensed and therefore would not be considered small businesses. Using the SBA's definition of a small insurer as a business with less than $7 million in revenues, premiums earned as a measure of revenue,[42] and data obtained from the National Association of Insurance Commissioners,[43] the Department estimates that approximately 276 out of 730 insurers had revenues of less than $7 million.[44]

From the approximately $225.4 million (upper estimate) in costs we are able to identify, the cost per covered entity may be as low as $80 (for the vast majority of covered entities) and as high as $843 (for those entities that experience a breach), and we estimate that the cost per affected business associate will be between $84.32 and $282. These costs are discussed in detail in the regulatory impact analysis and below. We do not view this as a significant burden because, for example, even the highest average compliance cost per covered entity we have identified ($843) represents just 0.0001% of annual revenues for a small entity with only $7 million in receipts (see the low end of SBA's size standard for health care providers). We include 750 third party administrators in the calculation of covered entities, to represent approximately 2.5 million ERISA plans,[45] most of which are small entities, on whose behalf they carry our

[42] U.S. Small Business Administration, ''Table of Small Business Standards Matched to North American Industry Classification System Codes,'' available at *http://www.sba.gov/content/small-business-size-standards*.

[43] HHS ASPE analysis of 2010 NAIC Supplemental Health Care Exhibit Data.

[44] These counts could be an overestimate. Only health insurance premiums from both the group and individual market were counted. If insurers also offered other types of insurance, their revenues could be higher.

[45] Source: 2010 Medical Expenditure Survey—Insurance Component.

compliance activities. We have no information on how many of these plans self-administer, and we did not receive any information from commenters in this area and so do not include a separate estimate for plans that self-administer.

We estimate that the breach notification requirements will result in $14.5 million in annual costs to covered entities. Dividing that amount by the approximately 19,000 entities that will actually experience a breach of protected health information each year, we estimate that the costs of complying with the breach notification requirements will amount to, on average, $763 per covered entity that must respond to a breach. Smaller covered entities likely will face much lower costs, as these entities generally have protected health information for far fewer individuals than do larger covered entities and breach notification costs are closely linked to the number of individuals affected by a given breach incident.

The other source of costs for covered entities arises from the requirement to provide revised NPPs to the individuals they serve. We estimate that the approximately 700,000 covered entities will experience total costs of approximately $55.9 million for compliance with the NPP requirements, or about $80 per covered entity.

We estimate the costs for 200,000–400,000 business associates to come into full compliance with the Security Rule to be approximately $22.6–$113 million. The average cost per affected business associate would be approximately $198.

Finally, we estimate that 250,000 to 500,000 business associates will incur costs totaling between $21 million and $42 million, respectively, to establish or significantly modify contracts with subcontractors to be in compliance with the rule's requirements for business associate agreements. The average cost per business associate would be approximately $84.

Based on the relatively small cost per covered entity and per business associate, the Secretary certifies that the Rule will not have a significant impact on a substantial number of small entities. Still, we considered and adopted several solutions for reducing the burden on small entities.

First, we combined several required rules into one rulemaking, which will allow affected entities to revise and distribute their notices of privacy practices at one time rather than multiple times, as each separate rule was published. Second, in the final rule we increase flexibility for health plans by allowing them to send the revised notices with their annual mailings rather than requiring plans to send them to individuals in a separate mailing.

Third, we allow covered entities and business associates with existing HIPAA compliant contracts twelve months from the date of the rule to renegotiate their contracts unless the contract is otherwise renewed or modified before such date. This amount of time plus the eight months from the publication date of the rule to the compliance date generally gives the parties 20 months to renegotiate their agreements. We believe that the added time will reduce the cost to revise agreements because the changes the rule requires will be incorporated into the routine updating of covered entities' and business associates' contracts.

Finally, the Department has also published on its web site sample language for revising the contracts between covered entities and business associates. While the language is generic and may not suit all entities and agreements, particularly larger entities and those with more complex business relationships, we believe that it will particularly help small entities with their contract revisions and save them time and money in redrafting their contracts to conform to the rule.

2. Unfunded Mandates Reform Act

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates would require spending in any one year $100 million in 1995 dollars, updated annually for inflation. In 2011, that threshold is approximately $136 million. UMRA does not address the total cost of a rule. Rather, it focuses on certain categories of cost, mainly those ''Federal mandate'' costs resulting from: (1) Imposing enforceable duties on State, local, or Tribal governments, or on the private sector; or (2) increasing the stringency of conditions in, or decreasing the funding of, State, local, or Tribal governments under entitlement programs.

We are able to identify between $114 and $225.4 million in costs on both the private sector and State and Federal entities for compliance with the final modifications to the HIPAA Privacy and Security Rules, and for compliance with the final Breach Notification Rule. As stated above, there may be other costs we are not able to monetize because we lack data, and the rule may produce savings that may offset some or all of the added costs. We must also separately identify costs to be incurred by the private sector and those incurred by State and Federal entities.

Some of the costs of the regulation will fall on covered entities, which are primarily health care providers and health plans.[46] For the purpose of these calculations, we included all provider costs as private sector costs. While we recognize that some providers are State or Federal entities, we do not have adequate information to estimate the number of public providers, but we believe the number to be significantly less than 10 percent of all providers shown in Table 1. Therefore, as we did for the RFA analysis and for ease of calculation, we assumed that all provider costs are private sector costs. We did not receive any comments on this assumption.

With respect to health plans, based on the data discussed in section C, we estimate that 60 percent of policy holders are served by private sector health plans and 40 percent of policy holders are served by public sector plans. Therefore, we attribute 60 percent of health plan costs to the private sector and 40 percent of plan costs to the public sector.

The remaining costs of complying with the regulation will be borne by business associates of covered entities. We do not have data with which to estimate the numbers of private versus public entity business associates. However, we believe that the vast majority of, if not all, business associates, are private entities. Therefore, we assumed all business associate costs are private sector costs.

Of the specific costs we can identify, we estimate that approximately 91 percent of all costs, or between $103.7 and $205 million, will fall on private sector health care providers, health plans, and business associates. The remaining costs, approximately $10.3–20.4 million, will fall on public sector health plans. The following paragraphs outline the distribution of costs arising from the four cost-bearing elements of the final rule: (1) Covered entities must revise and distribute notices of privacy practices, (2) Covered entities that experience a breach of protected health information must comply with the breach notification requirements, (3) certain business associates must revise contracts with subcontractors to meet business associate agreement requirements, and (4) Certain business associates must make efforts to achieve full compliance with the administrative requirements of the Security Rule.

[46] Another type of covered entity, health care clearinghouses, generally will not bear these costs, as clearinghouses are not required to provide a notice of private practices to individuals and are involved in a miniscule fraction of breach incidents, if any.

We estimate the costs for to comply with the NPP provisions will reach about $55.9 million, which will be shared by providers and health plans. Providers will bear approximately $40.4 million of these costs, all of which we attribute to the private sector. Health plans will bear approximately $15.5 million and, as explained above, we have allocated 60 percent of health plan costs for NPPs, or $9.3 million, as private sector costs. Public plans will bear the remaining $6.2 million.

We estimate that private entities will bear 93 percent of the costs of compliance with the breach notification requirements, or about $13.5 million. This is because the majority of breach reports are filed by health care providers, all of whose costs we attribute to the private sector. Consistent with our estimate that 60 percent of health plan members are enrolled in private sector plans, we also include as private costs 60 percent of the breach notification costs borne by health plans (based on the number of health plans that have filed breach reports).

Finally, we estimate that all of the costs for business associates to create or revise business associate agreements with subcontractors ($42 million outer estimate), and to come into full compliance with the Security Rule ($113 million outer estimate), will be private sector costs.

As the estimated costs to private entities alone may exceed the $136 million threshold, UMRA requires us to prepare an analysis of the costs and benefits of the rule. We have already done so, in accordance with Executive Orders 12866 and 13563, and present this analysis in sections C and D.

3. Federalism

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a rule that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications.

The Federalism implications of the Privacy and Security Rules were assessed as required by Executive Order 13132 and published as part of the preambles to the final rules on December 28, 2000 (65 FR 82462, 82797) and February 20, 2003 (68 FR 8334, 8373), respectively. Regarding preemption, the preamble to the final Privacy Rule explains that the HIPAA statute dictates the relationship between State law and Privacy Rule requirements. Therefore, the Privacy Rule's preemption provisions do not raise Federalism issues. The HITECH Act, at section 13421(a), provides that the HIPAA preemption provisions shall apply to the HITECH provisions and requirements. While we have made minor technical changes to the preemption provisions in Subpart B of Part 160 to conform to and incorporate the HITECH Act preemption provisions, these changes do not raise new Federalism issues. The changes include: (1) Amending the definitions of ''contrary'' and ''more stringent'' to reference business associates; and (2) further amending the definition of contrary to provide that State law would be contrary to the HIPAA Administrative Simplification provisions if it stands as an obstacle to the accomplishment and execution of the full purposes and objectives of not only HIPAA, but also the HITECH Act.

We do not believe that the rule will impose substantial direct compliance costs on State and local governments that are not required by statute. It is our understanding that State and local government covered entities do not engage in marketing, the sale of protected health information, or fundraising. Therefore, the modifications in these areas would not cause additional costs to State and local governments. We anticipate that the most significant direct costs on State and local governments will be the cost for State and local government-owned covered entities of drafting, printing, and distributing revised notices of privacy practices, which would include the cost of mailing these notices for State health plans, such as Medicaid. However, the costs involved can be attributed to the statutory requirements, which provide individuals with strengthened rights about which they need to be notified.

In considering the principles in and requirements of Executive Order 13132, the Department has determined that these modifications to the Privacy and Security Rules will not significantly affect the rights, roles, and responsibilities of the States.

F. Accounting Statement

Whenever a rule is considered a significant rule under Executive Order 12866, we are required to develop an accounting statement indicating the costs associated with promulgating the rule. Below, we present overall monetary annualized costs discounted at 3 percent and 7 percent as described in the Regulatory Impact Analysis.

ESTIMATED COSTS OF THE FINAL RULE

[In 2011 millions]

Costs (annualized)	Primary estimate ($M)	Minimum estimate ($M)	Maximum estimate ($M)
Discounted @7%	42.8	34.8	50.6
@3%	35.2	28.7	41.7

In the RIA, we acknowledged several potential sources of costs that we were unable to quantify. Because we have no way to determine the extent to which entities currently engage in certain activities for which they now need authorization, or who will need to take on a new burden because of the rule, we cannot predict the magnitude of these costs with any certainty. These potential sources of cost include:

1. Potential lost revenue to covered entities who forgo making certain subsidized health-related communications to individuals rather than obtain those individuals' authorization for such communications;

2. Costs to researchers to obtain authorization to make incentive payments (above the costs to prepare the data) to covered entities to produce data or, alternatively, a loss in revenue for covered entities who agree to accept only the costs to prepare and transmit the data;

3. Potential costs to certain covered entities who purchase software or hardware to allow them to produce an electronic copy of individuals' protected health information; and

4. The burden to some health care providers of ensuring that an individual's request to restrict a disclosure to a health plan is honored where it might not have been before the final rule.

While we are certain the changes in this final rule also represent distinct

benefits to individuals with regard to the privacy and security of their health information, and with regard to their rights to that information, we are unable to quantify the benefits. Other expected qualitative benefits, which are described in detail above, include savings due to provisions simplifying and streamlining requirements and increasing flexibility. Such savings arise from:

1. Eliminating the need for multiple forms for certain research studies by permitting compound authorizations;
2. Obviating the need to find past research participants and obtain new authorizations for new research by allowing individuals to authorize future research uses and disclosures at the time of initial enrollment;
3. Limiting the period of protection for decedent information to permit family members and historians to obtain information about a decedent without needing to find a personal representative of the deceased individual to authorize the disclosure;
4. Permitting disclosures to a decedent's family members or others involved in the care or payment for care prior to the decedent's death; and
5. Permitting covered entities to document a parent's informal agreement to disclose immunization information to a child's school rather than requiring a signed authorization form.

VIII. Collection of Information Requirements

This final rule contains the following information collections (i.e., reporting, recordkeeping, and third-party disclosures) under the Paperwork Reduction Act. Some of those provisions involve changes from the information collections set out in the proposed and interim final rules. These changes are noted below.

A. Reporting

• Notification to the Secretary of breaches of unsecured protected health information (§ 164.408). In the final rule, we revise our estimated number of respondents and responses to reflect our experience administering the interim final rule.

B. Recordkeeping

• Documentation of safeguards and policies and procedures under the Security Rule (§ 164.316). In the proposed rule, we assumed that all business associates were in compliance with the Security Rule's documentation standard because of their contractual obligations to covered entities under the HIPAA Rules. In the final rule, we recognize that a minority of business associates, who have not previously maintained documentation of their policies and procedures and administrative safeguards under the Security Rule, may experience a burden coming into compliance with the documentation standard for the first time because they are now subject to direct liability under the Security Rule.

• Business Associate Agreements (§ 164.504(e)). We assumed in the proposed rule that business associates and their subcontractors were complying with their existing contractual obligations but acknowledged that some contracts would have to be modified to reflect changes in the law. We requested comments on how many entities would be unable able to revise contracts, in the normal course of business, within the phase-in period. We did not receive comments that would allow us to make a specific estimate; nonetheless, in the final rule we assume that a significant minority of business associates will need to revise their business associate agreements with subcontractors (or establish such agreements for the first time if they were not previously in compliance).

C. Third-Party Disclosures

• Breach notification to affected individuals and the media (§§ 164.404 & 164.406). We revise our estimates of the numbers of breaches, covered entities, and individuals affected to reflect our experience in administering the breach notification requirements under the interim final rule.

• Revision and dissemination of notices of privacy practices for protected health information (§ 164.520). Our burden estimates for this provision in the proposed rule were based on the requirement for covered entities to send a separate mailing containing the new notice to each policy holder. As part of an effort to reduce overall burden, the final rule instead permits health plans to send the revised notice of privacy practices in their next annual mailing to policy holders, allowing them to avoid additional distribution burdens. We also revise the estimated number of affected covered entities based on updated information from the Department of Labor and the Small Business Administration.

In addition to the changes summarized above, the information collections described in this final rule have been submitted to the Office of Management and Budget for review and approval.

List of Subjects

45 CFR Part 160

Administrative practice and procedure, Computer technology, Electronic information system, Electronic transactions, Employer benefit plan, Health, Health care, Health facilities, Health insurance, Health records, Hospitals, Investigations, Medicaid, Medical research, Medicare, Penalties, Privacy, Reporting and record keeping requirements, Security.

45 CFR Part 164

Administrative practice and procedure, Computer technology, Electronic information system, Electronic transactions, Employer benefit plan, Health, Health care, Health facilities, Health insurance, Health records, Hospitals, Medicaid, Medical research, Medicare, Privacy, Reporting and record keeping requirements, Security.

For the reasons set forth in the preamble, the Department amends 45 CFR Subtitle A, Subchapter C, parts 160 and 164, as set forth below:

PART 160—GENERAL ADMINISTRATIVE REQUIREMENTS

■ 1. The authority citation for part 160 is revised to read as follows:

Authority: 42 U.S.C. 1302(a); 42 U.S.C. 1320d–1320d–9; sec. 264, Pub. L. 104–191, 110 Stat. 2033–2034 (42 U.S.C. 1320d–2 (note)); 5 U.S.C. 552; secs. 13400–13424, Pub. L. 111–5, 123 Stat. 258–279; and sec. 1104 of Pub. L. 111–148, 124 Stat. 146–154.

■ 2. Revise § 160.101 to read as follows:

§ 160.101 Statutory basis and purpose.

The requirements of this subchapter implement sections 1171–1180 of the Social Security Act (the Act), sections 262 and 264 of Public Law 104–191, section 105 of Public Law 110–233, sections 13400–13424 of Public Law 111–5, and section 1104 of Public Law 111–148.

■ 3. Amend § 160.102 as follows:
■ a. Redesignate paragraph (b) as paragraph (c); and
■ b. Add new paragraph (b) to read as follows:

§ 160.102 Applicability.

* * * * *

(b) Where provided, the standards, requirements, and implementation specifications adopted under this subchapter apply to a business associate.

* * * * *

■ 4. Amend § 160.103 as follows:
■ a. Revise the definitions of ''Business associate'', ''Compliance date'',

''Disclosure'', ''Electronic media'', the introductory text of the definition of ''Health information'', paragraphs (1)(vi) through (xi), and (xv) of the definition of ''Health plan'', paragraph (2) of the definition of ''Protected health information,'' and the definitions of ''Standard'', ''State'', and ''Workforce''; and

■ b. Add, in alphabetical order, new definitions of ''Administrative simplification provision'', ''ALJ'', ''Civil money penalty or penalty'', ''Family member'', ''Genetic information'', ''Genetic services'', ''Genetic test'', ''Manifestation or manifested'', ''Respondent'', ''Subcontractor'', and ''Violation or violate''.

The revisions and additions read as follows:

§ 160.103 Definitions.

* * * * *

Administrative simplification provision means any requirement or prohibition established by:

(1) 42 U.S.C. 1320d–1320d–4, 1320d–7, 1320d–8, and 1320d–9;

(2) Section 264 of Pub. L. 104–191;

(3) Sections 13400–13424 of Public Law 111–5; or

(4) This subchapter.

ALJ means Administrative Law Judge.

* * * * *

Business associate: (1) Except as provided in paragraph (4) of this definition, business associate means, with respect to a covered entity, a person who:

(i) On behalf of such covered entity or of an organized health care arrangement (as defined in this section) in which the covered entity participates, but other than in the capacity of a member of the workforce of such covered entity or arrangement, creates, receives, maintains, or transmits protected health information for a function or activity regulated by this subchapter, including claims processing or administration, data analysis, processing or administration, utilization review, quality assurance, patient safety activities listed at 42 CFR 3.20, billing, benefit management, practice management, and repricing; or

(ii) Provides, other than in the capacity of a member of the workforce of such covered entity, legal, actuarial, accounting, consulting, data aggregation (as defined in § 164.501 of this subchapter), management, administrative, accreditation, or financial services to or for such covered entity, or to or for an organized health care arrangement in which the covered entity participates, where the provision of the service involves the disclosure of protected health information from such covered entity or arrangement, or from another business associate of such covered entity or arrangement, to the person.

(2) A covered entity may be a business associate of another covered entity.

(3) *Business associate* includes:

(i) A Health Information Organization, E-prescribing Gateway, or other person that provides data transmission services with respect to protected health information to a covered entity and that requires access on a routine basis to such protected health information.

(ii) A person that offers a personal health record to one or more individuals on behalf of a covered entity.

(iii) A subcontractor that creates, receives, maintains, or transmits protected health information on behalf of the business associate.

(4) *Business associate* does not include:

(i) A health care provider, with respect to disclosures by a covered entity to the health care provider concerning the treatment of the individual.

(ii) A plan sponsor, with respect to disclosures by a group health plan (or by a health insurance issuer or HMO with respect to a group health plan) to the plan sponsor, to the extent that the requirements of § 164.504(f) of this subchapter apply and are met.

(iii) A government agency, with respect to determining eligibility for, or enrollment in, a government health plan that provides public benefits and is administered by another government agency, or collecting protected health information for such purposes, to the extent such activities are authorized by law.

(iv) A covered entity participating in an organized health care arrangement that performs a function or activity as described by paragraph (1)(i) of this definition for or on behalf of such organized health care arrangement, or that provides a service as described in paragraph (1)(ii) of this definition to or for such organized health care arrangement by virtue of such activities or services.

Civil money penalty or *penalty* means the amount determined under § 160.404 of this part and includes the plural of these terms.

* * * * *

Compliance date means the date by which a covered entity or business associate must comply with a standard, implementation specification, requirement, or modification adopted under this subchapter.

* * * * *

Disclosure means the release, transfer, provision of access to, or divulging in any manner of information outside the entity holding the information.

* * * * *

Electronic media means:

(1) Electronic storage material on which data is or may be recorded electronically, including, for example, devices in computers (hard drives) and any removable/transportable digital memory medium, such as magnetic tape or disk, optical disk, or digital memory card;

(2) Transmission media used to exchange information already in electronic storage media. Transmission media include, for example, the Internet, extranet or intranet, leased lines, dial-up lines, private networks, and the physical movement of removable/transportable electronic storage media. Certain transmissions, including of paper, via facsimile, and of voice, via telephone, are not considered to be transmissions via electronic media if the information being exchanged did not exist in electronic form immediately before the transmission.

* * * * *

Family member means, with respect to an individual:

(1) A dependent (as such term is defined in 45 CFR 144.103), of the individual; or

(2) Any other person who is a first-degree, second-degree, third-degree, or fourth-degree relative of the individual or of a dependent of the individual. Relatives by affinity (such as by marriage or adoption) are treated the same as relatives by consanguinity (that is, relatives who share a common biological ancestor). In determining the degree of the relationship, relatives by less than full consanguinity (such as half-siblings, who share only one parent) are treated the same as relatives by full consanguinity (such as siblings who share both parents).

(i) First-degree relatives include parents, spouses, siblings, and children.

(ii) Second-degree relatives include grandparents, grandchildren, aunts, uncles, nephews, and nieces.

(iii) Third-degree relatives include great-grandparents, great-grandchildren, great aunts, great uncles, and first cousins.

(iv) Fourth-degree relatives include great-great grandparents, great-great grandchildren, and children of first cousins.

Genetic information means:

(1) Subject to paragraphs (2) and (3) of this definition, with respect to an individual, information about:

(i) The individual's genetic tests;

(ii) The genetic tests of family members of the individual;

(iii) The manifestation of a disease or disorder in family members of such individual; or

(iv) Any request for, or receipt of, genetic services, or participation in clinical research which includes genetic services, by the individual or any family member of the individual.

(2) Any reference in this subchapter to genetic information concerning an individual or family member of an individual shall include the genetic information of:

(i) A fetus carried by the individual or family member who is a pregnant woman; and

(ii) Any embryo legally held by an individual or family member utilizing an assisted reproductive technology.

(3) Genetic information excludes information about the sex or age of any individual.

Genetic services means:

(1) A genetic test;

(2) Genetic counseling (including obtaining, interpreting, or assessing genetic information); or

(3) Genetic education.

Genetic test means an analysis of human DNA, RNA, chromosomes, proteins, or metabolites, if the analysis detects genotypes, mutations, or chromosomal changes. Genetic test does not include an analysis of proteins or metabolites that is directly related to a manifested disease, disorder, or pathological condition.

* * * * *

Health information means any information, including genetic information, whether oral or recorded in any form or medium, that: * * *

* * * * *

Health plan means * * *

(1) * * *

(vi) The Voluntary Prescription Drug Benefit Program under Part D of title XVIII of the Act, 42 U.S.C. 1395w–101 through 1395w–152.

(vii) An issuer of a Medicare supplemental policy (as defined in section 1882(g)(1) of the Act, 42 U.S.C. 1395ss(g)(1)).

(viii) An issuer of a long-term care policy, excluding a nursing home fixed indemnity policy.

(ix) An employee welfare benefit plan or any other arrangement that is established or maintained for the purpose of offering or providing health benefits to the employees of two or more employers.

(x) The health care program for uniformed services under title 10 of the United States Code.

(xi) The veterans health care program under 38 U.S.C. chapter 17.

* * * * *

(xv) The Medicare Advantage program under Part C of title XVIII of the Act, 42 U.S.C. 1395w–21 through 1395w–28.

* * * * *

Manifestation or *manifested* means, with respect to a disease, disorder, or pathological condition, that an individual has been or could reasonably be diagnosed with the disease, disorder, or pathological condition by a health care professional with appropriate training and expertise in the field of medicine involved. For purposes of this subchapter, a disease, disorder, or pathological condition is not manifested if the diagnosis is based principally on genetic information.

* * * * *

Protected health information * * *

(2) Protected health information excludes individually identifiable health information:

(i) In education records covered by the Family Educational Rights and Privacy Act, as amended, 20 U.S.C. 1232g;

(ii) In records described at 20 U.S.C. 1232g(a)(4)(B)(iv);

(iii) In employment records held by a covered entity in its role as employer; and

(iv) Regarding a person who has been deceased for more than 50 years.

* * * * *

Respondent means a covered entity or business associate upon which the Secretary has imposed, or proposes to impose, a civil money penalty.

* * * * *

Standard means a rule, condition, or requirement:

(1) Describing the following information for products, systems, services, or practices:

(i) Classification of components;

(ii) Specification of materials, performance, or operations; or

(iii) Delineation of procedures; or

(2) With respect to the privacy of protected health information.

* * * * *

State refers to one of the following:

(1) For a health plan established or regulated by Federal law, State has the meaning set forth in the applicable section of the United States Code for such health plan.

(2) For all other purposes, *State* means any of the several States, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Commonwealth of the Northern Mariana Islands.

Subcontractor means a person to whom a business associate delegates a function, activity, or service, other than in the capacity of a member of the workforce of such business associate.

* * * * *

Violation or *violate* means, as the context may require, failure to comply with an administrative simplification provision.

Workforce means employees, volunteers, trainees, and other persons whose conduct, in the performance of work for a covered entity or business associate, is under the direct control of such covered entity or business associate, whether or not they are paid by the covered entity or business associate.

■ 5. Add § 160.105 to subpart A to read as follows:

§ 160.105 Compliance dates for implementation of new or modified standards and implementation specifications.

Except as otherwise provided, with respect to rules that adopt new standards and implementation specifications or modifications to standards and implementation specifications in this subchapter in accordance with § 160.104 that become effective after January 25, 2013, covered entities and business associates must comply with the applicable new standards and implementation specifications, or modifications to standards and implementation specifications, no later than 180 days from the effective date of any such standards or implementation specifications.

■ 6. Revise § 160.201 to read as follows:

§ 160.201 Statutory basis.

The provisions of this subpart implement section 1178 of the Act, section 262 of Public Law 104–191, section 264(c) of Public Law 104–191, and section 13421(a) of Public Law 111–5.

■ 7. In § 160.202, revise the definition of ''Contrary'' and paragraph (1)(i) of the definition of ''More stringent'' to read as follows:

§ 160.202 Definitions.

* * * * *

Contrary, when used to compare a provision of State law to a standard, requirement, or implementation specification adopted under this subchapter, means:

(1) A covered entity or business associate would find it impossible to comply with both the State and Federal requirements; or

(2) The provision of State law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of part C of title XI of the Act,

section 264 of Public Law 104–191, or sections 13400–13424 of Public Law 111–5, as applicable.

More stringent * * *

(1) * * *

(i) Required by the Secretary in connection with determining whether a covered entity or business associate is in compliance with this subchapter; or

* * * * *

■ 8. Revise § 160.300 to read as follows:

§ 160.300 Applicability.

This subpart applies to actions by the Secretary, covered entities, business associates, and others with respect to ascertaining the compliance by covered entities and business associates with, and the enforcement of, the applicable provisions of this part 160 and parts 162 and 164 of this subchapter.

§ 160.302 [Removed and Reserved]

■ 9. Remove and reserve § 160.302.

■ 10. Revise § 160.304 to read as follows:

§ 160.304 Principles for achieving compliance.

(a) *Cooperation.* The Secretary will, to the extent practicable and consistent with the provisions of this subpart, seek the cooperation of covered entities and business associates in obtaining compliance with the applicable administrative simplification provisions.

(b) *Assistance.* The Secretary may provide technical assistance to covered entities and business associates to help them comply voluntarily with the applicable administrative simplification provisions.

■ 11. In § 160.306, revise paragraphs (a) and (c) to read as follows:

§ 160.306 Complaints to the Secretary.

(a) *Right to file a complaint.* A person who believes a covered entity or business associate is not complying with the administrative simplification provisions may file a complaint with the Secretary.

* * * * *

(c) *Investigation.* (1) The Secretary will investigate any complaint filed under this section when a preliminary review of the facts indicates a possible violation due to willful neglect.

(2) The Secretary may investigate any other complaint filed under this section.

(3) An investigation under this section may include a review of the pertinent policies, procedures, or practices of the covered entity or business associate and of the circumstances regarding any alleged violation.

(4) At the time of the initial written communication with the covered entity or business associate about the complaint, the Secretary will describe the acts and/or omissions that are the basis of the complaint.

■ 12. Revise § 160.308 to read as follows:

§ 160.308 Compliance reviews.

(a) The Secretary will conduct a compliance review to determine whether a covered entity or business associate is complying with the applicable administrative simplification provisions when a preliminary review of the facts indicates a possible violation due to willful neglect.

(b) The Secretary may conduct a compliance review to determine whether a covered entity or business associate is complying with the applicable administrative simplification provisions in any other circumstance.

■ 13. Revise § 160.310 to read as follows:

§ 160.310 Responsibilities of covered entities and business associates.

(a) *Provide records and compliance reports.* A covered entity or business associate must keep such records and submit such compliance reports, in such time and manner and containing such information, as the Secretary may determine to be necessary to enable the Secretary to ascertain whether the covered entity or business associate has complied or is complying with the applicable administrative simplification provisions.

(b) *Cooperate with complaint investigations and compliance reviews.* A covered entity or business associate must cooperate with the Secretary, if the Secretary undertakes an investigation or compliance review of the policies, procedures, or practices of the covered entity or business associate to determine whether it is complying with the applicable administrative simplification provisions.

(c) *Permit access to information.* (1) A covered entity or business associate must permit access by the Secretary during normal business hours to its facilities, books, records, accounts, and other sources of information, including protected health information, that are pertinent to ascertaining compliance with the applicable administrative simplification provisions. If the Secretary determines that exigent circumstances exist, such as when documents may be hidden or destroyed, a covered entity or business associate must permit access by the Secretary at any time and without notice.

(2) If any information required of a covered entity or business associate under this section is in the exclusive possession of any other agency, institution, or person and the other agency, institution, or person fails or refuses to furnish the information, the covered entity or business associate must so certify and set forth what efforts it has made to obtain the information.

(3) Protected health information obtained by the Secretary in connection with an investigation or compliance review under this subpart will not be disclosed by the Secretary, except if necessary for ascertaining or enforcing compliance with the applicable administrative simplification provisions, if otherwise required by law, or if permitted under 5 U.S.C. 552a(b)(7).

■ 14. Revise § 160.312 to read as follows:

§ 160.312 Secretarial action regarding complaints and compliance reviews.

(a) *Resolution when noncompliance is indicated.* (1) If an investigation of a complaint pursuant to § 160.306 or a compliance review pursuant to § 160.308 indicates noncompliance, the Secretary may attempt to reach a resolution of the matter satisfactory to the Secretary by informal means. Informal means may include demonstrated compliance or a completed corrective action plan or other agreement.

(2) If the matter is resolved by informal means, the Secretary will so inform the covered entity or business associate and, if the matter arose from a complaint, the complainant, in writing.

(3) If the matter is not resolved by informal means, the Secretary will—

(i) So inform the covered entity or business associate and provide the covered entity or business associate an opportunity to submit written evidence of any mitigating factors or affirmative defenses for consideration under §§ 160.408 and 160.410 of this part. The covered entity or business associate must submit any such evidence to the Secretary within 30 days (computed in the same manner as prescribed under § 160.526 of this part) of receipt of such notification; and

(ii) If, following action pursuant to paragraph (a)(3)(i) of this section, the Secretary finds that a civil money penalty should be imposed, inform the covered entity or business associate of such finding in a notice of proposed determination in accordance with § 160.420 of this part.

(b) *Resolution when no violation is found.* If, after an investigation pursuant to § 160.306 or a compliance review pursuant to § 160.308, the Secretary determines that further action is not

warranted, the Secretary will so inform the covered entity or business associate and, if the matter arose from a complaint, the complainant, in writing.

■ 15. In § 160.316, revise the introductory text to read as follows:

§ 160.316 Refraining from intimidation or retaliation.

A covered entity or business associate may not threaten, intimidate, coerce, harass, discriminate against, or take any other retaliatory action against any individual or other person for—

* * * * *

■ 16. In § 160.401, revise the definition of ''Reasonable cause'' to read as follows:

§ 160.401 Definitions.

* * * * *

Reasonable cause means an act or omission in which a covered entity or business associate knew, or by exercising reasonable diligence would have known, that the act or omission violated an administrative simplification provision, but in which the covered entity or business associate did not act with willful neglect.

* * * * *

■ 17. Revise § 160.402 to read as follows:

§ 160.402 Basis for a civil money penalty.

(a) *General rule.* Subject to § 160.410, the Secretary will impose a civil money penalty upon a covered entity or business associate if the Secretary determines that the covered entity or business associate has violated an administrative simplification provision.

(b) *Violation by more than one covered entity or business associate.* (1) Except as provided in paragraph (b)(2) of this section, if the Secretary determines that more than one covered entity or business associate was responsible for a violation, the Secretary will impose a civil money penalty against each such covered entity or business associate.

(2) A covered entity that is a member of an affiliated covered entity, in accordance with § 164.105(b) of this subchapter, is jointly and severally liable for a civil money penalty for a violation of part 164 of this subchapter based on an act or omission of the affiliated covered entity, unless it is established that another member of the affiliated covered entity was responsible for the violation.

(c) *Violation attributed to a covered entity or business associate.* (1) A covered entity is liable, in accordance with the Federal common law of agency, for a civil money penalty for a violation based on the act or omission of any agent of the covered entity, including a workforce member or business associate, acting within the scope of the agency.

(2) A business associate is liable, in accordance with the Federal common law of agency, for a civil money penalty for a violation based on the act or omission of any agent of the business associate, including a workforce member or subcontractor, acting within the scope of the agency.

■ 18. In § 160.404, revise the introductory text of paragraphs (b)(2)(i), (b)(2)(iii), and (b)(2)(iv) to read as follows:

§ 160.404 Amount of a civil money penalty.

* * * * *

(b) * * *

(2) * * *

(i) For a violation in which it is established that the covered entity or business associate did not know and, by exercising reasonable diligence, would not have known that the covered entity or business associate violated such provision,

* * * * *

(iii) For a violation in which it is established that the violation was due to willful neglect and was corrected during the 30-day period beginning on the first date the covered entity or business associate liable for the penalty knew, or, by exercising reasonable diligence, would have known that the violation occurred,

* * * * *

(iv) For a violation in which it is established that the violation was due to willful neglect and was not corrected during the 30-day period beginning on the first date the covered entity or business associate liable for the penalty knew, or, by exercising reasonable diligence, would have known that the violation occurred,

* * * * *

■ 19. Revise § 160.406 to read as follows:

§ 160.406 Violations of an identical requirement or prohibition.

The Secretary will determine the number of violations of an administrative simplification provision based on the nature of the covered entity's or business associate's obligation to act or not act under the provision that is violated, such as its obligation to act in a certain manner, or within a certain time, or to act or not act with respect to certain persons. In the case of continuing violation of a provision, a separate violation occurs each day the covered entity or business associate is in violation of the provision.

■ 20. Revise § 160.408 to read as follows:

§ 160.408 Factors considered in determining the amount of a civil money penalty.

In determining the amount of any civil money penalty, the Secretary will consider the following factors, which may be mitigating or aggravating as appropriate:

(a) The nature and extent of the violation, consideration of which may include but is not limited to:

(1) The number of individuals affected; and

(2) The time period during which the violation occurred;

(b) The nature and extent of the harm resulting from the violation, consideration of which may include but is not limited to:

(1) Whether the violation caused physical harm;

(2) Whether the violation resulted in financial harm;

(3) Whether the violation resulted in harm to an individual's reputation; and

(4) Whether the violation hindered an individual's ability to obtain health care;

(c) The history of prior compliance with the administrative simplification provisions, including violations, by the covered entity or business associate, consideration of which may include but is not limited to:

(1) Whether the current violation is the same or similar to previous indications of noncompliance;

(2) Whether and to what extent the covered entity or business associate has attempted to correct previous indications of noncompliance;

(3) How the covered entity or business associate has responded to technical assistance from the Secretary provided in the context of a compliance effort; and

(4) How the covered entity or business associate has responded to prior complaints;

(d) The financial condition of the covered entity or business associate, consideration of which may include but is not limited to:

(1) Whether the covered entity or business associate had financial difficulties that affected its ability to comply;

(2) Whether the imposition of a civil money penalty would jeopardize the ability of the covered entity or business associate to continue to provide, or to pay for, health care; and

(3) The size of the covered entity or business associate; and

(e) Such other matters as justice may require.

■ 21. Revise § 160.410 to read as follows:

§ 160.410 Affirmative defenses.

(a) The Secretary may not:

(1) Prior to February 18, 2011, impose a civil money penalty on a covered entity or business associate for an act that violates an administrative simplification provision if the covered entity or business associate establishes that the violation is punishable under 42 U.S.C. 1320d–6.

(2) On or after February 18, 2011, impose a civil money penalty on a covered entity or business associate for an act that violates an administrative simplification provision if the covered entity or business associate establishes that a penalty has been imposed under 42 U.S.C. 1320d–6 with respect to such act.

(b) For violations occurring prior to February 18, 2009, the Secretary may not impose a civil money penalty on a covered entity for a violation if the covered entity establishes that an affirmative defense exists with respect to the violation, including the following:

(1) The covered entity establishes, to the satisfaction of the Secretary, that it did not have knowledge of the violation, determined in accordance with the Federal common law of agency, and by exercising reasonable diligence, would not have known that the violation occurred; or

(2) The violation is—

(i) Due to circumstances that would make it unreasonable for the covered entity, despite the exercise of ordinary business care and prudence, to comply with the administrative simplification provision violated and is not due to willful neglect; and

(ii) Corrected during either:

(A) The 30-day period beginning on the first date the covered entity liable for the penalty knew, or by exercising reasonable diligence would have known, that the violation occurred; or

(B) Such additional period as the Secretary determines to be appropriate based on the nature and extent of the failure to comply.

(c) For violations occurring on or after February 18, 2009, the Secretary may not impose a civil money penalty on a covered entity or business associate for a violation if the covered entity or business associate establishes to the satisfaction of the Secretary that the violation is—

(1) Not due to willful neglect; and

(2) Corrected during either:

(i) The 30-day period beginning on the first date the covered entity or business associate liable for the penalty knew, or, by exercising reasonable diligence, would have known that the violation occurred; or

(ii) Such additional period as the Secretary determines to be appropriate based on the nature and extent of the failure to comply.

■ 22. Revise § 160.412 to read as follows:

§ 160.412 Waiver.

For violations described in § 160.410(b)(2) or (c) that are not corrected within the period specified under such paragraphs, the Secretary may waive the civil money penalty, in whole or in part, to the extent that the payment of the penalty would be excessive relative to the violation.

■ 23. Revise § 160.418 to read as follows:

§ 160.418 Penalty not exclusive.

Except as otherwise provided by 42 U.S.C. 1320d–5(b)(1) and 42 U.S.C. 299b–22(f)(3), a penalty imposed under this part is in addition to any other penalty prescribed by law.

■ 24. Amend § 160.534 as follows:

■ a. Revise paragraph (b)(1)(iii);

■ b. Add paragraph (b)(1)(iv); and

■ c. Revise paragraph (b)(2).

The revisions read as follows:

§ 160.534 The hearing.

* * * * *

(b)(1) * * *

(iii) Claim that a proposed penalty should be reduced or waived pursuant to § 160.412 of this part; and

(iv) Compliance with subpart D of part 164, as provided under § 164.414(b).

(2) The Secretary has the burden of going forward and the burden of persuasion with respect to all other issues, including issues of liability other than with respect to subpart D of part 164, and the existence of any factors considered aggravating factors in determining the amount of the proposed penalty.

* * * * *

PART 164—SECURITY AND PRIVACY

■ 25. The authority citation for part 164 is revised to read as follows:

Authority: 42 U.S.C. 1302(a); 42 U.S.C. 1320d–1320d–9; sec. 264, Pub. L. 104–191, 110 Stat. 2033–2034 (42 U.S.C. 1320d–2(note)); and secs. 13400–13424, Pub. L. 111–5, 123 Stat. 258–279.

■ 26. Revise § 164.102 to read as follows:

§ 164.102 Statutory basis.

The provisions of this part are adopted pursuant to the Secretary's authority to prescribe standards, requirements, and implementation specifications under part C of title XI of the Act, section 264 of Public Law 104–191, and sections 13400–13424 of Public Law 111–5.

■ 27. In § 164.104, revise paragraph (b) to read as follows:

§ 164.104 Applicability.

* * * * *

(b) Where provided, the standards, requirements, and implementation specifications adopted under this part apply to a business associate.

■ 28. Amend § 164.105 as follows:

■ a. Revise the introductory text of paragraph (a)(1), the introductory text of paragraph (a)(2)(i), paragraph (a)(2)(ii), the introductory text of paragraph (a)(2)(iii), and paragraphs (a)(2)(iii)(A) and (B);

■ b. Redesignate paragraph (a)(2)(iii)(C) as paragraph (a)(2)(iii)(D) and add new paragraph (a)(2)(iii)(C);

■ c. Revise newly redesignated paragraph (a)(2)(iii)(D); and

■ d. Revise paragraph (b).

The revisions read as follows:

§ 164.105 Organizational requirements.

(a)(1) *Standard: Health care component.* If a covered entity is a hybrid entity, the requirements of this part, other than the requirements of this section, § 164.314, and § 164.504, apply only to the health care component(s) of the entity, as specified in this section.

(2) * * *

(i) *Application of other provisions.* In applying a provision of this part, other than the requirements of this section, § 164.314, and § 164.504, to a hybrid entity:

* * * * *

(ii) *Safeguard requirements.* The covered entity that is a hybrid entity must ensure that a health care component of the entity complies with the applicable requirements of this part. In particular, and without limiting this requirement, such covered entity must ensure that:

(A) Its health care component does not disclose protected health information to another component of the covered entity in circumstances in which subpart E of this part would prohibit such disclosure if the health care component and the other component were separate and distinct legal entities;

(B) Its health care component protects electronic protected health information with respect to another component of the covered entity to the same extent that it would be required under subpart C of this part to protect such information if the health care

component and the other component were separate and distinct legal entities;

(C) If a person performs duties for both the health care component in the capacity of a member of the workforce of such component and for another component of the entity in the same capacity with respect to that component, such workforce member must not use or disclose protected health information created or received in the course of or incident to the member's work for the health care component in a way prohibited by subpart E of this part.

(iii) *Responsibilities of the covered entity.* A covered entity that is a hybrid entity has the following responsibilities:

(A) For purposes of subpart C of part 160 of this subchapter, pertaining to compliance and enforcement, the covered entity has the responsibility of complying with this part.

(B) The covered entity is responsible for complying with § 164.316(a) and § 164.530(i), pertaining to the implementation of policies and procedures to ensure compliance with applicable requirements of this part, including the safeguard requirements in paragraph (a)(2)(ii) of this section.

(C) The covered entity is responsible for complying with § 164.314 and § 164.504 regarding business associate arrangements and other organizational requirements.

(D) The covered entity is responsible for designating the components that are part of one or more health care components of the covered entity and documenting the designation in accordance with paragraph (c) of this section, provided that, if the covered entity designates one or more health care components, it must include any component that would meet the definition of a covered entity or business associate if it were a separate legal entity. Health care component(s) also may include a component only to the extent that it performs covered functions.

(b)(1) *Standard: Affiliated covered entities.* Legally separate covered entities that are affiliated may designate themselves as a single covered entity for purposes of this part.

(2) *Implementation specifications.*

(i) *Requirements for designation of an affiliated covered entity.*

(A) Legally separate covered entities may designate themselves (including any health care component of such covered entity) as a single affiliated covered entity, for purposes of this part, if all of the covered entities designated are under common ownership or control.

(B) The designation of an affiliated covered entity must be documented and the documentation maintained as required by paragraph (c) of this section.

(ii) *Safeguard requirements.* An affiliated covered entity must ensure that it complies with the applicable requirements of this part, including, if the affiliated covered entity combines the functions of a health plan, health care provider, or health care clearinghouse, § 164.308(a)(4)(ii)(A) and § 164.504(g), as applicable.

* * * * *

■ 29. Revise § 164.106 to read as follows:

§ 164.106 Relationship to other parts.

In complying with the requirements of this part, covered entities and, where provided, business associates, are required to comply with the applicable provisions of parts 160 and 162 of this subchapter.

■ 30. The authority citation for subpart C of part 164 is revised to read as follows:

Authority: 42 U.S.C. 1320d–2 and 1320d–4; sec. 13401, Pub. L. 111–5, 123 Stat. 260.

■ 31. Revise § 164.302 to read as follows:

§ 164.302 Applicability.

A covered entity or business associate must comply with the applicable standards, implementation specifications, and requirements of this subpart with respect to electronic protected health information of a covered entity.

■ 32. In § 164.304, revise the definitions of ''Administrative safeguards'' and ''Physical safeguards'' to read as follows:

§ 164.304 Definitions.

* * * * *

Administrative safeguards are administrative actions, and policies and procedures, to manage the selection, development, implementation, and maintenance of security measures to protect electronic protected health information and to manage the conduct of the covered entity's or business associate's workforce in relation to the protection of that information.

* * * * *

Physical safeguards are physical measures, policies, and procedures to protect a covered entity's or business associate's electronic information systems and related buildings and equipment, from natural and environmental hazards, and unauthorized intrusion.

* * * * *

■ 33. Amend § 164.306 as follows:

■ a. Revise the introductory text of paragraph (a) and paragraph (a)(1);

■ b. Revise paragraph (b)(1), the introductory text of paragraph (b)(2), and paragraphs (b)(2)(i) and (b)(2)(ii);

■ c. Revise paragraph (c);

■ d. Revise paragraph (d)(2), the introductory text of paragraph (d)(3), paragraph (d)(3)(i), and the introductory text of paragraph (d)(3)(ii); and

■ e. Revise paragraph (e).

The revisions read as follows:

§ 164.306 Security standards: General rules.

(a) *General requirements.* Covered entities and business associates must do the following:

(1) Ensure the confidentiality, integrity, and availability of all electronic protected health information the covered entity or business associate creates, receives, maintains, or transmits.

* * * * *

(b) * * *

(1) Covered entities and business associates may use any security measures that allow the covered entity or business associate to reasonably and appropriately implement the standards and implementation specifications as specified in this subpart.

(2) In deciding which security measures to use, a covered entity or business associate must take into account the following factors:

(i) The size, complexity, and capabilities of the covered entity or business associate.

(ii) The covered entity's or the business associate's technical infrastructure, hardware, and software security capabilities.

* * * * *

(c) *Standards.* A covered entity or business associate must comply with the applicable standards as provided in this section and in § 164.308, § 164.310, § 164.312, § 164.314 and § 164.316 with respect to all electronic protected health information.

(d) * * *

(2) When a standard adopted in § 164.308, § 164.310, § 164.312, § 164.314, or § 164.316 includes required implementation specifications, a covered entity or business associate must implement the implementation specifications.

(3) When a standard adopted in § 164.308, § 164.310, § 164.312, § 164.314, or § 164.316 includes addressable implementation specifications, a covered entity or business associate must—

(i) Assess whether each implementation specification is a

reasonable and appropriate safeguard in its environment, when analyzed with reference to the likely contribution to protecting electronic protected health information; and

(ii) As applicable to the covered entity or business associate—

* * * * *

(e) *Maintenance.* A covered entity or business associate must review and modify the security measures implemented under this subpart as needed to continue provision of reasonable and appropriate protection of electronic protected health information, and update documentation of such security measures in accordance with § 164.316(b)(2)(iii).

■ 34. Amend § 164.308 as follows:

■ a. Revise the introductory text of paragraph (a), paragraph (a)(1)(ii)(A), paragraph (a)(1)(ii)(C), paragraph (a)(2), paragraph (a)(3)(ii)(C), paragraph (a)(4)(ii)(C), paragraph (a)(6)(ii), and paragraph (a)(8); and

■ b. Revise paragraph (b).

The revisions read as follows:

§ 164.308 Administrative safeguards.

(a) A covered entity or business associate must, in accordance with § 164.306:

(1) * * *

(ii) * * *

(A) *Risk analysis (Required).* Conduct an accurate and thorough assessment of the potential risks and vulnerabilities to the confidentiality, integrity, and availability of electronic protected health information held by the covered entity or business associate.

* * * * *

(C) *Sanction policy (Required).* Apply appropriate sanctions against workforce members who fail to comply with the security policies and procedures of the covered entity or business associate.

* * * * *

(2) *Standard: Assigned security responsibility.* Identify the security official who is responsible for the development and implementation of the policies and procedures required by this subpart for the covered entity or business associate.

(3) * * *

(ii) * * *

(C) *Termination procedures (Addressable).* Implement procedures for terminating access to electronic protected health information when the employment of, or other arrangement with, a workforce member ends or as required by determinations made as specified in paragraph (a)(3)(ii)(B) of this section.

(4) * * *

(ii) * * *

(C) *Access establishment and modification (Addressable).* Implement policies and procedures that, based upon the covered entity's or the business associate's access authorization policies, establish, document, review, and modify a user's right of access to a workstation, transaction, program, or process.

* * * * *

(6) * * *

(ii) *Implementation specification: Response and reporting (Required).* Identify and respond to suspected or known security incidents; mitigate, to the extent practicable, harmful effects of security incidents that are known to the covered entity or business associate; and document security incidents and their outcomes.

* * * * *

(8) *Standard: Evaluation.* Perform a periodic technical and nontechnical evaluation, based initially upon the standards implemented under this rule and, subsequently, in response to environmental or operational changes affecting the security of electronic protected health information, that establishes the extent to which a covered entity's or business associate's security policies and procedures meet the requirements of this subpart.

(b)(1) *Business associate contracts and other arrangements.* A covered entity may permit a business associate to create, receive, maintain, or transmit electronic protected health information on the covered entity's behalf only if the covered entity obtains satisfactory assurances, in accordance with § 164.314(a), that the business associate will appropriately safeguard the information. A covered entity is not required to obtain such satisfactory assurances from a business associate that is a subcontractor.

(2) A business associate may permit a business associate that is a subcontractor to create, receive, maintain, or transmit electronic protected health information on its behalf only if the business associate obtains satisfactory assurances, in accordance with § 164.314(a), that the subcontractor will appropriately safeguard the information.

(3) *Implementation specifications: Written contract or other arrangement (Required).* Document the satisfactory assurances required by paragraph (b)(1) or (b)(2) of this section through a written contract or other arrangement with the business associate that meets the applicable requirements of § 164.314(a).

■ 35. Revise the introductory text of § 164.310 to read as follows:

§ 164.310 Physical safeguards.

A covered entity or business associate must, in accordance with § 164.306:

* * * * *

■ 36. Revise the introductory text of § 164.312 to read as follows:

§ 164.312 Technical safeguards.

A covered entity or business associate must, in accordance with § 164.306:

* * * * *

■ 37. Amend § 164.314 by revising paragraphs (a) and (b)(2)(iii) to read as follows:

§ 164.314 Organizational requirements.

(a)(1) *Standard: Business associate contracts or other arrangements.* The contract or other arrangement required by § 164.308(b)(4) must meet the requirements of paragraph (a)(2)(i), (a)(2)(ii), or (a)(2)(iii) of this section, as applicable.

(2) *Implementation specifications (Required).*

(i) *Business associate contracts.* The contract must provide that the business associate will—

(A) Comply with the applicable requirements of this subpart;

(B) In accordance with § 164.308(b)(2), ensure that any subcontractors that create, receive, maintain, or transmit electronic protected health information on behalf of the business associate agree to comply with the applicable requirements of this subpart by entering into a contract or other arrangement that complies with this section; and

(C) Report to the covered entity any security incident of which it becomes aware, including breaches of unsecured protected health information as required by § 164.410.

(ii) *Other arrangements.* The covered entity is in compliance with paragraph (a)(1) of this section if it has another arrangement in place that meets the requirements of § 164.504(e)(3).

(iii) *Business associate contracts with subcontractors.* The requirements of paragraphs (a)(2)(i) and (a)(2)(ii) of this section apply to the contract or other arrangement between a business associate and a subcontractor required by § 164.308(b)(4) in the same manner as such requirements apply to contracts or other arrangements between a covered entity and business associate.

(b) * * *

(2) * * *

(iii) Ensure that any agent to whom it provides this information agrees to implement reasonable and appropriate security measures to protect the information; and

* * * * *

■ 38. Revise the introductory text of § 164.316 and the third sentence of paragraph (a) to read as follows:

§ 164.316 Policies and procedures and documentation requirements.

A covered entity or business associate must, in accordance with § 164.306:

(a) * * * A covered entity or business associate may change its policies and procedures at any time, provided that the changes are documented and are implemented in accordance with this subpart.

* * * * *

■ 39. Revise § 164.402 to read as follows:

§ 164.402 Definitions.

As used in this subpart, the following terms have the following meanings:

Breach means the acquisition, access, use, or disclosure of protected health information in a manner not permitted under subpart E of this part which compromises the security or privacy of the protected health information.

(1) Breach excludes:

(i) Any unintentional acquisition, access, or use of protected health information by a workforce member or person acting under the authority of a covered entity or a business associate, if such acquisition, access, or use was made in good faith and within the scope of authority and does not result in further use or disclosure in a manner not permitted under subpart E of this part.

(ii) Any inadvertent disclosure by a person who is authorized to access protected health information at a covered entity or business associate to another person authorized to access protected health information at the same covered entity or business associate, or organized health care arrangement in which the covered entity participates, and the information received as a result of such disclosure is not further used or disclosed in a manner not permitted under subpart E of this part.

(iii) A disclosure of protected health information where a covered entity or business associate has a good faith belief that an unauthorized person to whom the disclosure was made would not reasonably have been able to retain such information.

(2) Except as provided in paragraph (1) of this definition, an acquisition, access, use, or disclosure of protected health information in a manner not permitted under subpart E is presumed to be a breach unless the covered entity or business associate, as applicable, demonstrates that there is a low probability that the protected health information has been compromised based on a risk assessment of at least the following factors:

(i) The nature and extent of the protected health information involved, including the types of identifiers and the likelihood of re-identification;

(ii) The unauthorized person who used the protected health information or to whom the disclosure was made;

(iii) Whether the protected health information was actually acquired or viewed; and

(iv) The extent to which the risk to the protected health information has been mitigated.

Unsecured protected health information means protected health information that is not rendered unusable, unreadable, or indecipherable to unauthorized persons through the use of a technology or methodology specified by the Secretary in the guidance issued under section 13402(h)(2) of Public Law 111–5.

■ 40. In § 164.406, revise paragraph (a) to read as follows:

§ 164.406 Notification to the media.

(a) *Standard.* For a breach of unsecured protected health information involving more than 500 residents of a State or jurisdiction, a covered entity shall, following the discovery of the breach as provided in § 164.404(a)(2), notify prominent media outlets serving the State or jurisdiction.

* * * * *

■ 41. In § 164.408, revise paragraph (c) to read as follows:

§ 164.408 Notification to the Secretary.

* * * * *

(c) *Implementation specifications: Breaches involving less than 500 individuals.* For breaches of unsecured protected health information involving less than 500 individuals, a covered entity shall maintain a log or other documentation of such breaches and, not later than 60 days after the end of each calendar year, provide the notification required by paragraph (a) of this section for breaches discovered during the preceding calendar year, in the manner specified on the HHS web site.

■ 42. In § 164.410, revise paragraph (a) to read as follows:

§ 164.410 Notification by a business associate.

(a) *Standard*—(1) *General rule.* A business associate shall, following the discovery of a breach of unsecured protected health information, notify the covered entity of such breach.

(2) *Breaches treated as discovered.* For purposes of paragraph (a)(1) of this section, a breach shall be treated as discovered by a business associate as of the first day on which such breach is known to the business associate or, by exercising reasonable diligence, would have been known to the business associate. A business associate shall be deemed to have knowledge of a breach if the breach is known, or by exercising reasonable diligence would have been known, to any person, other than the person committing the breach, who is an employee, officer, or other agent of the business associate (determined in accordance with the Federal common law of agency).

* * * * *

■ 43. The authority citation for subpart E of part 164 is revised to read as follows:

Authority: 42 U.S.C. 1320d–2, 1320d–4, and 1320d–9; sec. 264 of Pub. L. 104–191, 110 Stat. 2033–2034 (42 U.S.C. 1320d–2 (note)); and secs. 13400–13424, Pub. L. 111–5, 123 Stat. 258–279.

■ 44. In § 164.500, redesignate paragraph (c) as paragraph (d) and add new paragraph (c) to read as follows:

§ 164.500 Applicability.

* * * * *

(c) Where provided, the standards, requirements, and implementation specifications adopted under this subpart apply to a business associate with respect to the protected health information of a covered entity.

* * * * *

■ 45. Amend § 164.501 as follows:

■ a. Revise paragraphs (1) and (3) of the definition of ''Health care operations'';

■ b. Revise the definition of ''Marketing''; and

■ c. Revise paragraph (1)(i) of the definition of ''Payment''.

The revisions read as follows:

§ 164.501 Definitions.

* * * * *

Health care operations means * * *

(1) Conducting quality assessment and improvement activities, including outcomes evaluation and development of clinical guidelines, provided that the obtaining of generalizable knowledge is not the primary purpose of any studies resulting from such activities; patient safety activities (as defined in 42 CFR 3.20); population-based activities relating to improving health or reducing health care costs, protocol development, case management and care coordination, contacting of health care providers and patients with information about treatment alternatives; and related functions that do not include treatment;

* * * * *

(3) Except as prohibited under § 164.502(a)(5)(i), underwriting,

enrollment, premium rating, and other activities related to the creation, renewal, or replacement of a contract of health insurance or health benefits, and ceding, securing, or placing a contract for reinsurance of risk relating to claims for health care (including stop-loss insurance and excess of loss insurance), provided that the requirements of § 164.514(g) are met, if applicable;

* * * * *

Marketing: (1) Except as provided in paragraph (2) of this definition, marketing means to make a communication about a product or service that encourages recipients of the communication to purchase or use the product or service.

(2) Marketing does not include a communication made:

(i) To provide refill reminders or otherwise communicate about a drug or biologic that is currently being prescribed for the individual, only if any financial remuneration received by the covered entity in exchange for making the communication is reasonably related to the covered entity's cost of making the communication.

(ii) For the following treatment and health care operations purposes, except where the covered entity receives financial remuneration in exchange for making the communication:

(A) For treatment of an individual by a health care provider, including case management or care coordination for the individual, or to direct or recommend alternative treatments, therapies, health care providers, or settings of care to the individual;

(B) To describe a health-related product or service (or payment for such product or service) that is provided by, or included in a plan of benefits of, the covered entity making the communication, including communications about: the entities participating in a health care provider network or health plan network; replacement of, or enhancements to, a health plan; and health-related products or services available only to a health plan enrollee that add value to, but are not part of, a plan of benefits; or

(C) For case management or care coordination, contacting of individuals with information about treatment alternatives, and related functions to the extent these activities do not fall within the definition of treatment.

(3) *Financial remuneration* means direct or indirect payment from or on behalf of a third party whose product or service is being described. Direct or indirect payment does not include any payment for treatment of an individual.

Payment means:

(1) * * *

(i) Except as prohibited under § 164.502(a)(5)(i), a health plan to obtain premiums or to determine or fulfill its responsibility for coverage and provision of benefits under the health plan; or

* * * * *

■ 46. In § 164.502, revise paragraphs (a), (b)(1), (e), and (f) to read as follows:

§ 164.502 Uses and disclosures of protected health information: General rules.

(a) *Standard.* A covered entity or business associate may not use or disclose protected health information, except as permitted or required by this subpart or by subpart C of part 160 of this subchapter.

(1) *Covered entities: Permitted uses and disclosures.* A covered entity is permitted to use or disclose protected health information as follows:

(i) To the individual;

(ii) For treatment, payment, or health care operations, as permitted by and in compliance with § 164.506;

(iii) Incident to a use or disclosure otherwise permitted or required by this subpart, provided that the covered entity has complied with the applicable requirements of §§ 164.502(b), 164.514(d), and 164.530(c) with respect to such otherwise permitted or required use or disclosure;

(iv) Except for uses and disclosures prohibited under § 164.502(a)(5)(i), pursuant to and in compliance with a valid authorization under § 164.508;

(v) Pursuant to an agreement under, or as otherwise permitted by, § 164.510; and

(vi) As permitted by and in compliance with this section, § 164.512, § 164.514(e), (f), or (g).

(2) *Covered entities: Required disclosures.* A covered entity is required to disclose protected health information:

(i) To an individual, when requested under, and required by § 164.524 or § 164.528; and

(ii) When required by the Secretary under subpart C of part 160 of this subchapter to investigate or determine the covered entity's compliance with this subchapter.

(3) *Business associates: Permitted uses and disclosures.* A business associate may use or disclose protected health information only as permitted or required by its business associate contract or other arrangement pursuant to § 164.504(e) or as required by law. The business associate may not use or disclose protected health information in a manner that would violate the requirements of this subpart, if done by the covered entity, except for the purposes specified under § 164.504(e)(2)(i)(A) or (B) if such uses or disclosures are permitted by its contract or other arrangement.

(4) *Business associates: Required uses and disclosures.* A business associate is required to disclose protected health information:

(i) When required by the Secretary under subpart C of part 160 of this subchapter to investigate or determine the business associate's compliance with this subchapter.

(ii) To the covered entity, individual, or individual's designee, as necessary to satisfy a covered entity's obligations under § 164.524(c)(2)(ii) and (3)(ii) with respect to an individual's request for an electronic copy of protected health information.

(5) *Prohibited uses and disclosures.*

(i) *Use and disclosure of genetic information for underwriting purposes:* Notwithstanding any other provision of this subpart, a health plan, excluding an issuer of a long-term care policy falling within paragraph (1)(viii) of the definition of *health plan,* shall not use or disclose protected health information that is genetic information for underwriting purposes. For purposes of paragraph (a)(5)(i) of this section, underwriting purposes means, with respect to a health plan:

(A) Except as provided in paragraph (a)(5)(i)(B) of this section:

(*1*) Rules for, or determination of, eligibility (including enrollment and continued eligibility) for, or determination of, benefits under the plan, coverage, or policy (including changes in deductibles or other cost-sharing mechanisms in return for activities such as completing a health risk assessment or participating in a wellness program);

(*2*) The computation of premium or contribution amounts under the plan, coverage, or policy (including discounts, rebates, payments in kind, or other premium differential mechanisms in return for activities such as completing a health risk assessment or participating in a wellness program);

(*3*) The application of any pre-existing condition exclusion under the plan, coverage, or policy; and

(*4*) Other activities related to the creation, renewal, or replacement of a contract of health insurance or health benefits.

(B) Underwriting purposes does not include determinations of medical appropriateness where an individual seeks a benefit under the plan, coverage, or policy.

(ii) *Sale of protected health information:*

(A) Except pursuant to and in compliance with § 164.508(a)(4), a covered entity or business associate may not sell protected health information.

(B) For purposes of this paragraph, sale of protected health information means:

(*1*) Except as provided in paragraph (a)(5)(ii)(B)(*2*) of this section, a disclosure of protected health information by a covered entity or business associate, if applicable, where the covered entity or business associate directly or indirectly receives remuneration from or on behalf of the recipient of the protected health information in exchange for the protected health information.

(*2*) Sale of protected health information does not include a disclosure of protected health information:

(*i*) For public health purposes pursuant to § 164.512(b) or § 164.514(e);

(*ii*) For research purposes pursuant to § 164.512(i) or § 164.514(e), where the only remuneration received by the covered entity or business associate is a reasonable cost-based fee to cover the cost to prepare and transmit the protected health information for such purposes;

(*iii*) For treatment and payment purposes pursuant to § 164.506(a);

(*iv*) For the sale, transfer, merger, or consolidation of all or part of the covered entity and for related due diligence as described in paragraph (6)(iv) of the definition of health care operations and pursuant to § 164.506(a);

(*v*) To or by a business associate for activities that the business associate undertakes on behalf of a covered entity, or on behalf of a business associate in the case of a subcontractor, pursuant to §§ 164.502(e) and 164.504(e), and the only remuneration provided is by the covered entity to the business associate, or by the business associate to the subcontractor, if applicable, for the performance of such activities;

(*vi*) To an individual, when requested under § 164.524 or § 164.528;

(*vii*) Required by law as permitted under § 164.512(a); and

(*viii*) For any other purpose permitted by and in accordance with the applicable requirements of this subpart, where the only remuneration received by the covered entity or business associate is a reasonable, cost-based fee to cover the cost to prepare and transmit the protected health information for such purpose or a fee otherwise expressly permitted by other law.

(b) * * *

(1) *Minimum necessary applies.* When using or disclosing protected health information or when requesting protected health information from another covered entity or business associate, a covered entity or business associate must make reasonable efforts to limit protected health information to the minimum necessary to accomplish the intended purpose of the use, disclosure, or request.

* * * * *

(e)(1) *Standard: Disclosures to business associates.* (i) A covered entity may disclose protected health information to a business associate and may allow a business associate to create, receive, maintain, or transmit protected health information on its behalf, if the covered entity obtains satisfactory assurance that the business associate will appropriately safeguard the information. A covered entity is not required to obtain such satisfactory assurances from a business associate that is a subcontractor.

(ii) A business associate may disclose protected health information to a business associate that is a subcontractor and may allow the subcontractor to create, receive, maintain, or transmit protected health information on its behalf, if the business associate obtains satisfactory assurances, in accordance with § 164.504(e)(1)(i), that the subcontractor will appropriately safeguard the information.

(2) *Implementation specification: Documentation.* The satisfactory assurances required by paragraph (e)(1) of this section must be documented through a written contract or other written agreement or arrangement with the business associate that meets the applicable requirements of § 164.504(e).

(f) *Standard: Deceased individuals.* A covered entity must comply with the requirements of this subpart with respect to the protected health information of a deceased individual for a period of 50 years following the death of the individual.

* * * * *

■ 47. In § 164.504, revise paragraphs (e), (f)(1)(ii) introductory text, and (f)(2)(ii)(B) to read as follows:

§ 164.504 Uses and disclosures: Organizational requirements.

* * * * *

(e)(1) *Standard: Business associate contracts.* (i) The contract or other arrangement required by § 164.502(e)(2) must meet the requirements of paragraph (e)(2), (e)(3), or (e)(5) of this section, as applicable.

(ii) A covered entity is not in compliance with the standards in § 164.502(e) and this paragraph, if the covered entity knew of a pattern of activity or practice of the business associate that constituted a material breach or violation of the business associate's obligation under the contract or other arrangement, unless the covered entity took reasonable steps to cure the breach or end the violation, as applicable, and, if such steps were unsuccessful, terminated the contract or arrangement, if feasible.

(iii) A business associate is not in compliance with the standards in § 164.502(e) and this paragraph, if the business associate knew of a pattern of activity or practice of a subcontractor that constituted a material breach or violation of the subcontractor's obligation under the contract or other arrangement, unless the business associate took reasonable steps to cure the breach or end the violation, as applicable, and, if such steps were unsuccessful, terminated the contract or arrangement, if feasible.

(2) *Implementation specifications: Business associate contracts.* A contract between the covered entity and a business associate must:

(i) Establish the permitted and required uses and disclosures of protected health information by the business associate. The contract may not authorize the business associate to use or further disclose the information in a manner that would violate the requirements of this subpart, if done by the covered entity, except that:

(A) The contract may permit the business associate to use and disclose protected health information for the proper management and administration of the business associate, as provided in paragraph (e)(4) of this section; and

(B) The contract may permit the business associate to provide data aggregation services relating to the health care operations of the covered entity.

(ii) Provide that the business associate will:

(A) Not use or further disclose the information other than as permitted or required by the contract or as required by law;

(B) Use appropriate safeguards and comply, where applicable, with subpart C of this part with respect to electronic protected health information, to prevent use or disclosure of the information other than as provided for by its contract;

(C) Report to the covered entity any use or disclosure of the information not provided for by its contract of which it becomes aware, including breaches of unsecured protected health information as required by § 164.410;

(D) In accordance with § 164.502(e)(1)(ii), ensure that any

subcontractors that create, receive, maintain, or transmit protected health information on behalf of the business associate agree to the same restrictions and conditions that apply to the business associate with respect to such information;

(E) Make available protected health information in accordance with § 164.524;

(F) Make available protected health information for amendment and incorporate any amendments to protected health information in accordance with § 164.526;

(G) Make available the information required to provide an accounting of disclosures in accordance with § 164.528;

(H) To the extent the business associate is to carry out a covered entity's obligation under this subpart, comply with the requirements of this subpart that apply to the covered entity in the performance of such obligation.

(I) Make its internal practices, books, and records relating to the use and disclosure of protected health information received from, or created or received by the business associate on behalf of, the covered entity available to the Secretary for purposes of determining the covered entity's compliance with this subpart; and

(J) At termination of the contract, if feasible, return or destroy all protected health information received from, or created or received by the business associate on behalf of, the covered entity that the business associate still maintains in any form and retain no copies of such information or, if such return or destruction is not feasible, extend the protections of the contract to the information and limit further uses and disclosures to those purposes that make the return or destruction of the information infeasible.

(iii) Authorize termination of the contract by the covered entity, if the covered entity determines that the business associate has violated a material term of the contract.

(3) *Implementation specifications: Other arrangements.* (i) If a covered entity and its business associate are both governmental entities:

(A) The covered entity may comply with this paragraph and § 164.314(a)(1), if applicable, by entering into a memorandum of understanding with the business associate that contains terms that accomplish the objectives of paragraph (e)(2) of this section and § 164.314(a)(2), if applicable.

(B) The covered entity may comply with this paragraph and § 164.314(a)(1), if applicable, if other law (including regulations adopted by the covered entity or its business associate) contains requirements applicable to the business associate that accomplish the objectives of paragraph (e)(2) of this section and § 164.314(a)(2), if applicable.

(ii) If a business associate is required by law to perform a function or activity on behalf of a covered entity or to provide a service described in the definition of business associate in § 160.103 of this subchapter to a covered entity, such covered entity may disclose protected health information to the business associate to the extent necessary to comply with the legal mandate without meeting the requirements of this paragraph and § 164.314(a)(1), if applicable, provided that the covered entity attempts in good faith to obtain satisfactory assurances as required by paragraph (e)(2) of this section and § 164.314(a)(1), if applicable, and, if such attempt fails, documents the attempt and the reasons that such assurances cannot be obtained.

(iii) The covered entity may omit from its other arrangements the termination authorization required by paragraph (e)(2)(iii) of this section, if such authorization is inconsistent with the statutory obligations of the covered entity or its business associate.

(iv) A covered entity may comply with this paragraph and § 164.314(a)(1) if the covered entity discloses only a limited data set to a business associate for the business associate to carry out a health care operations function and the covered entity has a data use agreement with the business associate that complies with § 164.514(e)(4) and § 164.314(a)(1), if applicable.

(4) *Implementation specifications: Other requirements for contracts and other arrangements.* (i) The contract or other arrangement between the covered entity and the business associate may permit the business associate to use the protected health information received by the business associate in its capacity as a business associate to the covered entity, if necessary:

(A) For the proper management and administration of the business associate; or

(B) To carry out the legal responsibilities of the business associate.

(ii) The contract or other arrangement between the covered entity and the business associate may permit the business associate to disclose the protected health information received by the business associate in its capacity as a business associate for the purposes described in paragraph (e)(4)(i) of this section, if:

(A) The disclosure is required by law; or

(B)(*1*) The business associate obtains reasonable assurances from the person to whom the information is disclosed that it will be held confidentially and used or further disclosed only as required by law or for the purposes for which it was disclosed to the person; and

(*2*) The person notifies the business associate of any instances of which it is aware in which the confidentiality of the information has been breached.

(5) *Implementation specifications: Business associate contracts with subcontractors.* The requirements of § 164.504(e)(2) through (e)(4) apply to the contract or other arrangement required by § 164.502(e)(1)(ii) between a business associate and a business associate that is a subcontractor in the same manner as such requirements apply to contracts or other arrangements between a covered entity and business associate.

(f)(1)* * *

(ii) Except as prohibited by § 164.502(a)(5)(i), the group health plan, or a health insurance issuer or HMO with respect to the group health plan, may disclose summary health information to the plan sponsor, if the plan sponsor requests the summary health information for purposes of:

* * * * *

(2) * * *

(ii) * * *

(B) Ensure that any agents to whom it provides protected health information received from the group health plan agree to the same restrictions and conditions that apply to the plan sponsor with respect to such information;

* * * * *

■ 48. In § 164.506, revise paragraphs (a) and (c)(5) to read as follows:

§ 164.506 Uses and disclosures to carry out treatment, payment, or health care operations.

(a) *Standard: Permitted uses and disclosures.* Except with respect to uses or disclosures that require an authorization under § 164.508(a)(2) through (4) or that are prohibited under § 164.502(a)(5)(i), a covered entity may use or disclose protected health information for treatment, payment, or health care operations as set forth in paragraph (c) of this section, provided that such use or disclosure is consistent with other applicable requirements of this subpart.

* * * * *

(c) * * *

(5) A covered entity that participates in an organized health care arrangement

may disclose protected health information about an individual to other participants in the organized health care arrangement for any health care operations activities of the organized health care arrangement.

■ 49. Amend § 164.508 as follows:
■ a. Revise the headings of paragraphs (a), (a)(1), and (a)(2);
■ b. Revise paragraph (a)(3)(ii);
■ c. Add new paragraph (a)(4); and
■ d. Revise paragraphs (b)(1)(i), and (b)(3).

The revisions and additions read as follows:

§ 164.508 Uses and disclosures for which an authorization is required.

(a) *Standard: Authorizations for uses and disclosures*—(1) *Authorization required: General rule.* * * *

(2) *Authorization required: Psychotherapy notes.* * * *

(3) * * *

(ii) If the marketing involves financial remuneration, as defined in paragraph (3) of the definition of marketing at § 164.501, to the covered entity from a third party, the authorization must state that such remuneration is involved.

(4) *Authorization required: Sale of protected health information.*

(i) Notwithstanding any provision of this subpart, other than the transition provisions in § 164.532, a covered entity must obtain an authorization for any disclosure of protected health information which is a sale of protected health information, as defined in § 164.501 of this subpart. (ii) Such authorization must state that the disclosure will result in remuneration to the covered entity.

(b) * * *

(1) * * *

(i) A valid authorization is a document that meets the requirements in paragraphs (a)(3)(ii), (a)(4)(ii), (c)(1), and (c)(2) of this section, as applicable.

* * * * *

(3) *Compound authorizations.* An authorization for use or disclosure of protected health information may not be combined with any other document to create a compound authorization, except as follows:

(i) An authorization for the use or disclosure of protected health information for a research study may be combined with any other type of written permission for the same or another research study. This exception includes combining an authorization for the use or disclosure of protected health information for a research study with another authorization for the same research study, with an authorization for the creation or maintenance of a research database or repository, or with a consent to participate in research. Where a covered health care provider has conditioned the provision of research-related treatment on the provision of one of the authorizations, as permitted under paragraph (b)(4)(i) of this section, any compound authorization created under this paragraph must clearly differentiate between the conditioned and unconditioned components and provide the individual with an opportunity to opt in to the research activities described in the unconditioned authorization.

(ii) An authorization for a use or disclosure of psychotherapy notes may only be combined with another authorization for a use or disclosure of psychotherapy notes.

(iii) An authorization under this section, other than an authorization for a use or disclosure of psychotherapy notes, may be combined with any other such authorization under this section, except when a covered entity has conditioned the provision of treatment, payment, enrollment in the health plan, or eligibility for benefits under paragraph (b)(4) of this section on the provision of one of the authorizations. The prohibition in this paragraph on combining authorizations where one authorization conditions the provision of treatment, payment, enrollment in a health plan, or eligibility for benefits under paragraph (b)(4) of this section does not apply to a compound authorization created in accordance with paragraph (b)(3)(i) of this section.

* * * * *

■ 50. Amend § 164.510 as follows:
■ a. Revise paragraph (a)(1)(ii) introductory text;
■ b. Revise paragraph (b)(1)(i), the second sentence of paragraph (b)(1)(ii), paragraph (b)(2)(iii), the first sentence of paragraph (b)(3), and paragraph (b)(4); and
■ c. Add new paragraph (b)(5).

The revisions and additions read as follows:

§ 164.510 Uses and disclosures requiring an opportunity for the individual to agree or to object.

* * * * *

(a) * * *

(1) * * *

(ii) Use or disclose for directory purposes such information:

* * * * *

(b) * * *

(1) * * *

(i) A covered entity may, in accordance with paragraphs (b)(2), (b)(3), or (b)(5) of this section, disclose to a family member, other relative, or a close personal friend of the individual, or any other person identified by the individual, the protected health information directly relevant to such person's involvement with the individual's health care or payment related to the individual's health care.

(ii) * * * Any such use or disclosure of protected health information for such notification purposes must be in accordance with paragraphs (b)(2), (b)(3), (b)(4), or (b)(5) of this section, as applicable.

* * * * *

(2) * * *

(iii) Reasonably infers from the circumstances, based on the exercise of professional judgment, that the individual does not object to the disclosure.

(3) * * * If the individual is not present, or the opportunity to agree or object to the use or disclosure cannot practicably be provided because of the individual's incapacity or an emergency circumstance, the covered entity may, in the exercise of professional judgment, determine whether the disclosure is in the best interests of the individual and, if so, disclose only the protected health information that is directly relevant to the person's involvement with the individual's care or payment related to the individual's health care or needed for notification purposes. * * *

(4) *Uses and disclosures for disaster relief purposes.* A covered entity may use or disclose protected health information to a public or private entity authorized by law or by its charter to assist in disaster relief efforts, for the purpose of coordinating with such entities the uses or disclosures permitted by paragraph (b)(1)(ii) of this section. The requirements in paragraphs (b)(2), (b)(3), or (b)(5) of this section apply to such uses and disclosures to the extent that the covered entity, in the exercise of professional judgment, determines that the requirements do not interfere with the ability to respond to the emergency circumstances.

(5) *Uses and disclosures when the individual is deceased.* If the individual is deceased, a covered entity may disclose to a family member, or other persons identified in paragraph (b)(1) of this section who were involved in the individual's care or payment for health care prior to the individual's death, protected health information of the individual that is relevant to such person's involvement, unless doing so is inconsistent with any prior expressed preference of the individual that is known to the covered entity.

■ 51. Amend § 164.512 as follows:
■ a. Revise the paragraph heading for paragraph (b), the introductory text of

paragraph (b)(1) and the introductory text of paragraph (b)(1)(v)(A);

■ b. Add new paragraph (b)(1)(vi);

■ c. Revise the introductory text of paragraph (e)(1)(iii) and paragraph (e)(1)(vi);

■ d. Revise paragraph (i)(2)(iii); and

■ e. Revise paragraphs (k)(1)(ii), (k)(3), and (k)(5)(i)(E).

The revisions and additions read as follows:

§ 164.512 Uses and disclosures for which an authorization or opportunity to agree or object is not required.

* * * * *

(b) *Standard: Uses and disclosures for public health activities.* (1) *Permitted uses and disclosures.* A covered entity may use or disclose protected health information for the public health activities and purposes described in this paragraph to:

* * * * *

(v) * * *

(A) The covered entity is a covered health care provider who provides health care to the individual at the request of the employer:

* * * * *

(vi) A school, about an individual who is a student or prospective student of the school, if:

(A) The protected health information that is disclosed is limited to proof of immunization;

(B) The school is required by State or other law to have such proof of immunization prior to admitting the individual; and

(C) The covered entity obtains and documents the agreement to the disclosure from either:

(1) A parent, guardian, or other person acting *in loco parentis* of the individual, if the individual is an unemancipated minor; or

(2) The individual, if the individual is an adult or emancipated minor.

* * * * *

(e) * * *

(1) * * *

(iii) For the purposes of paragraph (e)(1)(ii)(A) of this section, a covered entity receives satisfactory assurances from a party seeking protected health information if the covered entity receives from such party a written statement and accompanying documentation demonstrating that:

* * * * *

(vi) Notwithstanding paragraph (e)(1)(ii) of this section, a covered entity may disclose protected health information in response to lawful process described in paragraph (e)(1)(ii) of this section without receiving satisfactory assurance under paragraph (e)(1)(ii)(A) or (B) of this section, if the covered entity makes reasonable efforts to provide notice to the individual sufficient to meet the requirements of paragraph (e)(1)(iii) of this section or to seek a qualified protective order sufficient to meet the requirements of paragraph (e)(1)(v) of this section.

* * * * *

(i) * * *

(2) * * *

(iii) *Protected health information needed.* A brief description of the protected health information for which use or access has been determined to be necessary by the institutional review board or privacy board, pursuant to paragraph (i)(2)(ii)(C) of this section;

* * * * *

(k) * * *

(1) * * *

(ii) *Separation or discharge from military service.* A covered entity that is a component of the Departments of Defense or Homeland Security may disclose to the Department of Veterans Affairs (DVA) the protected health information of an individual who is a member of the Armed Forces upon the separation or discharge of the individual from military service for the purpose of a determination by DVA of the individual's eligibility for or entitlement to benefits under laws administered by the Secretary of Veterans Affairs.

* * * * *

(3) *Protective services for the President and others.* A covered entity may disclose protected health information to authorized Federal officials for the provision of protective services to the President or other persons authorized by 18 U.S.C. 3056 or to foreign heads of state or other persons authorized by 22 U.S.C. 2709(a)(3), or for the conduct of investigations authorized by 18 U.S.C. 871 and 879.

* * * * *

(5) * * *

(i) * * *

(E) Law enforcement on the premises of the correctional institution; or

* * * * *

■ 52. In § 164.514, revise paragraphs (e)(4)(ii)(C)(*4*), (f), and (g) to read as follows:

§ 164.514 Other requirements relating to uses and disclosures of protected health information.

* * * * *

(e) * * *

(4) * * *

(ii) * * *

(C) * * *

(*4*) Ensure that any agents to whom it provides the limited data set agree to the same restrictions and conditions that apply to the limited data set recipient with respect to such information; and

* * * * *

(f) *Fundraising communications.*

(1) *Standard: Uses and disclosures for fundraising.* Subject to the conditions of paragraph (f)(2) of this section, a covered entity may use, or disclose to a business associate or to an institutionally related foundation, the following protected health information for the purpose of raising funds for its own benefit, without an authorization meeting the requirements of § 164.508:

(i) Demographic information relating to an individual, including name, address, other contact information, age, gender, and date of birth;

(ii) Dates of health care provided to an individual;

(iii) Department of service information;

(iv) Treating physician;

(v) Outcome information; and

(vi) Health insurance status.

(2) *Implementation specifications: Fundraising requirements.* (i) A covered entity may not use or disclose protected health information for fundraising purposes as otherwise permitted by paragraph (f)(1) of this section unless a statement required by § 164.520(b)(1)(iii)(A) is included in the covered entity's notice of privacy practices.

(ii) With each fundraising communication made to an individual under this paragraph, a covered entity must provide the individual with a clear and conspicuous opportunity to elect not to receive any further fundraising communications. The method for an individual to elect not to receive further fundraising communications may not cause the individual to incur an undue burden or more than a nominal cost.

(iii) A covered entity may not condition treatment or payment on the individual's choice with respect to the receipt of fundraising communications.

(iv) A covered entity may not make fundraising communications to an individual under this paragraph where the individual has elected not to receive such communications under paragraph (f)(1)(ii)(B) of this section.

(v) A covered entity may provide an individual who has elected not to receive further fundraising communications with a method to opt back in to receive such communications.

(g) *Standard: uses and disclosures for underwriting and related purposes.* If a health plan receives protected health information for the purpose of underwriting, premium rating, or other activities relating to the creation,

renewal, or replacement of a contract of health insurance or health benefits, and if such health insurance or health benefits are not placed with the health plan, such health plan may only use or disclose such protected health information for such purpose or as may be required by law, subject to the prohibition at § 164.502(a)(5)(i) with respect to genetic information included in the protected health information.

* * * * *

■ 53. Amend § 164.520:
■ a. Revise paragraphs (b)(1)(ii)(E), (b)(1)(iii), (b)(1)(iv)(A), (b)(1)(v)(A), (c)(1)(i) introductory text, and (c)(1)(i)(B);
■ b. Remove paragraph (c)(1)(i)(C); and
■ c. Add paragraph (c)(1)(v).

The revisions and addition read as follows:

§ 164.520 Notice of privacy practices for protected health information.

* * * * *

(b) * * *

(1) * * *

(ii) * * *

(E) A description of the types of uses and disclosures that require an authorization under § 164.508(a)(2)–(a)(4), a statement that other uses and disclosures not described in the notice will be made only with the individual's written authorization, and a statement that the individual may revoke an authorization as provided by § 164.508(b)(5).

(iii) *Separate statements for certain uses or disclosures.* If the covered entity intends to engage in any of the following activities, the description required by paragraph (b)(1)(ii)(A) of this section must include a separate statement informing the individual of such activities, as applicable:

(A) In accordance with § 164.514(f)(1), the covered entity may contact the individual to raise funds for the covered entity and the individual has a right to opt out of receiving such communications; (B) In accordance with § 164.504(f), the group health plan, or a health insurance issuer or HMO with respect to a group health plan, may disclose protected health information to the sponsor of the plan; or

(C) If a covered entity that is a health plan, excluding an issuer of a long-term care policy falling within paragraph (1)(viii) of the definition of *health plan,* intends to use or disclose protected health information for underwriting purposes, a statement that the covered entity is prohibited from using or disclosing protected health information that is genetic information of an individual for such purposes.

(iv) * * *

(A) The right to request restrictions on certain uses and disclosures of protected health information as provided by § 164.522(a), including a statement that the covered entity is not required to agree to a requested restriction, except in case of a disclosure restricted under § 164.522(a)(1)(vi);

* * * * *

(v) * * *

(A) A statement that the covered entity is required by law to maintain the privacy of protected health information, to provide individuals with notice of its legal duties and privacy practices with respect to protected health information, and to notify affected individuals following a breach of unsecured protected health information;

* * * * *

(c) * * *

(1) * * *

(i) A health plan must provide the notice:

* * * * *

(B) Thereafter, at the time of enrollment, to individuals who are new enrollees.

* * * * *

(v) If there is a material change to the notice:

(A) A health plan that posts its notice on its web site in accordance with paragraph (c)(3)(i) of this section must prominently post the change or its revised notice on its web site by the effective date of the material change to the notice, and provide the revised notice, or information about the material change and how to obtain the revised notice, in its next annual mailing to individuals then covered by the plan.

(B) A health plan that does not post its notice on a web site pursuant to paragraph (c)(3)(i) of this section must provide the revised notice, or information about the material change and how to obtain the revised notice, to individuals then covered by the plan within 60 days of the material revision to the notice.

* * * * *

■ 54. Amend § 164.522 as follows:
■ a. Revise paragraph (a)(1)(ii);
■ b. Add new paragraph (a)(1)(vi); and
■ c. Revise the introductory text of paragraph (a)(2), and paragraphs (a)(2)(iii), and paragraph (a)(3).

The revisions and additions read as follows:

§ 164.522 Rights to request privacy protection for protected health information.

(a)(1) * * *

(ii) Except as provided in paragraph (a)(1)(vi) of this section, a covered entity is not required to agree to a restriction.

* * * * *

(vi) A covered entity must agree to the request of an individual to restrict disclosure of protected health information about the individual to a health plan if:

(A) The disclosure is for the purpose of carrying out payment or health care operations and is not otherwise required by law; and

(B) The protected health information pertains solely to a health care item or service for which the individual, or person other than the health plan on behalf of the individual, has paid the covered entity in full.

(2) *Implementation specifications: Terminating a restriction.* A covered entity may terminate a restriction, if:

* * * * *

(iii) The covered entity informs the individual that it is terminating its agreement to a restriction, except that such termination is:

(A) Not effective for protected health information restricted under paragraph (a)(1)(vi) of this section; and

(B) Only effective with respect to protected health information created or received after it has so informed the individual.

(3) *Implementation specification: Documentation.* A covered entity must document a restriction in accordance with § 160.530(j) of this subchapter.

* * * * *

■ 55. Amend § 164.524 as follows:
■ a. Remove paragraph (b)(2)(ii) and redesignate paragraph (b)(2)(iii) as paragraph (b)(2)(ii);
■ b. Revise newly designated paragraph (b)(2)(ii);
■ c. Revise paragraph (c)(2)(i);
■ d. Redesignate paragraph (c)(2)(ii) as paragraph (c)(2)(iii);
■ e. Add new paragraph (c)(2)(ii);
■ f. Revise paragraphs (c)(3) and (c)(4)(i);
■ g. Redesignate paragraphs (c)(4)(ii) and (c)(4)(iii) as paragraphs (c)(4)(iii) and (c)(4)(iv), respectively; and
■ h. Add new paragraph (c)(4)(ii).

The revisions and additions read as follows:

§ 164.524 Access of individuals to protected health information.

* * * * *

(b) * * *

(2) * * *

(ii) If the covered entity is unable to take an action required by paragraph (b)(2)(i)(A) or (B) of this section within the time required by paragraph (b)(2)(i) of this section, as applicable, the covered entity may extend the time for such actions by no more than 30 days, provided that:

(A) The covered entity, within the time limit set by paragraph (b)(2)(i) of

this section, as applicable, provides the individual with a written statement of the reasons for the delay and the date by which the covered entity will complete its action on the request; and

(B) The covered entity may have only one such extension of time for action on a request for access.

(c) * * *

(2) *Form of access requested.* (i) The covered entity must provide the individual with access to the protected health information in the form and format requested by the individual, if it is readily producible in such form and format; or, if not, in a readable hard copy form or such other form and format as agreed to by the covered entity and the individual.

(ii) Notwithstanding paragraph (c)(2)(i) of this section, if the protected health information that is the subject of a request for access is maintained in one or more designated record sets electronically and if the individual requests an electronic copy of such information, the covered entity must provide the individual with access to the protected health information in the electronic form and format requested by the individual, if it is readily producible in such form and format; or, if not, in a readable electronic form and format as agreed to by the covered entity and the individual.

* * * * *

(3) *Time and manner of access.* (i) The covered entity must provide the access as requested by the individual in a timely manner as required by paragraph (b)(2) of this section, including arranging with the individual for a convenient time and place to inspect or obtain a copy of the protected health information, or mailing the copy of the protected health information at the individual's request. The covered entity may discuss the scope, format, and other aspects of the request for access with the individual as necessary to facilitate the timely provision of access.

(ii) If an individual's request for access directs the covered entity to transmit the copy of protected health information directly to another person designated by the individual, the covered entity must provide the copy to the person designated by the individual. The individual's request must be in writing, signed by the individual, and clearly identify the designated person and where to send the copy of protected health information.

(4) * * *

(i) Labor for copying the protected health information requested by the individual, whether in paper or electronic form;

(ii) Supplies for creating the paper copy or electronic media if the individual requests that the electronic copy be provided on portable media;

* * * * *

■ 56. In § 164.532, revise paragraphs (a), (c)(2), (c)(3), (d), (e)(1), and (e)(2), and add paragraphs (c)(4) and (f) to read as follows:

§ 164.532 Transition provisions.

(a) *Standard: Effect of prior authorizations.* Notwithstanding §§ 164.508 and 164.512(i), a covered entity may use or disclose protected health information, consistent with paragraphs (b) and (c) of this section, pursuant to an authorization or other express legal permission obtained from an individual permitting the use or disclosure of protected health information, informed consent of the individual to participate in research, a waiver of informed consent by an IRB, or a waiver of authorization in accordance with § 164.512(i)(1)(i).

* * * * *

(c) * * *

(2) The informed consent of the individual to participate in the research;

(3) A waiver, by an IRB, of informed consent for the research, in accordance with 7 CFR 1c.116(d), 10 CFR 745.116(d), 14 CFR 1230.116(d), 15 CFR 27.116(d), 16 CFR 1028.116(d), 21 CFR 50.24, 22 CFR 225.116(d), 24 CFR 60.116(d), 28 CFR 46.116(d), 32 CFR 219.116(d), 34 CFR 97.116(d), 38 CFR 16.116(d), 40 CFR 26.116(d), 45 CFR 46.116(d), 45 CFR 690.116(d), or 49 CFR 11.116(d), provided that a covered entity must obtain authorization in accordance with § 164.508 if, after the compliance date, informed consent is sought from an individual participating in the research; or

(4) A waiver of authorization in accordance with § 164.512(i)(1)(i).

(d) *Standard: Effect of prior contracts or other arrangements with business associates.* Notwithstanding any other provisions of this part, a covered entity, or business associate with respect to a subcontractor, may disclose protected health information to a business associate and may allow a business associate to create, receive, maintain, or transmit protected health information on its behalf pursuant to a written contract or other written arrangement with such business associate that does not comply with §§ 164.308(b), 164.314(a), 164.502(e), and 164.504(e), only in accordance with paragraph (e) of this section.

(e) *Implementation specification: Deemed compliance.* (1) *Qualification.* Notwithstanding other sections of this part, a covered entity, or business associate with respect to a subcontractor, is deemed to be in compliance with the documentation and contract requirements of §§ 164.308(b), 164.314(a), 164.502(e), and 164.504(e), with respect to a particular business associate relationship, for the time period set forth in paragraph (e)(2) of this section, if:

(i) Prior to January 25, 2013, such covered entity, or business associate with respect to a subcontractor, has entered into and is operating pursuant to a written contract or other written arrangement with the business associate that complies with the applicable provisions of §§ 164.314(a) or 164.504(e) that were in effect on such date; and

(ii) The contract or other arrangement is not renewed or modified from March 26, 2013, until September 23, 2013.

(2) *Limited deemed compliance period.* A prior contract or other arrangement that meets the qualification requirements in paragraph (e) of this section shall be deemed compliant until the earlier of:

(i) The date such contract or other arrangement is renewed or modified on or after September 23, 2013; or

(ii) September 22, 2014.

* * * * *

(f) *Effect of prior data use agreements.* If, prior to [January 25, 2013, a covered entity has entered into and is operating pursuant to a data use agreement with a recipient of a limited data set that complies with § 164.514(e), notwithstanding § 164.502(a)(5)(ii), the covered entity may continue to disclose a limited data set pursuant to such agreement in exchange for remuneration from or on behalf of the recipient of the protected health information until the earlier of:

(1) The date such agreement is renewed or modified on or after September 23, 2013; or

(2) September 22, 2014.

* * * * *

Dated: January 15, 2013.

Kathleen Sebelius,

Secretary.

[FR Doc. 2013–01073 Filed 1–17–13; 4:15 pm]

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FEDERAL REGISTER

Vol. 78 Friday,

No. 17 January 25, 2013

Part III

The President

Memorandum of January 15, 2013—Delegation of Certain Functions Under Section 6 of Public Law 112–150

Federal Register
Vol. 78, No. 17
Friday, January 25, 2013

Presidential Documents

Title 3—

The President

Memorandum of January 15, 2013

Delegation of Certain Functions Under Section 6 of Public Law 112–150

Memorandum for the Secretary of State

By the authority vested in me as President by the Constitution and the laws of the United States of America, including section 301 of title 3, United States Code, I hereby delegate to you all functions conferred upon the President by subsections (a) and (b) of section 6 of Public Law 112–150. You will exercise these functions in coordination with the Secretary of Defense.

You are authorized and directed to publish this memorandum in the **Federal Register**.

THE WHITE HOUSE,
Washington, January 15, 2013

[FR Doc. 2013–01804
Filed 1–24–13; 11:15 am]
Billing code 4710–10

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